UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: GUIDANT CORP. IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABILITY LITIGATION	MDL No. 05-1708 (DWF/AJB)
This Document Relates to Eugene Clasby vs. Guidant Corp., et al.	Case No. 05-02596

[REDACTED] DEFENDANTS' CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT

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I. INTRODUCTION

Dr. Clasby's VENTAK PRIZM 2 DR 1861 ("PRIZM 2") never malfunctioned and was never recalled by the FDA. Out of the 11,000 devices implanted after the April 16, 2002 Engineering Change Order, only one such device has been reported to have failed due to arcing in the header. Despite these facts, Dr. Clasby elected to have his device explanted. Before doing so, Dr. Clasby chose to wait a considerable time. He waited six months after learning of the May 2005 advisory before he consulted his cardiologist about the possible recall of his device. He waited eleven months before discussing the recall with his psychiatrist. He also waited eleven months before deciding to voluntarily explant his PRIZM 2. Once explanted, the device was tested and showed no sign of arcing in the header. In short, Dr. Clabsy's device was not recalled and did not malfunction. Yet he explanted his device and now seeks recovery from Guidant[1] for emotional distress. For the reasons set forth in the following subsections, this Court should dismiss each of Dr. Clasby's claims with prejudice.

II. DEFENDANTS' CONSOLIDATED STATEMENT OF FACTS

A. Sudden cardiac death and implantable cardioverter defibrillators.

The heart is a complex organ that may present many varied disease processes. These disease processes include genetic, structural, acute, and chronic conditions that result in a variety of symptoms and may be life-threatening. Adding to this complexity, many cardiac patients suffer from a combination of cardiac,

[1] For purposes of this motion, Defendants Guidant Corporation, Guidant Sales Corporation, and Cardiac Pacemakers, Inc., shall be referred to collectively as "Guidant."

cardiopulmonary, and other disease processes that impact both their disease process and treatment.

To facilitate its pumping action, the heart has a complex electrical system that controls the pace and volume of blood supply to the body. When this electrical system is disturbed, abnormal heart rhythms – or arrhythmias – occur. There are three basic kinds of arrhythmias: bradycardia, tachycardia, and fibrillation.

- Bradycardia is an abnormally slow heart rate. Bradycardia may result in lack of energy, syncope (fainting episodes due to poor oxygenation), and in some instances, death. This condition can be effectively managed with an internal pacemaker.

- Tachycardia is an abnormally fast heart rate. This condition accelerates the heart beat above what most people would experience during vigorous exercise. Tachycardia can be controlled through resynchronization of the heart's electrical system.

- Fibrillation can be described as completely disorganized electrical impulses in the heart, which result in the heart muscle "quivering" and a compete inability to move blood.

Both tachycardia and fibrillation can occur in the heart's atria and ventricles. When a person experiences ventricular tachycardia (VT) or ventricular fibrillation (VF), that person suffers sudden cardiac death (SCD).

The heart's electrical conduction system emits electrical impulses over one million times during the average life. The normal electrical impulse, called a sinus rhythm, keeps the heart moving blood through the circulatory system at a steady, continuous pace. When a sudden cardiac arrest victim experiences VT, the heart pumps at a rate so high that the ventricles can never fully fill with blood, preventing adequate blood supply to both the heart and the body as a whole. After a period of VT, the heart

becomes electrically disorganized and enters into VF. During VF, the heart is incapable of circulating blood because the pumping action is no longer present. Asystole (cardiac death) follows.

Absent prompt intervention, the survival rate for sudden cardiac arrest is extremely low. The onset and rapid progression of sudden cardiac death is so fast that victims have mere minutes to receive treatment before losing any hope of survival. SCD is a leading cause of death in the United States. The implantable cardioverter defibrillator (ICD) is the most effective therapy for preventing SCD.

The ICD can is a metal (e.g., titanium) case consisting of a battery, a capacitor, and electronic components. ICD batteries provide power to the device for four to six years, depending on use. The capacitor stores power to the device for therapy. ICD capacitors can be explained somewhat by comparison to a camera's flash device. In a photographic flash, the battery provides power that the capacitor stores and eventually releases in a burst on demand. Similarly, the ICD capacitor stores energy until the device recognizes an arrhythmia. The capacitor then discharges, providing therapy, and rapidly recharges to provide additional therapy if needed. The electronic components manage the device, monitor the patient's heart rhythms, determine the patient's therapy needs, and record heart rhythms and device performance data.

The cardiac conditions that result in sudden death are not the same from patient-to-patient. Each individual at risk must be carefully assessed for all cardiac conditions that may result in sudden death. Once the exact set of medical conditions from which the patient suffers are ascertained, then treatment options can be considered.

When evaluating an ICD as a therapeutic option, physicians and patients have a wide range of choices. The exceptional quality and versatility of modern ICDs allow physicians to tailor device therapy to precise patients needs. For example, today's ICDs are capable of a wide range of programmable settings that are determined by individual patient characteristics and risks. Once determined, the settings are programmed into the device. Unlike early devices, modern devices, once implanted, can be reprogrammed without surgical intervention. This added capability allows physicians to continually reassess the patient's risks and tailor device therapy to meet the patient's changing needs.

B. Known risks associated with ICDs.

It is important to understand that ICDs are complicated, man-made devices. Like all such devices, ICDs may malfunction. ICDs are composed of thousands of electrical components and are placed in the inhospitable environment of the human body. Physicians are well aware of the fact that ICDs may occasionally fail to operate as intended. *See* March 22, 2007 Affidavit of Steven L. Higgins, M.D. at ¶¶ 5, 9 ("Higgins Affidavit") (Dkt. # 1745, Ex. 1); *See* Deposition of Charles Swerdlow, M.D. at 93:10 – 94:19 (Dkt. # 1745, Ex. 2); Deposition of Dr. Geddes Frank Owen Tyres at 121:14-20 (Ex. 1)

Device-related problems may be simple ones, such as discomfort due to the device's presence under the skin or inappropriate shocks (which can be addressed by adjusting the ICD's settings). Further, "[f]alse shocks, also known as inappropriate shocks, do not indicate abnormal function." Report of Thomas Ross at p. 5 (Ex. 2). Or problems may be sufficiently serious to warrant device replacement – for example,

battery failure or lead disruption. Further, all ICDs have a finite life span. When the battery depletes, the device must be replaced. No device – no matter the manufacturer – will last forever, and this fact is well known to the electrophysiology community.

Guidant's System Guide and Physician's Technical Manual for the PRIZM 2 expressly warn of the following potential physical complications and adverse events including: acceleration of arrhythmias, air embolism, bleeding, chronic nerve damage, erosion, excessive fibrotic tissue growth, extrusion, fluid accumulation, formation of hematomas or cysts, inappropriate shocks, infection, keloid formation, lead abrasion, lead discontinuity, lead migration or dislodgement, myocardial damage, pneumothorax, potential mortality due to inability to defibrillate or pace, shunting current or insulating myocardium during defibrillation with internal or external paddles, thromboemboli, venous occlusion, and venous or cardiac perforation. *See* CPI 34 00001459-60 (excerpt from VENTAK PRIZM 2 DR, Model 1861 System Guide at 1-9 – 1-10) ("System Guide") (Dkt. # 1745, Ex. 3); CPI 34 00000218 (excerpt from VENTAK PRIZM 2 DR, Model 1861 Physician's Technical Manual at 4) ("Physician's Technical Manual") (Dkt. # 1745, Ex. 4).

In addition, Guidant's labeling for the PRIZM 2 warns that patients receiving shock therapy may develop dependency, depression, fear of premature battery depletion, fear of shocking while conscious, fear that shocking capability may be lost, and imagined shocking. *See* CPI 00001460 (excerpt from System Guide at 1-10); CPI 00000218 (excerpt from Physician's Technical Manual at 4). Physicians are also expressly advised to counsel their patients that "the pulse generator is subject to random

component failure. Such failure could cause inappropriate shocks, induction of arrhythmias or inability to sense arrhythmias, and could lead to the patient's death." *See* CPI 34 00001469 (excerpt from System Guide at 1-19); CPI 34 00000220 (excerpt from Physician's Technical Manual at 6). The list of potential complications and adverse events included in Guidant's labeling has been approved by the federal Food and Drug Administration (FDA). *See* CPI 2 00000001-2 (August 4, 2000 PRIZM 2 approval letter from James E. Dillard to Laura L. Shepler) ("Prizm 2 Approval Letter") (Dkt. # 1745, Ex. 5); CPI 95 00000033-37 (PRIZM 2 Conditions of Approval) (Dkt. # 1745, Ex. 6); 21 C.F.R. § 814.80.

C. The role of the FDA.

The United States Congress has delegated exclusive regulatory authority over medical devices to the FDA, and has determined that satisfaction of the FDA's requirements is adequate, as a matter of law, to safeguard the American public in its use of medical devices. As a Class III, restricted medical device, the PRIZM 2 is subject to the FDA's most rigorous and comprehensive approval and post-approval regulations. Before the FDA permitted Guidant to introduce the PRIZM 2 for sale in the United States, the FDA required Guidant to demonstrate that the device was both safe and effective through a process known as Pre-market Approval ("PMA"). *See* Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*. Under the PMA process, the FDA first evaluated, and then approved, every aspect of the design, manufacturing process, and labeling of the PRIZM 2. *See* CPI 2 00000001-2 (PRIZM 2 approval letter).

The rigors of the PMA process are reserved for only a small percentage of medical devices. *See* Affidavit of Robert Sheridan ("Sheridan Aff.") at ¶ 14 (Dkt. # 1745, Ex. 7). Among other things, a PMA submission must include:

- A full statement of the components, ingredients, and properties of the principle or principles of operation, of [the] device;
- A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, [the] device;
- Full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
- Specimens of the labeling proposed to be used for [the] device," including product warnings, warranties, instructions for installation and other literature or advertising;
- Samples of the device or its components, if requested by the FDA; and
- Such other information as the FDA may reasonably require the manufacturer to submit.

See 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20; Sheridan Aff. at ¶¶ 14-19. An original PMA application must also include data from animal studies and any clinical investigations relating to the device. For example, the FDA requires manufacturers to submit the results of non-clinical laboratory studies, including microbiological, toxicological, immunological, biocompatibility, stress, wear and shelf-life tests, if appropriate. *See* 21 C.F.R. § 814.20(b)(6)(i).

Throughout the PMA approval process, the FDA can, and frequently does, pose additional questions and/or request additional information from the applicant manufacturer. A final order is issued if the manufacturer has demonstrated to the

satisfaction of the FDA that the device's safety and effectiveness are reasonably assured. 21 U.S.C. § 360e(d)(1)(A); 21 C.F.R. § 814.44(d). The FDA approval order authorizes a manufacturer to market the device with the particular labeling (including specific product warnings). *See* CPI 2 00000001-2 (PRIZM 2 approval letter); CPI 95 00000033-37 (PRIZM 2 Conditions of Approval); 21 C.F.R. §§ 814.40, 814.44(d). After approval, the FDA requires the manufacturer to maintain certain records and to make certain reports, including alleged adverse events. *See* 21 U.S.C. § 360(i); 21 C.F.R. §§ 814.82(7), 814.84, 803.50, *et seq*.

FDA regulations expressly permit manufacturers to seek approval for device modifications by, among other ways, submitting supplements to a prior PMA. "All procedures and actions that apply to [a PMA] application . . . also apply to PMA supplements . . . ." 21 C.F.R. § 814.39(c); *see also* Sheridan Aff. at ¶¶ 28-29. The FDA uses the same device-specific analysis for a proposed supplemental PMA that it employs for the original PMA. *See* Sheridan Aff. at ¶ 29. The PMA supplement process, while no less substantively rigorous, obviates the need to submit redundant information to the FDA regarding design features, manufacturing processes, or labeling that have already been approved.

The entire PMA, including the original and all prior supplements, are deemed to be "before the agency at the time the supplement is reviewed." 51 Fed. Reg. 26342, 26354 (1986). The description of the device included within the Supplemental PMA application is thus limited to the changes to the original PMA baseline or last approved supplement. *See* Deposition of Brian Novak at 460:2-22, 489:13-25 (Dkt. #

1745, Ex. 8). The PRIZM 2 supplemental PMA application contained over 1,800 pages of data. That application also relied in part upon many additional thousands of pages of data previously submitted with respect to other members of its predecessor device "family" and even other original Guidant PMAs. *See* Second Amended Affidavit of Brian Novak ("Novak Aff.") at ¶¶ 7, 25 (Dkt. # 1745, Ex. 9); Novak Deposition at 47:8 – 48:16, 467:1 – 468:18.

The FDA retains full regulatory authority over Class III devices after it approves those devices. *See* Sheridan Aff. at ¶¶ 28-32; 21 C.F.R. §§ 814.80-814.84. Under certain conditions, a manufacturer may choose to take voluntary action, including the initiation of a voluntary device recall. The FDA may elect to classify voluntary manufacturer action as a recall pursuant to 21 C.F.R. Part 7. Such classification, however, does not constitute a revocation, withdrawal, rescission, or suspension of the recalled device's approval. *See* Sheridan Aff. at ¶ 27.

The FDA is a fierce regulatory watchdog. Among the FDA's employees are physicians, biomedical engineers, chemists, toxicologists, and specialists in public health education and communication. As stated by Guidant's regulatory expert, Robert Sheridan:

> FDA is not an uninformed, passive arbiter that is content with simply "calling balls and strikes." Rather, it is a well-informed, actively engaged agency that aggressively carries out its legislative mandate, including the control of virtually every aspect of the design, labeling, manufacturing, distribution, and sale of Class III medical devices. While FDA pre-market approval orders state that an approval is based on information provided by the applicant, the applicant does not decide what is needed for the approval of a PMA.

> FDA reviews what is submitted, but it also requires applicants to submit any additional information it judges to be needed for making a well-informed decision regarding a device's safety and effectiveness. FDA's staff are well-trained, well-informed and broadly exposed to scientific and technical issues involved in the design and manufacture of ICDs. They know what information to ask for to satisfy themselves that the regulatory standards are satisfied, and they ask for it before approving the related device.

Supplemental Report of Robert L. Sheridan at 4 (Dkt. # 1745, Ex. 10). In sum, the FDA actively reviews PMA submissions, monitors device performance and safety, conducts on-site inspections both routinely and as questions arise, and takes compliance actions when necessary. Over the years, the FDA has seen first-hand how Guidant operates its CRM business and has confirmed that the company has appropriate procedures in place to protect patient safety.

The FDA approved the PRIZM 2 on August 4, 2000. *See* CPI 2 00000001 (PRIZM 2 approval letter). The FDA has never revoked, suspended, or withdrawn that approval. Guidant has complied and continues to comply with the extensive federal requirements imposed on it by written conditions the FDA communicated with that approval.

D. The people of Guidant.

Guidant subsidiary Cardiac Pacemakers, Inc. has been located in Arden Hills, Minnesota since 1972. The professionals of CRM include all kinds of engineers, technical experts, scientists, nurses, physicians, reliability assurance experts, failure analysis specialists, regulatory associates, technical services representatives, manufacturing operators, and many others. As demonstrated by the testimony of

numerous company witnesses, the CRM personnel are conscientious professionals of the highest integrity, pride, and ability. The culture of the company has always been focused on providing the highest level of patient care and device quality. CRM employees are proud of the innovation of the company – innovation that has improved the lives of heart patients all over the world. CRM is also proud to make some of the most reliable heart devices on the market.

E. The VENTAK PRIZM 2, Model 1861

1. The first event.

On February 1, 2002, Guidant received a report that one of its PRIZM 2 devices could not be interrogated. *See* CPI 103 00000038-42 at 38 (Event Summary for Event No. 812844) ("Event Summary # 812844") (Dkt. # 1745, Ex. 11) The device, which two nights earlier had delivered three shocks to the patient while she was dancing, displayed no telemetry, no magnet tone and no pacing upon interrogation. *Id*; *see also* CPI 35 00000001 (Field Discrepancy Notification Report No. 02026) ("Field Discrepancy Notification #0206") (Dkt. # 1745, Ex. 12). Three days later, the device was explanted and returned to Guidant's Reliability Assurance Lab for analysis. *See* CPI 00000038-42 (Event Summary # 812844) at 38. The patient was uninjured and received a full warranty credit for the device. *See id.* at 40.

Upon inspection in Minnesota, Guidant analysts noticed a "darkened area" around the device header and noted damage to the power module. *Id.* In addition, a small hole had been found in the header's insulation tubing. *See* CPI 35 00000001 (Field Discrepancy Notification #0206). Guidant engineers would later determine the cause of

the device's battery depletion and loss of telemetry to be a "circuit short within the header." *See* CPI 103 00000038-42 (Event Summary # 812844) at 40. The failure was classified as a random event. *See* CPI 35 00000001 (Field Discrepancy Notification #0206).

Dr. Clasby's experts concede that Guidant owed no duty to tell the medical community about the February 2002 arcing incident. For example, Dr. Charles Swerdlow testified as follows:

> Q. With respect to your view that Guidant should have notified physicians about the arcing in the header of the 1861 at an earlier time than it did -- you certainly believe that, do you not?
>
> A. I do.
>
> Q. But you also accept the idea that Guidant is entitled to do some analysis and evaluation, as any manufacturer should, into a reported failure?
>
> A. Yes.
>
> Q. Do you have an opinion of a precise date in your view at which you believe Guidant should have communicated to the physician population the problems with arcing in the header of the 1861?
>
> A. Well, I think Guidant should have done it within a short time after it made the manufacturing change in April of 2002.

Dr. Charles Swerdlow Dep. Tr. 276:17 – 277:10. Dr. Clasby's engineering expert, Randy Armstrong, also testified that, Guidant owed no duty to tell the medical community about the February 2002 arcing incident:

> Q. What document can you point to that shows that it is -- there was a conclusion by anyone within the company

> that it would be inappropriate to route the DF- wire over the backfill tube as of February of 2002?
>
> A. I take the ECO of April '02 as a recognition that placing the wire over the backfill tube is inappropriate.
>
> Q. So that would be their first indication. Therefore, there's nothing prior to February of 2002?
>
> A. That is the first documentation I saw as a recognition of a problem.

Randy Armstrong Dep. Tr. 171:14 – 172:2 ("Armstrong Deposition") (Dkt. # 1745, Ex. 55). Thus, according to Dr. Clasby's experts, Guidant owed no duty to warn about the February 2002 arcing incident prior to April 2002.

On March 4, 2002 – one month after receiving the device – Guidant sent a letter to the patient's doctor. *See* CPI 103 00000038-42 at 40. The letter stated plainly: "Engineers have determined that the root cause of the battery depletion and loss of telemetry was a short circuit within the header. . . . [t]his appears to be a random failure – it is the first failure of this type that we have seen." *Id.* Guidant, in adherence with the FDA's Adverse Event Reporting Program, submitted to the FDA a Medical Device Report detailing the circumstances of the February 1, 2002 event. *See* CPI 35 00000016-17 (Medical Device Report for Patient No. 0000100090) (Dkt. # 1745, Ex. 13).

2. The April change.

On April 2, 2002, a second device, which had been explanted in "Safety Mode" was returned to Guidant for analysis. *See* CPI 103 00000033-37 (Event Summary for Event No. 813198) (Dkt. # 1745, Ex. 14). Although the device passed Guidant's pacer testing, it failed the post-explant laboratory shock testing, which had provoked a

circuit short or "arc" within the device header. *Id. at* 35. Guidant engineers suspected the cause to be an unknown breach in the negative feedthru wire, which, when exposed to the positively charged backfill tube, caused an arc. *Id.*; *see also* CPI 35 00000002 (Field Discrepancy Notification Report No. 02051) (Dkt. # 1745, Ex. 15). The more fundamental question, however, remained unresolved: *why*?

Although only two known failures existed – both of which that had been brought to FDA's attention by the filing of MDRs – Guidant issued Engineering Change Order ("ECO") No. 40773 on April 16, 2002. *See* CPI 90 00041300-41322 (Engineering Change Order No. 40773) (Dkt. # 1745, Ex. 16). The primary change included in ECO 40773 was a staging of the medical adhesive in the manufacturing process that, upon curing, would prevent the feedthru wire from shorting against the backfill tube. *Id.* at 41303, 41309. Guidant, however, did not know whether the change would actually prevent arcing failures in future devices. It did, as there has been only one additional reported arcing incident in post-April 2002 device population.

In May 2002, a third device was returned to Guidant following a report that the device administered three shocks before going into "fallback mode." *See* CPI 35 00000003 (Field Discrepancy Notification No. 02065) (Dkt. #1745, Ex. 17). The feedthru wire had shorted against the backfill tube, leaving the device unable to be interrogated. *See id.* As with the February and March devices, Guidant submitted to the FDA an MDR on the May device.

On June 14, 2002, Guidant conducted a Health Risk Assessment on the 24,427 PRIZM 2s in distribution in the United States. *See* CPI 35 00000004-6 (Risk

Assessment, June 14, 2002) (Dkt. # 1745, Ex. 18). The Company concluded that the probability of occurrence of arcing between the feedthru wire and backfill tube was "rare" and the risk "very low." *Id.* at 5. Six days later, on June 20, 2002, the first Trend Report was issued setting forth the facts surrounding the PRIZM 2 arcing issue. *See* 35 00000066-68 (TR-02019, Revision A) (Dkt. # 1745, Ex. 19). The Report detailed, among other things, Guidant's two primary areas of investigation as to the cause of the breach in the polyimide insulation. *See id.* at 67.

First, Guidant questioned whether the insulation breach could have been caused during the manufacturing process. *See id.* The Company had discovered, for example, that in two of three failed devices, the "Bond Top" process – *i.e.*, the bending of the wires for routing into the header channels – had been performed by the same operator in the Company's Clonmel, Ireland facility. *See id.*

The second possibility involved the potential for cold flow, a phenomenon that might also cause the insulation to breach. *Id.* Guidant also continued to assess the effectiveness of the April 2002 change. *See id.* As part of its continuous improvement process, the Company began investigating what additional changes would be required to ensure the arcing failures were minimized. *See id.*

At the time of the June 20 Trend Report, the PRIZM 2 population exhibited a failure rate of 0.001% per implant month – far below the failure rated predicted by Guidant in the FDA-approved Pre-Market Application. *See id*; CPI 2 00001361-1375 (Reliability Prediction Report, Revision C) (Dkt. # 1745, Ex. 20).

3. The November change.

On November 13, 2002, a second change – ECO No. 41940 – was implemented for the PRIZM 2 device. *See* CPI 90 00044609-44626 (Engineering Change Order No. 41940) (Dkt. #1745, Ex. 21). Only three incidents had been reported at this point, and there had been no injuries at the time of the November 2002 ECO. *See* CPI 35 00000069-71 (January 30, 2003 Trend Report) (Ex. 3). The change involved adding polyimide tubing over the backfill tube. The tubing sleeve was designed to minimize the likelihood of arcing between the feedthru wire and the backfill tube. *See* Engineering Change Order No. 41940 at 44612-613.

In 2003, after Dr. Clasby's device had already been implanted, a third change was also contemplated. The proposed change, which involved re-molding of the header, would reroute the feedthru wire away from the backfill tube. *See* CPI 35 00000069-71 (TR-2019, Revision B) (Dkt. # 1745, Ex. 22). In light of the results of the April and November changes, the remolding was determined to be unnecessary and, thus, never made. *See* CPI 35 00000072-74 (TR-2019, Revision C) (Dkt. # 1745, Ex. 23). Guidant's decision proved prescient. The overall effectiveness of the April and November changes has been remarkable. To date, only one post-April device has exhibited a short-circuit. *See* CPI 3900000571-772 at 750 (Boston Scientific CRM Product Performance Report 2007, Q1) (Dkt. # 1745, Ex. 24). No post-November devices are known to have short-circuited. *See id.*

F. Guidant's interactions with Dr. Barry Maron and Dr. Robert Hauser.

On or about May 4, 2005, Dr. Maron and Dr. Adrian Almquist gave a poster presentation at the annual Heart Rhythm Society meeting in New Orleans. Their presentation showed the results of Dr. Hauser's registry of device implants in patients with Hypertrophic Cardiomyopathy (HCM), the disease from which a patient named Joshua Oukrop suffered. The presentation included a note about Mr. Oukrop's death. *See* CPI 81 00000158-60 (May 10, 2005 e-mail from Pete Sommerness to Keith Johnson and others) (Dkt. # 1745, Ex. 25). On Saturday, May 7, Guidant Manager of Regional Sales, Pete Sommerness, met with Dr. Maron in New Orleans to discuss other Abbott Northwestern patients who had been implanted with PRIZM 2 devices. *See* CPI 116 0000298-300 (May 9, 2005 e-mail from Pete Sommerness to Dr. Maron) (Dkt. # 1745, Ex. 26); CPI 84 00001778-79 (July 25, 2005 e-mail from Pete Sommerness to Dr. Joseph Smith) (Dkt. # 1745, Ex. 27).

Mr. Sommerness and others then met separately with Drs. Gornick and Maron regarding the PRIZM 2 situation on or around May 9, 2005. On May 12, 2005, Mr. Sommerness, Dr. Smith and others again met with Dr. Maron to discuss PRIZM 2 issues. *See* CPI 84 00001778-79 (July 25, 2005 e-mail from Pete Sommerness to Dr. Joseph Smith). During this time, Dr. Gornick informed Guidant that he was planning to write up the Oukrop event for "accelerated" publication. Dr. Gornick requested Guidant's assistance in making his analysis and numbers as accurate as possible. *See* CPI 81 00000158-60 (May 10, 2005 e-mail from Pete Sommerness to Keith Johnson and others). Guidant agreed to collaborate. *See* Deposition of Joseph Smith, M.D. at 342:7 –

343:16 (Dkt. # 1745, Ex. 28); Deposition of Allan Gorsett at 325:5 – 326:19 (Dkt. # 1745, Ex.29).

On Saturday, May 14, 2005, Dr. Joseph Smith, then Guidant's Chief Medical Officer and a board-certified electrophysiologist, began drafting an editorial to accompany the article being written by Dr. Hauser, Dr. Maron, Dr. Gornick, and others. Dr. Smith's editorial was titled "Painfully Short of Perfection," and attempted to provide context for an academic discussion of when manufacturers should communicate concerning rare and unpredictable failure modes. As Dr. Smith explained:

> Just as clinicians work to extend the lifesaving benefits of ICD therapy to the populations identified by recent clinical science, engineers and scientists work to continuously improve the quality and functionality of these devices, and to be sure, much work needs to be done. Flawless device function is not yet at hand. The implantable cardioverter defibrillator is a complex device, made of thousands of discrete components, dozens of materials, subjected to hundreds of individual production steps. Quality and process control processes number into the millions, and each finished device is subjected to full functionality testing prior to release for use in patients. And yet, perfect device behavior over its lifetime cannot be a realistic expectation. Individual components, no matter how well screened, can and do suffer "random" failures. A confluence of rare and unanticipated events can conspire to create a mode of failure not contemplated in the initial design and construction. And such is the case described in the attendant case report.
>
> . . .
>
> Guidant's quality system successfully identified [the PRIZM 2] trend, and design and manufacturing changes were made to continuously improve the quality of these devices. All instances were reported to the regulatory bodies. As overall performance of PRIZM II ICDs continue to expectations and design criteria, and as no strategy could be identified to

> improve clinical outcomes relative to these rare events, no extraordinary communication was undertaken. On this last point, some may take issue. However, it must be recognized that clinical response to advisories regarding rare events can and do lead to their own series of adverse outcomes, including deaths. In this case, in the absence of any approach to further risk stratify a population with a per person risk of 0.002% per month, and against the backdrop of exceptional overall device performance, communication was judged more likely to create many more adverse events than the rate underlying rate. One need look no further than examining the results of the recent advisories regarding the much more frequent and unpredictable battery behavior by one manufacturer, or lead malfunction by another to validate the wisdom of these concerns.

CPI 116 00000850-52 (May 14, 2005 e-mail from Dr. Joseph Smith to Dr. Richard Fogoros and attached editorial) (Dkt. # 1745, Ex. 30). Dr. Smith shared his draft editorial with another company physician, electrophysiologist Richard Fogoros, M.D., and asked for feedback. *See id.*

The following Monday, May 16, 2005, Mr. Sommerness and others from Guidant met with Dr. Hauser regarding the PRIZM 2. *See* CPI 84 00001778-79 (July 25, 2005 e-mail from Pete Sommerness to Dr. Joseph Smith). The next day, Dr. Hauser called Dr. Smith for help with a technical figure for the PRIZM 2 article. Dr. Smith requested that Allan Gorsett, Vice President of Reliability and Quality Assurance, and Dan Tich, Manager of Reliability and Quality Assurance, assist Dr. Hauser.

On Wednesday, May 18, 2005 – *before* Guidant ever received an inquiry from the New York Times – Dr. Smith determined that Guidant's communication criteria had been activated. *See* Smith Deposition at 339:1 – 341:5, 341:21 – 348:7; CPI 81 00000127 (May 18, 2005 (12:01 p.m.) e-mail from Dr. Joseph Smith to Dale DeVries)

(Dkt. # 1745, Ex. 31). Dr. Smith recommended that Guidant communicate with physicians and prepared a draft physician advisory, which he then shared with Guidant's Vice President of Regulatory Affairs, Dale DeVries. *See* CPI 81 00000317-19 (May 18, 2005 (3:57 p.m.) e-mail from Dr. Joseph Smith to Dale DeVries) (Dkt. # 1745, Ex. 32); CPI 81 00000228-30 (May 18, 2005 e-mail from Dale DeVries to Dr. Joseph Smith) (Dkt. # 1745, Ex. 33). On the same day, Drs. Maron and Hauser submitted a draft of their article to the Heart Rhythm Society for publication. The article was available to physicians on-line a few days later. *See* CPI 82 00003151-64 (May 31, 2005 e-mail from Dr. Beverly Lorell to the Guidant Management Committee) (Dkt. # 1745, Ex. 34).

On May 19, 2005, Guidant received its first inquiry from the New York Times about the PRIZM 2. Dr. Smith agreed to speak with the Times reporter, and was interviewed by Barry Meier on May 20, 2005. On May 23, 2005, Guidant issued a physician advisory about the PRIZM 2 arcing failure mechanism. The New York Times article appeared the following day.

G. The reliability of the PRIZM 2.

The PRIZM 2 DR, Model 1861 is one of the most reliable ICDs ever marketed. As previously discussed, there is a known and expected background risk of failure with all ICDs. Reports have placed the rate of ICD malfunction requiring replacement as low as 1% to as high as 2.65%. *See Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines,* Heart Rhythm Society, October 2006 (Dkt. # 1745, Ex. 35). The PRIZM 2 was approved for marketing nearly seven years ago. The confirmed malfunction rate from all causes for

that product line is only 0.44%. *See* Boston Scientific CRM 2007, Q1 Product Performance Report at 126. Indeed, when one compares the failure rate of those devices manufactured before April 16, 2002, with those manufactured after that date, the reliability is virtually "superimposable," meaning that there is no meaningful difference in the reliability between the two. *See* Deposition of Richard Fogoros, M.D. at 195:24 – 197:3 (rough transcript) (Dkt. # 1745, Ex. 36); Deposition of Renold Russie at 270:24 – 274:3 (Dkt. # 1745, Ex. 37).

Looking specifically at the incidence of short-circuiting in the header of the device, as of the last Advisory Update of January 5, 2007, Guidant has received reports of 36 clinical failures out of the entire worldwide population of 26,000 devices manufactured before April 16, 2002, which is a failure rate of 0.13%. This information highlights the rarity of short-circuiting in the header of the PRIZM 2, as well as the extraordinarily low malfunction rate from all causes across the product line. *See* Deposition of Randy Nuerenberg at 758:12 – 760:13 (Dkt. # 1745, Ex. 38).

H. The polyimide story.

Polyimide is a synthetic polymer that is resistant to high temperatures, wear and corrosion, and is used primarily as an insulating coating or film. This material "enjoys widespread use in a variety of applications from *medical devices*, to microelectronics, to aerospace applications. Polyimide is recognized as having a unique combination of electrical, thermal, chemical, and mechanical properties." Report of John E. Moalli, Sc.D. at ¶ 2.1.1.1 (Dkt. # 1745, Ex. 39). More than two decades ago, medical

device companies such as Guidant began using polyimide as an insulator. *See* Report of David F. Williams, Ph.D. at 11 (Dkt. # 1745, Ex. 40).

Guidant successfully incorporated polyimide in various forms in its devices for many years. "We [Guidant] have used polyimide insulation in a variety of applications for over a decade and in generations of devices before PRIZM 2 DR and RENEWAL 1/2 defibrillators." CPI 83 00049474-49580 at 49476 (November 22, 2005 e-mail from Paul Stone to Brian King) (Dkt. # 1745, Ex. 41). In fact, more than 200,000 other Guidant devices, with more than five million combined implant months, had employed polyimide tubing insulation successfully. There had been no reports of shorting failures which inhibited therapy in any of these devices. *See id.* at 49477-49478.

The FDA was first informed of Guidant's use of polyimide tubing in ICD headers on March 27, 1992. *See* CPI 100 00056084-56117 (March 27, 1992 VENTAK PRx IDE submission) (Dkt. # 1745, Ex. 42). In 1992, Guidant had requested approval "to change the insulation material on the feedthrough wires from silicone rubber tubing to polyimide tubing" for the VENTAK PRx device. Guidant's request included qualification test results for the polyimide tubing Guidant conducted. Testing included: visual inspection, dimensional inspection, bend test, high-voltage breakdown, toxicity, pyrogenicity, infrared analysis, and resistance to solvents. *See id*. at 56109, 56093. Thus, the use of polyimide on feedthru wires in device headers was expressly approved by FDA as early as 1992 and, for ten years thereafter, Guidant had favorable experience with that selection of insulating material. *See* CPI 100 00056084 (April 30, 1992 letter

from CDRH to CPI) (Dkt. # 1745, Ex. 43); CPI 100 00056087 (June 3, 1992 letter from CDRH to CPI) (Dkt. # 1745, Ex. 44).

Guidant continued to make the FDA aware of its use of polyimide in a number of submissions:

- September 1, 1994, FDA submission for the VENTAK PRx II device referenced/listed polyimide tubing in the component testing matrix for the device, and again included Guidant's polyimide Component Qualification Testing as an exhibit. *See* CPI 100 00004893-4935 (Sept. 27, 1995 VENTAK PRx II PMA, P910077, Vol. I) (Dkt. # 1745, Ex. 45); CPI 100 00007193-7197 (Section 4.0, Non-Clinical Laboratory Studies, Sept. 27, 1995 VENTAK PRx II PMA, P910077, Vol. 6) (Dkt. # 1745, Ex. 46); CPI 100 00007231 (Section 4.5, Exhibits to Non-Clinical Laboratory Studies, Sept. 27, 1995 VENTAK PRx PMA, P910077, Vol. 6) (Dkt. # 1745, Ex.47); CPI 100 00007642-7651 (Exhibit 29 to Sept. 27, 1995 VENTAK PRx PMA, P910077, Vol. 6, Polyimide Tubing Component Evaluation Test Report) (Dkt. # 1745, Ex. 48).

- August 23, 1999 PMA for VENTAK PRIZM contained a Biocompatibility Assessment of the VENTAK PRIZM which stated that the feedthru wires were "prepped with polyimide." *See* CPI 100 00004203-4214 (June 11, 1999 Biocompatibility Assessment for VENTAK PRIZM, Rev. C) (Dkt. # 1745, Ex. 49).

- May 30, 2000 PRIZM 2 PMA Biocompatibility Assessment stating that feedthru wires are "prepped with polyimide." CPI 100 00056180-6187 (Dkt. # 1745, Ex. 50).

All subsequent PMA supplements incorporated the materials submitted in connection with the PRx PMA. *See* Novak Deposition at 504:2-19. This includes the PMA submission for the VENTAK AV which ultimately became the PRIZM 2's direct predecessor device. Thus, the FDA knew about Guidant's use of polyimide insulation in the header of the PRIZM 2 and had approved of polyimide's use.

Guidant employed polyimide tubing in devices following successful material testing in 1991 and 1992. *See* CPI 100 00056151-61 (January 31, 1992 Component Evaluation Test Report on Polyimide Tubing) (Dkt. # 1745, Ex. 51). Moreover, polyimide has long been used as an electrical insulator and its specifications are well-developed. *See* CPI 12 00030520 (MST Polyimide Tubing Specifications, revision dated March 27, 2002) (Dkt. # 1745, Ex. 52). In the development and testing of the PRIZM 2 device, the device's extensive functional requirements were exceeded by polyimide tubing's electrical insulating capabilities. *See* CPI 539 0000043898 (PRIZM 2 documents) (Dkt. # 1745, Ex. 53).

The polyimide tubing covering PRIZM 2 feedthru wires was 2.8 mil thick. *See* CPI 46 00497207-7221 (Physical Spacing PRIZM 2, Rev. A, Aug. 2, 2000) (Dkt. # 1745, Ex. 54). The feedthru wires (including the DF- wire) were designed to carry electrical loads from 0 to 645 Volts. *See id*. Polyimide is uniquely capable of insulating such high-energy applications. Exhibiting dielectric strength in excess of 4000 volts per mil, polyimide far exceeds the expected voltage requirements of the DF- feedthru wire. *See* CPI 12 00030520 (MST Polyimide Tubing Specifications, revision dated March 27, 2002); *see also* Armstrong Deposition at 89:16 – 90:8. In short, the polyimide tubing in the PRIZM 2 device can withstand *five times* the DF- feedthru wire's expected voltage.

I. Guidant leads a changing industry.

For the last two years, the medical-device industry has been working to determine uniform standards for device-performance reporting. Since 2005, Guidant has

been working to provide physicians and patients with more information about expected and actual device performance. Guidant has led the industry in these efforts.

In June 2005, Guidant announced its intention to establish an Independent Panel of experts to review, assess, and make recommendations pertaining to various policies and procedures of CRM. *See* CPI 101 00026584 (June 22, 2005 Guidant Press Release) (Dkt. # 1745, Ex. 57). The Panel was charged with providing recommendations to the company on ways in which it could improve: (1) surveillance and understanding of infrequently occurring events among life-sustaining implantable devices that may affect physician decisions for their patients; (2) assessment of the benefit and risk to patients; and (3) processes related to communication to physicians and patients. *See id*.

Guidant's Independent Panel was given complete and unfettered access to company employees, documents, and facilities. The entire Panel met on six occasions during late 2005 and early 2006, and also made two site visits to Guidant facilities during late 2005. Numerous Guidant employees participated in interviews and/or group discussion sessions with the Panel covering many topics relevant to the Panel's Charter. *See* Independent Panel Report at 40-42 (Dkt. # 1745, Ex. 58).

The Independent Panel issued its final Report on March 20, 2006. *See* Independent Panel Report. The Report consists of the Panel's observations, conclusions, and recommendations pertaining to the handling of low-frequency events and trends. Guidant made the report public because the entire medical-device industry could benefit from the Panel's recommendations.

Guidant has also participated in the dialogue among physicians, patients, the FDA, device manufacturers, and advocacy groups on the topic of when manufacturers should communicate concerning low-level failures. At a conference sponsored by the Heart Rhythm Society in September 2005, all of these stakeholders came together to discuss ways in which to improve communication, and Guidant employees participated in that discussion as presenters and panel members. The October 2006 publication of *Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines* was the result of the frank dialogue that took place between physicians, patients, the FDA, and members of industry one year earlier. Guidant has since been working to integrate the HRS Recommendations into its processes and procedures.

In addition to commissioning the Independent Panel and participating in open discussions about how to improve device reliability and reporting, Guidant has pioneered an enhanced Product Performance Report that provides significantly more information than versions published in the past. Beginning in 2006, Guidant began publishing its PPR quarterly, and the new format includes information on: (1) how to use the report; (2) the statistical methodology used to create the report; (3) graphs and charts depicting the percentage of explanted devices returned Guidant; (4) charts and graphs on U.S. survival probability; (5) data on products subject to safety advisories; (6) data on confirmed malfunctions; and (7) device longevity estimates. *See* Report of Stephen D. Walter at 2 (Dkt. # 1745, Ex. 59). The detailed information contained in Guidant's new PPR sets the standard for the industry. *See* Russie Deposition at 263:3 – 266:17.

Finally, Guidant is leading the industry by offering groundbreaking products to enhance patient health and safety. For example, Guidant's new LATITUDE Patient Management System monitors the patient's ICD remotely through a small piece of equipment that sits in the patient's home and connects to a standard phone jack. The LATITUDE system is capable of checking battery status, lead status, and device settings – all without the patient ever leaving his or her home. The System will automatically notify the patient's doctor if certain conditions are detected. *See* http://www.aboutlatitude.com/what-is-latitude/index.html. Although implantable cardiac devices will likely never be 100% reliable, Guidant is doing everything it can to give patients and their physicians peace of mind.

J. Eugene Clasby

1. Dr. Clasby's device was not recalled.

Dr. Clasby was implanted with a PRIZM 2 DR, Model 1861 device on December 30, 2002, after he collapsed on the tennis court and suffered cardiac arrest. Plaintiff's Fact Sheet at 6 (Ex. 4); Dep. Tr. of Eugene Clasby at 135: 16-22 (Ex. 5). On May 4, 2006, 11 months after hearing of the recall of other 1861 devices, Dr. Clasby voluntarily elected to have his device explanted. Report of Dr. Thomas Ross at 11. Guidant paid for Dr. Clasby's Replacement device. *See* Plaintiff's 5/24/06 Revision to Plaintiff's Fact Sheet at IV(E)(9) (Ex. 6); Dep. Tr. of Eugene Clasby at 210:1-5, 211:6-9. Guidant issued a $17735 credit for Dr. Clasby's first device. *See* CPI 176 00007582 (Clasby Credit Memo) (Ex. 7).

However, Dr. Clasby's device was not part of the recall, and his physicians were aware of this fact. See CPI 53500 000 12206 (Field Actions Mailed 6/17/06 - 7/22/06) (Ex. 8). The FDA recall regarding PRIZM 2 DR, Model 1861 devices was explicitly limited to those manufactured on or before April 16, 2002. Press Release, Food & Drug Administration, FDA Issues Nationwide Notification of Recall of Certain Guidant Implantable Defibrillators and Cardiac Resynchronozation Therapy Defibrillators (June 17, 2005) (June 17, 2005 FDA Press Release) (Ex. 9). The manufacture of Dr. Clasby's device did not begin until May 2002. CPI 176 00007228 (Device History Report) (Ex. 10)

On April 16, 2002, Engineering Change Order (ECO) 40773 made changes to the design and manufacturing process of the PRIZM 2. Guidant Engineering Change Order No. 40773/C001247. At the time of the FDA recall regarding PRIZM 2 DR, Model 1861 devices, no devices manufactured after April 2002 had demonstrated any malfunction or failure associated with arcing. June 17, 2005 Press Release. Since the FDA recall, only one such malfunction has occurred in Dr. Clasby's device population. Advisory Update, Guidant, VENTAK PRIZM 2 DR Model 1861 (May 9, 2006) (Ex. 11). Out of a total of approximately 11,000 devices in this population, a single malfunction represents an occurrence rate of 0.009%. Boston Scientific: CRM Product Performance Report 2007: Q1 at p. 178. Testing of 877 post-April, pre-November returned devices did not provoke a single malfunction. Boston Scientific CRM Product Performance Report 2007, Q1.

2. Dr. Clasby's device functioned perfectly.

Dr. Clasby's device worked properly until he voluntarily elected to have it explanted after using it malfunction-free for almost three-and-one-half years. His device never manifested an arc in the header or any other defect while implanted in him. At no time did Dr. Clasby's doctors tell him that his device exhibited any type of malfunction, as Dr. Clasby testified during his deposition:

> Q Did any physician tell you that your PRIZM 2 defibrillator was defective?
>
> A No.
>
> * * *
>
> Q Did Dr. Feldman ever tell you that your device, the one that you had implanted, your PRIZM 2, was defective or had manifested some type of defect?
>
> A No.
>
> * * *
>
> Q During any of these kind of three-month checkups, did the technician or doctor ever tell you that your device had malfunctioned?
>
> A No.
>
> Q During these checkups, did any technician or doctor tell you that your device had manifested a defect or had a defect in it?
>
> A No.
>
> Q During any of these checkups, these three-month checkups with your PRIZM 2, did any technician or doctor tell you that your device wasn't working properly?
>
> A No.

Dep. Tr. of Eugene Clasby at 38:19-21, 39:24-40:2, 156:3-15. His medical records support his testimony that at each of his three-month checkups, the device was shown to be working properly. *See* SMH00341, JMH00282-00290, SMH00727, and DGA00060-00066 (medical records) (Ex. 12).

In January 2003, Dr. Clasby's physician, Dr. Myerburg, instructed him to refrain from playing tennis until fall 2003, almost a year after his implant surgery. Eugene Clasby Dep. Tr. 157:9 – 158:3. Yet on April 1, 2003 – just three months after his implant surgery – Dr. Clasby played a "fairly aggressive" and "vigorous" game of tennis. Eugene Clasby Dep. Tr. 159:16-24; *see also* SMH00722 (medical records). During that game of tennis, Dr. Clasby's heart rate reached 184 beats per minute, and his PRIZM 2 shocked him several times to correct sinus tachycardia. *See* RBM-00006 (medical records).

Dr. Clasby cites the April 2003 tennis incident as his sole evidence of "inappropriate shocks," Dr. Myerburg noted following the tennis incident that, "the main issue here is sinus tachycardia during exercise. If we can keep him under the current ICD detection rate, I would be satisfied with that or we could increase the rate if needed." *Id.* Dr. Clasby's PRIZM 2 was interrogated two days after the tennis incident and the results were: "Normal function. No changes made to device." *See* SMH00727 (medical records). After this incident, Dr. Clasby's physicians prescribed him a "beta blocker" to keep his heart rate under the ICD detection rate. Dep. Tr. of Eugene Clasby at 48:10-12.

Dr. Clasby's PRIZM 2 never shocked him again.[2] *Id*. at 46:6-9. None of his physicians told him that his device was defective or malfunctioned:

> Q. So no physician told you that your device, at that point, was defective?
>
> A. No…
>
> Q. At any point, did a doctor or physician tell you that your device had malfunctioned after it had shocked you?
>
> A. No…

Dep. Tr. of Eugene Clasby at 163:14-16; 24-25; 164:1-2.

Finally, both his final interrogation, taken on the day of his explant, and the post-explant visual inspection illustrate that Dr. Clasby's device was functioning appropriately. *See* PLTF0023-0039 (medical records); Device Evaluation Report at p.1 (Ex. 13)

In short, neither Dr. Clasby's doctors nor any Guidant representative ever told Dr. Clasby that his device malfunctioned in any way. Significantly, Dr. Clasby's device never short-circuited in the header, which is the basis of his defect claim.

3. The reliability of the PRIZM 2 was within the range expected by Dr. Clasby when the device was implanted.

Dr. Clasby understood that his PRIZM 2 device had some risk of failure. In its patient manual, Guidant warned Dr. Clasby that his device carried the risk of "inappropriate shocks" and "potential mortality due to the inability to defibrillate or pace." System Guide at 1-9 – 1-10; *see also* Physician's Technical Manual at 4. Further,

[2] Indeed, Dr. Clasby's claim that his device improperly shocked him is the antithesis of the claim that his device would be unable to deliver the necessary therapy when called upon to do so.

Guidant warned that patients may develop "psychological intolerance" leading to "depression." Physician's Technical Manual at 4.

In his deposition when he was asked whether the device positively impacted his life from a health standpoint, Dr. Clasby testified as follows:

> A [I]t gave me confidence that I had some – a device that would intervene in case of a repeat of a cardiac arrest so as to give me a chance of surviving it, not 100 percent, but better than zero.
>
> * * *
>
> Q Was it your personal understanding that your device was 100 percent guaranteed to work?
>
> A I was confident that it would work.
>
> Q Were you 100 percent confident that it was going to work?
>
> A I'm not 100 percent confident of anything . . . . You know, I'm confident. But nothing is 100 percent.
>
> * * *
>
> Q After you were implanted with your PRIZM 2, did any of your doctors or physicians tell you that even if your device works perfectly, it may not be able to save your life?
>
> A No one told me that that I can recall.
>
> Q Did you understand that on your own?
>
> A As I said before, there are no hundred percent deals that I know of in life. But I focused on the . . . positive aspect of it, that it was – it was presented to me as an extremely valuable device, one that was a lifesaver, and that would, all things being equal, give me a chance of surviving if I had another – let's put it this

> way: It was, in my mind, much, much better than not having one. I knew that there were – and I would be foolish not to think – to know that there were risks, but they seemed to be outweighed by the benefits, far away.
>
> * * *

Dep. Tr. of Eugene Clasby at 164:19-23, 143:24-144:6, 148:13-149:4. Yet, despite Dr. Clasby's understanding that there were risks involved, that having a device is much better than not having one, and that nothing is 100%, he elected to have his device explanted. But because this group of PRIZM 2 devices have been malfunction-free 99.9991% of the time, the actual risk of malfunction was well within the risk initially anticipated by Dr. Clasby.

Not only was the actual risk of malfunction within that which was expected, but Dr. Clasby unreasonably believed that the risk of failure was greater than what it is. Dr. Clasby held to this belief despite the reported failure-rate statistics, and the fact that his device exceeded Guidant's reliability projections submitted to the FDA both before and after the April 2002 Engineering Change Order. Moreover, Dr. Clasby employed flawed reasoning that discounted the evidence and the use of redundant safety measures in the design as indicated in his following testimony:

> A I suspected that the number [of device failures] actually was higher, though I had no evidence at that time to believe that that was so, except my own intuition and my own sense of – that the device was inherently flawed; and that these numbers were so low that the laws of physics would suggest that if they're using this insulation and its moisture sensitive, that it's going to fail more than the miniscule number they

were suggesting. That was my conclusion, for whatever it's worth.

Q Was that conclusion based on anything other than what you just told me?

A No one said that to me, no.

Q It was a conclusion you arrived at on your own?

A That's a conclusion I arrived at on my own. Yes. That's correct.

* * *

Dep. Tr. of Eugene Clasby at 225:12-226:3. Dr. Clasby also subjectively magnified the risk beyond that indicated by failure statistics as indicated when he explained his belief concerning the actual risk of device failure as follows:

A While there was no guaranty that the device would work under all circumstances forever, there was also a kind of implicit sense that it would, given half a chance, operate successfully. You know? And that the chances were much, much better with the device than without it. Then it started to occur that that margin of safety had been reduced significantly, in some people to zero.

Dep. Tr. of Eugene Clasby at 174:11-18. Later Dr. Clasby explained:

A Well, I knew someone had died; at least one person had died, from the failure of the device. And that seemed significant to me. Even though it was only one dead, that seemed significant.

Dep. Tr. of Eugene Clasby at 173:15-18.

In short, the actual risk of malfunction in Dr. Clasby's version of the PRIZM 2 is within the range of risk initially expected by Dr. Clasby. Although not 100%, the risk of malfunction is less than 0.0001%. As such, Dr. Clasby's belief

concerning his device's failure rate does not reflect reality as the margin of safety has not been reduced "significantly," much less "to zero."

4.

5. All of the significant contacts for this lawsuit are situated in Florida.

Dr. Clasby filed his lawsuit in Florida, where he has resided for forty years. *See* Class Action Compl. for Med. Monitoring and Inj. Relief, filed in the United States District Court for the Southern District of Florida; Dep. Tr. Eugene Clasby at 82:16-21; Plaintiff's Fact Sheet at II(C)-(D). Dr. Clasby's Florida doctors prescribed an implantable defibrillator, recommended that device to his wife, and implanted the device in him based on her consent—all in Florida. *See* Dep. Tr. of Eugene Clasby at 138:23–139:11; Plaintiff's Fact Sheet at IV(A)(2)-(3). A pamphlet prepared by Guidant was provided to Dr. Clasby in Florida by the Florida hospital where the implantation occurred. *See* Dep. Tr. of Eugene Clasby at 151:15–152:1; Plaintiff's Fact Sheet at IV(C). Dr. Clasby also received similar information in Florida from his Florida doctor. *See* Plaintiff's Fact Sheet at IV(D).

Dr. Clasby experienced an incident, in Florida, where his device allegedly shocked him. He was treated for that incident at a Florida hospital and then subsequently treated for the alleged effects of that incident by a Florida psychiatrist and psychologist. *See* Dep. Tr. of Eugene Clasby at 41:25–42:20; Plaintiff's Fact Sheet at I(C)(2), VI(B)(4)-(5), VII(A). Dr. Clasby spoke with Guidant's representative only once, and that occurred in Florida after the alleged shocking incident. *See* Dep. Tr. of Eugene Clasby at 42:18–44:5, 156:1-2.

Dr. Clasby had his device monitored at Florida hospitals and learned of potential problems with the device while reading the New York Times, as he does every day in Florida where he resides. *See* Dep. Tr. of Eugene Clasby at 62:13-21, 152:4-6, 154:11-18, 171:7-21; Plaintiff's Fact Sheet at IV(B)(1)-(2). The device was then explanted in a Florida hospital by a Florida surgeon based on a decision made by Dr. Clasby in Florida after consultation with his Florida doctor. *See* Dep. Tr. of Eugene Clasby at 15:20–16:1, 16:8-16, 222:25–223:14; Plaintiff's Fact Sheet at IV(F)(4); Plaintiff's 5/24/06 Revision to Plaintiff's Fact Sheet at IV(E)(2)-(4).

III. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT BASED ON FEDERAL PREEMPTION

Guidant is entitled to summary judgment because federal law preempts Dr. Clasby's Florida state-law claims.[3] Dr. Clasby's claims either conflict with, or add to, the

[3] Although choice of law principles require application of Florida law to Dr. Clasby's state statutory and common law claims, *see* Part IV, *infra,* when analyzing questions of federal law, including preemption, an MDL transferee court "should apply the law of the circuit in which it is located." *In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996); *see also In re Bridgestone/Firestone Inc., Tires Prod. Liabl. Litig.*, 256 F. Supp. 2d 884, 888 (S.D.

specific federal requirements imposed upon the manufacturers of medical devices by the federal Food and Drug Administration ("FDA"). Here, Dr. Clasby alleges a host of such claims, including strict product liability (failure to warn and design defect), negligence, negligence per se, breach of implied warranty, fraud, consumer protection, negligent and intentional infliction of emotional distress.[4]

The PRIZM 2 is subject to the FDA's most rigorous and comprehensive approval and post-approval regulations. *See* 21 C.F.R. § 860.3(c)(3). Before the FDA permitted Guidant to introduce the PRIZM 2 for sale in the United States, the FDA required Guidant to demonstrate that the device was safe and effective through a process known as Pre-market Approval ("PMA") – a process reserved only for Class III devices. *See generally*, Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Medical Device Amendments of 1976 ("MDA"). Guidant has, in its prior briefing to the Court, set forth facts and supporting evidence surrounding FDA's comprehensive regulation of medical devices generally, and the PRIZM 2 specifically. *See* MDL Dkt. #1430 at Part I. Guidant hereby incorporates that prior briefing by reference. Key among those facts are that under the PMA process, the FDA first evaluated, and then approved, *every* aspect of the design, manufacturing process, and labeling of the PRIZM 2. The FDA approved the PRIZM 2 on August 4, 2000. The

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Ind. 2003); *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993); *Hartline v. Sheet Metal Workers' Nat'l Pension Fund*, 286 F.3d 598, 599 (D.C. Cir. 2002).

[4] Preemption would not bar a true manufacturing defect claim, *see* discussion at section III.B.3.c, *infra*; however, Dr. Clasby has not pled facts or offered expert testimony in support of such a claim. *Id.*

FDA has *never* revoked, suspended, or withdrawn that approval. Guidant has and continues to comply with the extensive federal requirements imposed on it by written conditions the FDA communicated with that approval.

The United States Congress has ceded exclusive regulatory authority over medical devices to the FDA, and has determined that satisfaction of the FDA's requirements is adequate, as a matter of law, to safeguard the American public in its use of medical devices. As a measure of protection for the FDA's authority, and to insure against the imposition of varying state-law requirements, Congress expressly preempted certain state law regulations and legal claims. Such regulations and claims are preempted if they create "requirements" that are "different from, or in addition to" the federal requirements that apply to medical devices *and* "relate[]" either "to the safety or effectiveness of the device or to any other matter included in" a federal requirement. 21 U.S.C. § 360k(a) ("§ 360k(a)").

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), a majority of Supreme Court justices concluded that even judgments in state tort suits would constitute state "requirements" encompassed by § 360k(a). The vast majority of lower federal and state courts to have addressed this issue – including the Eighth Circuit – have concluded that the statute preempts precisely the sorts of design-related, failure-to-warn, misrepresentation, warranty, and consumer-fraud claims against PMA-approved devices asserted by Dr. Clasby in this case. According to these courts, these types of claims impermissibly challenge the FDA's authority by imposing on manufacturers different or additional state requirements related to the design, manufacture, and labeling of FDA-

approved devices. The doctrine of preemption protects the FDA from such meddling and second-guessing by plaintiffs and juries.

Dr. Clasby's claims are not only expressly preempted by the MDA, but also impliedly preempted. If allowed to proceed, these claims will conflict with and frustrate the federal purposes underlying the MDA, as well as impermissibly invite lay jurors to replace the expert judgment of the FDA concerning the safety and effectiveness of the PRIZM 2's design, method of manufacture and labeling with their own. *See Buckman v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001).

A. The U.S. Constitution provides the basis for federal preemption of state law claims.

Under our federal Constitution, the laws of the United States "shall be the supreme Law of the Land" notwithstanding "any Thing in the Constitution or Laws of any state to the Contrary." U.S. Const. art VI, cl. 2; *see also McCulloch v. Maryland*, 4 Wheat. 316, 427, 4 L. Ed. 579 (1819) ("It is of the very essence of supremacy, to remove all obstacles to its action within its own sphere, and so to modify every power vested in subordinate governments."); *Brooks v. Howmedica,* 273 F.3d 785, 792 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002). By virtue of this Supremacy Clause, "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group. Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Thus, where preemption applies, it cannot be involuntarily waived or stricken.

Because Congress has the power to displace state law through federal legislation, Congress's purpose "is the ultimate touchstone of pre-emption analysis."

Cipollone, 451 U.S. at 516. Federal preemption of a state law claim may occur by the *express language* in a congressional enactment, *see, e.g., id.* at 517; *Brooks*, 273 F.3d at 792; *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 728, n.3 (D. Minn. 2005). It may also occur by implication *because of a conflict* with a congressional enactment. *See, e.g., Geier v. American Honda Motor Co.*, 529 U.S. 861, 869-874 (2000). These bases for preemption are not mutually exclusive. *Geier*, 529 U.S. at 869. Thus, both express and implied preemption may apply. In fact, both apply here.

B. The medical device amendments expressly preempt Dr. Clasby's state-law claims.

When Congress created the MDA, it conferred upon the FDA comprehensive regulatory authority over medical devices, and simultaneously took deliberate steps to "prevent state requirements from unduly burdening interstate commerce." *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994). Congress sought to preserve the uniformity of the federal regulatory scheme and to protect innovations in device technology from being "stifled by unnecessary restrictions" by including in the MDA an express preemption provision that serves as a "general prohibition on non-Federal regulation." H.R. Rep. No. 94-853, at 12, 45 (1976).

The MDA expressly preempt state-law requirements governing certain medical devices:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this [Act] to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act]

21 U.S.C. § 360k(a).

Dr. Clasby's Florida state law claims relating to the PRIZM 2 are expressly preempted under the MDA because: (1) there are specific federal requirements applicable to the device at issue; (2) there are particular state requirements with respect to the medical device; and (3) the state requirements are in addition to or different from the federal requirement. *See Brooks,* 273 F.3d at 793-94; *see also Lohr*, 518 U.S. at 500.

1. The FDA's PMA approval process imposes device-specific federal requirements.

Under federal law, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a matter that is inconsistent with any conditions to approval specified in the PMA approval order for the device." C.F.R. § 814.80; *see also id.* at § 814.39. In other words, a Class III medical device manufacturer is *required* to follow the design and other specifications embodied in a PMA submission once the device is approved.

As a matter of law, the Eighth Circuit has recognized that the PMA process creates federal "requirements" with respect to the design manufacture, and sale of medical devices, and thereby requires preemption of claims such as those asserted by Dr. Clasby. "Through its approval of the PMA application . . . and its continuing series of directives, the [FDA] impose[s] specific federal requirements on [the manufacturer]." *Brooks*, 273 F.3d at 798; *see also McMullen v. Medtronic, Inc.,* 421 F.3d 482, 487-88 (7th Cir. 2005), *cert. denied,* 126 S. Ct. 1464 (2006) ("federal requirements specific to

individual products are imposed through [this] PMA process."); *Horn v. Thoratec Corp.*, 376 F.3d 163, 169-70 (3d Cir. 2004) ("the requirements imposed by the FDA . . . when it [grants] PMA approval are precisely 'the sort of concerns regarding a specific device' which the Supreme Court (in *Lohr)* intimated would give rise to preemption under § 360k(a)"); *Gomez v. St. Jude Medical Daig Div., Inc.*, 442 F.3d 919, 929 (5th Cir. 2006) (concluding that the PMA process "preempts state tort causes of action to the extent that they relate to safety, effectiveness, or other MDA requirements"); *Kemp v. Medtronic, Inc*., 231 F.3d 216, 227-28 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001) ("FDA approval of the . . . PMA Supplement, taken together with the conditions of approval imposed on the device by the FDA, constitutes a specific federal requirement applicable to the device."); *Martin v. Teletronics Pacing Systems, Inc.*, 105 F.3d 1090, 1099-1100 (6th Cir. 1997) (FDA approval of investigational device created federal requirements giving rise to preemption).

Indeed, since *Lohr*, numerous federal circuit courts, including the Eighth Circuit and district courts within it, have applied *Lohr's* preemption principles to affirm the dismissal of state-law claims pertaining to devices approved through the FDA's rigorous PMA process. *See, e.g., Brooks*, 273 F.3d at 785; *Reigel v. Medtronic, Inc.*, 451 F.3d 104, 106 (2d Cir. 2006); *Gomez*, 442 F.3d at 919; *Mattingly v. Medtronic*, No. 4:06-cv-00789-HEW, slip op. (E.D. Mo. Mar. 8, 2007) (Dkt. # 1745, Ex. 1745, Ex. 80). To date, the Supreme Court has consistently denied plaintiffs' writs of *certiorari* in these cases. *See, McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005), *cert. denied*, 126 S. Ct. 1464 (Mar. 6, 2006)*; Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001), *cert.*

denied, 534 U.S. 1078 (2002); *Brooks v. Howmedica, Inc*., 273 F.3d 785 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002); *Kemp v. Medtronic, Inc*., 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001); *Martin v. Telectronics Pacing Sys., Inc*., 105 F.3d 1090 (6th Cir. 1997), *cert. denied*, 522 U.S. 1075 (1998); *Mitchell v. Collagen Corp*., 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998); *Papike v. Tambrands, Inc*., 107 F.3d 737 (9th Cir. 1997), *cert. denied*, 522 U.S. 862 (1997).[5]

Several states' high courts, when facing the same issue, have also found medical device plaintiffs' state law claims preempted under the MDA. *See, e.g., Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Fry v. Allergan Medical Optics*, 695 A.2d 511, 516 (R.I.), *cert. denied*, 522 U.S. 952 (1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex.) (collecting cases), *cert. denied*, 524 U.S. 954 (1998).

In *Horn*, the Third Circuit actively sought out and received the FDA's views with respect the effect of the agency's PMA approval process.[6] The FDA made clear, in an amicus brief filed at the appellate court's request, the agency's view that the approval process for Class III devices *does* give rise to device-specific federal requirements:

> [T]he agency's approval of this device through the PMA process does impose specific requirements for the product, including requirements for its design, manufacturing,

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[6] The U.S. Supreme Court recently made the same request of the Solicitor General with respect to the pending petition for *certiorari* in another medical device preemption case. *See Reigel v. Medtronic Inc.*, 127 S. Ct. 575 (Nov. 6, 2006). No decision has been issued yet with respect to that petition.

> performance, labeling, and use. In approving the PMA for the [device at issue], FDA considered a variety of factors, such as the risk-benefit profile of the product, the nature of the medical conditions the product is intended to treat, and the availability of alternative therapies.
>
> ***
>
> Hence, although the FDA does not itself design any medical devices, through the PMA approval process it certainly establishes "specific requirements" applicable to a "particular device" because the specifications for that device's design, performance, manufacture, labeling, and use are approved by the agency based on what the applicant submits.

U.S. Brief in *Horn*, 376 F.3d 163 (emphasis added), available at 2004 WL 1143720, at *15-16 (May 14, 2004) ("*Horn* Amicus Brief") (Dkt. # 1430, Ex. C); *see also Horn*, 376 F.3d at 170-72, 177-178 (discussing the FDA's position). Indeed, as noted by the lower court in *Horn*, "[t]he vast majority of federal and state appellate courts that have addressed the issue have held that the PMA process is an example of a federal requirement that may trigger § 360k(a)) preemption." *Horn v. Thermo Cardiosystems, Inc.*, 229 F. Supp. 2d 381, 390 (M.D. Pa. 2002), *aff'd*, 376 F.3d 163 (3d Cir. 2004).

Of all the federal circuit courts to consider the issue, only the Eleventh Circuit has concluded that PMA approval does not create federal device-specific requirements.[7] *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999). *Goodlin*, however, is distinctly contrary to the Eighth Circuit's views, which bind this court. In *Brooks*, the Eighth Circuit clearly stated that PMA approval *can* create specific federal

[7] *Goodlin* was one of the first federal appellate decisions issued post-*Lohr* and has been repeatedly distinguished and rejected in the seven years since it was decided. *See, e.g.*, *Kemp*, 231 F.3d at 226-27; *Horn*, 376 F.3d at 170, n.11, *McMullen*, 421 F.3d at 488; *Brooks*, 273 F.3d at 796.

requirements, and concluded in that case that it *did*. *Brooks*, 273 F.3d at 798. *Goodlin* now stands alone – a minority of one against a majority of *seven* other federal circuit courts that have reached the opposite conclusion. The Second Circuit is the latest to join this "growing consensus" on the interpretation of the MDA. *See Reigel*, 451 F.3d at 105 ("[T]ort claims that allege liability as to a PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained premarket approval from the FDA, are preempted."). This Court should follow the extremely long line of federal circuit decisions, including the decision of the Eighth Circuit in *Brooks*, and grant summary judgment to Guidant.

2. The PRIZM 2 PMA approval was valid when issued and remains so today.

a. The FDA properly granted PRIZM 2 PMA approval.

There is no dispute that the FDA approved the PRIZM 2 on August 4, 2000 as Supplement 15 to PMA P960040. Guidant anticipates that Dr. Clasby will argue (inaccurately) that the company withheld information from the FDA that the FDA needed to fully evaluate the PRIZM 2 supplemental PMA application. Specifically, Dr. Clasby may wrongly claim that the FDA needed different or additional information related to Guidant's use of polyimide insulation in the PRIZM 2, but did not receive it.

The PRIZM 2 approval, however, was both well-founded and proper. Approval of a deficient PMA application is barred as a matter of law. Thus, had the FDA considered Guidant's supplemental PMA application deficient, the agency would have been required to deny PMA approval. *See* 21 C.F.R. § 814.45(b). It did not. The very

fact that the FDA approved the PRIZM 2 PMA supplement therefore establishes *as a matter of law* that the FDA had the information it needed to carry out its regulatory mandate. *Id.*

Moreover, the factual record unequivocally establishes that the FDA had:

(a) available thousands of pages of information concerning the PRIZM 2 in the PMA application,

(b) previously received and reviewed many thousands of pages of information in connection with PRIZM 2's predecessor devices, including the Ventak AV; and

(c) not only specifically considered, but also specifically approved the use of polyimide insulation of the same type and used for the very same purpose (electrical insulation in the device header) in Guidant AICD predecessors to the PRIZM 2 continuously since 1992.

See Novak Depo. Tr. at 490-494, 501 (Dkt. # 1430, Ex. B); *see also* Novak Depo. Ex. 369 (Dkt. # 1430, Ex. I).

Since the original approval for the use of polyimide insulation in Guidant's "PRx" device in 1992, subsequent PMA supplements, including the PMA submission for the VENTAK AV (the PRIZM 2's direct predecessor device), have all incorporated the materials submitted in connection with the PRx original PMA.[8] Novak Dep. Tr. at 504. Thus, the FDA was well aware of Guidant's use of polyimide insulation in the header of the PRIZM 2 and, in the exercise of its valid federal regulatory authority, had approved that use.

[8] The PMA submission for the Ventak AV was, at the request of the FDA, converted to an original PMA from a proposed supplement to the PRx PMA.

b. The PRIZM 2 PMA remains valid.

FDA's approval of the PRIZM remains in effect today. Plaintiff's own expert witness confirms that it remains approved. *See* Oct. 11, 2006 Suzanne Parisian Depo. Tr. at 148 (Dkt. # 1430, Ex. D) ("The PMA-approved device remains approved."); *id.* at 120:10-18. Federal regulations are clear that PMA approval cannot be withdrawn without a hearing, followed by prescribed statutory formalities. *See* 21 C.F.R. §§ 814.46, *et seq*. It is undisputed that the FDA has never commenced such due-process-based proceedings against Guidant with respect to the PRIZM 2. *See* Novak Dep. Tr. at 486 (testifying that FDA has never notified Guidant that the conditions of approval were not satisfied with respect to the PRIZM 2 or that there has been a suspension or withdrawal of the PRIZM 2 PMA).

Furthermore, although the FDA is fully empowered to order the removal of the device from the market or to seek restraining orders, injunctions, or seizures of product, the FDA has never taken *any* other action to prevent distribution of the PRIZM 2. Finally, the FDA has plainly continued to recognize the validity of Guidant's PRIZM 2 PMA, by continuing to require regulatory filings for the device, including annual reports. *See* Novak Dep. Tr. at 487. The undeniable facts are that the FDA properly approved the PRIZM 2 through the PMA process, and that the approval remains in effect today.

Even if Dr. Clasby's allegations of regulatory violations could be proven (and Guidant vigorously denies that they can be), the *availability* of the preemption defense would remain unaffected. *See Buckman*, 531 U.S. at 353-54 (Stevens, J.,

concurring); *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (rejecting argument that alleged failure to report to the FDA bars preemption as an impermissible attempt to "bootstrap" a "fraud-on-the-FDA" claim into a liability theory). Preemption is a function of constitutional law and cannot be "waived" or "forfeited." As the Supreme Court itself noted in *Cipollone*, state law that conflicts with federal law is simply "without effect." *Cipollone*, 505 U.S. at 516 (internal citations omitted).

Guidant anticipates that Dr. Clasby may attempt to avoid express statutory preemption by unilaterally "declaring" a violation or violations of the FDCA based on the improper legal conclusions of a retained "expert," and then relying upon Judge James Rosenbaum's recent denial of another medical device manufacturer's motion for summary judgment based on federal preemption. *See*, *In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886 (D. Minn. 2006).

In *Medtronic*, Judge Rosenbaum incorrectly concluded (relying in part upon plaintiffs' expert's improper legal conclusions) that Medtronic's alleged conduct would, if proven, render its PMA approval invalid. *See id.* at 895-896. The court also inappropriately narrowed application of the "fraud on the FDA" standard articulated by the U.S. Supreme Court in *Buckman*, ignoring the fact that the imposition of tort liability on a manufacturer based on an alleged withholding of information from the FDA would unquestionably conflict with the FDA's exclusive regulatory authority and would therefore be impliedly preempted. *See Buckman*, 531 U.S. at 349 n.4 ("it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA); *see also Raye v. Medtronic Corp.*, 696 F. Supp. 1273,

1274 (D. Minn. 1988); *Ledbetter v. Merck & Co., Inc.*, No. 2005-59499, slip op. at 6 (151st Dist. Ct. of Harris Cty, Apr. 20, 2007) (Dkt. # 1745, Ex. 81) (quoting *Buckman*, 531 U.S. at 349, 351) Finally, Judge Rosenbaum erroneously concluded that a medical device manufacturer can, by virtue of its alleged conduct, somehow place itself "beyond the ambit of federal preemption protection." 465 F. Supp. 2d at 900. In the absence of a withdrawal of PMA approval by the FDA, however, there is no legal basis for depriving a device manufacturer of this federal statutory defense, and Judge Rosenbaum cited none. Given these and other legal flaws, this Court should decline to follow Judge Rosenbaum's lead.

In addition to these legal bases, the *In re Medtronic* preemption decision should not affect the outcome of this motion for the independent reason that the Medtronic motion was decided at a point when disputed issues of fact had not yet been, and could not yet be, resolved. *See, e.g.*, 465 F. Supp. 2d at 896 (noting that "there is no question that there are unresolved fact issues here"), and at 897 (noting that "presently unrebutted facts" made it appear that Medtronic had failed to make timely reports to the FDA as required by federal regulation). Here, extensive fact discovery has been conducted in Dr. Clasby's case, a process that involved the depositions of more than twenty company witnesses and millions of pages of company documents. Unlike in *Medtronic*, the facts relevant to both Guidant's and the FDA's conduct are fully available to the parties and the Court.

3. Dr. Clasby's state-law claims create requirements related to safety and effectiveness that conflict with federal requirements and are therefore expressly preempted.

Under established law, the PMA process unquestionably creates device-specific federal requirements under the MDA with respect to the design, manufacturing, performance, labeling of the PRIZM 2. Dr. Clasby's state common-law and statutory causes of action impose state law "requirements" that relate to the safety or effectiveness of the PRIZM 2 as defined under *Lohr*, and are therefore preempted.

In *Lohr*, 518 U.S. at 509-11, the majority of Justices on the United States Supreme Court found that in the context of medical devices, "state common-law damages actions *do* impose [such] 'requirements' and are therefore pre-empted where such requirements differ from those imposed by the [Food Drug and Cosmetic Act as amended by the MDA]."[9] *Id.* at 509 (O'Connor, J., concurring and dissenting), 503 (Breyer, J., concurring in part); *see also Papike*, 107 F.3d at 741-42; *Worthy*, 967 S.W.2d at 370.[10] The same is true with respect to statutory or equitable claims that otherwise meet the standard of the MDA express preemption provision.

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[9] Construing another express preemption statute, the Supreme Court reiterated that "the term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Bates v. Dow AgroSciences LLC*, 125 S. Ct. 1788, 1798 (2005); *see also Geier*, 529 U.S. at 867 (noting that a majority of the Supreme Court in *Lohr* agreed that common-law tort actions may be preempted under the MDA's preemption clause); *accord McMullen*, 421 F.3d at 487.

[10] The Court in *Lohr* found that preemption did not apply because the device at issue was approved through the FDA's far less rigorous 510(k) process, rather than the PMA process applied to the PRIZM 2. *See also* Sheridan Aff. at ¶ 14. The Court noted that the "501(k) notification process *is by no means comparable* to the [more rigorous] PMA process." *Lohr*, 518 U.S. at 477-78 (emphasis added).

a. Dr. Clasby's design-based claims are preempted.

Dr. Clasby asserts products-liability design-related claims in both negligence and strict liability. Under applicable Florida law,[11] his strict-liability design-defect claim requires Dr. Clasby to establish that his PRIZM 2 was defectively designed. *See West v. Caterpillar Tractor Co.*, 336 So. 2d 80, 86-87 (Fla. 1976). Florida employs either of two tests to determine whether a product is defectively designed. Under the consumer expectation test, "a product is defectively designed if the plaintiff is able to demonstrate that the product did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner." *Force v. Ford Motor Co.*, 879 So. 2d 103, 106 (Fla. 5th DCA 2004). Under the alternative "risk-utility" approach, a product is defectively designed if the plaintiff proves that the design of the product proximately caused his injury and the defendant fails to establish that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design. *Id.*

Dr. Clasby's strict-liability claim is preempted under the consumer-expectation approach because, regardless of the level of performance an ordinary consumer would have expected of Dr. Clasby's PRIZM 2, to the extent the applicable state-law tort standard would require *any* degree of safety beyond that achievable with the FDA-approved design of the device (as Dr. Clasby plainly asserts), the claims are preempted. The PMA approval signifies the FDA's satisfaction that the PRIZM 2's design provided reasonable assurances of safety and effectiveness. But avoiding strict-

[11] Guidant contends that Florida law applies to Dr. Clasby's claims. *See* Part IV, *infra.*

liability under a tort claim requires perfection – either in the safety and performance of the PMA-approved design (which federal law does not require) or in a modified design (which federal law does not authorize). In either event, the consumer-expectation test requires something different from, or in addition to, the PMA-approved design.

Dr. Clasby's strict-liability design-defect claim fares no better under Florida's alternative risk-benefit test for such claims. Under Florida law, if Dr. Clasby were even able to make a *prima facie* showing that the product's design caused his injury, the burden would then shift to Guidant to prove that the benefits of the PMA-approved PRIZM 2 design outweigh its risks. *Id*. Federal law requires only that Guidant establish reasonable assurances of safety and effectiveness. Thus, requiring Guidant to make this showing (i.e., that benefits outweigh risks) in order to avoid civil liability imposes an *additional* requirement beyond those created by the existing and comprehensive federal regulatory structure. Such a result is impermissible under the MDA, and federal law expressly preempts Dr. Clasby's strict liability design defect claim as a matter of law.

Dr. Clasby also alleges that Guidant failed to exercise ordinary care in the design of the PRIZM 2.[12] Specifically, he alleges that Guidant failed to adequately test and study the PRIZM 2's specified components prior to obtaining FDA approval, including and especially the polyimide wire insulation used in the header of the

[12] To establish a claim for negligence under Florida law, Dr. Clasby must demonstrate all of the following: 1) the existence of a duty toward him; 2) a breach of that duty; and 3) that his injuries were actually and proximately caused by that breach. *See Rupp v. Bryant*, 417 So. 2d 658, 668 n.27 (Fla. 1982).

PRIZM 2. *See* Compl. by Adoption at ¶85.[13] But to the extent Dr. Clasby is suing over Guidant's use of polyimide in the design, he is plainly trying to use this lawsuit to supplant the FDA's regulatory authority with a state law standard imposing additional or different requirements. "[O]nce the FDA approves a specific design, that design becomes in effect the FDA requirement." *Easterling v. Cardiac Pacemakers, Inc.*, 986 F. Supp. 366, 374 (E.D. La. 1997); *see also Reigel*, 451 F.3d at 104; *Kemp*, 231 F.3d at 288 (recognizing that it is the totality of the FDA's design, manufacturing and labeling requirements and the prohibition against deviating from them, that constitute the FDA's requirements).

Once the FDA's PMA approval defined the PRIZM 2's design, Guidant was then bound to manufacture the device according to the approved specifications or risk loss of that approval. Novak Aff. at ¶ 32. Even the use of polyimide insulation itself was a specific regulatory requirement under the PRIZM 2 PMA, and required FDA approval to change. A state-law tort claim that demands a component part change that would be illegal if made without FDA approval clearly imposes different or additional requirements on a device manufacturer in contravention of the MDA's express-preemption provision.

Justice Breyer explained these design-related preemption principles in *Lohr* using the example of conflicting state and federal requirements concerning a hypothetical hearing-aid design. The Justice observed that the MDA would, without question,

[13] Similar design-based allegations form the foundation of Dr. Clasby's negligence, negligence *per se*, and implied warranty claims. First Am. Master Compl. at ¶¶ 288, 294, 299.

preempt a state regulation or common-law claim that required a manufacturer to make even a simple component change when that component was part of an FDA-approved design:

> If the federal law, embodied in the "2-inch" MDA regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical.
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> Consequently, I believe that ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.

Lohr, 518 U.S. at 504 (Breyer, J., concurring); *see also Brooks*, 273 F.3d at 796 (reiterating Justice Breyer's analogy).

In short, the FDA evaluated and approved *all* aspects of the design of the PRIZM 2, including the use of polyimide in the device header. Under the MDA, state-law claims cannot be used to "second guess" FDA regulation or impose liability for failure to use alternative product designs. All of Dr. Clasby's claims related to the design of the PRIZM 2 are thus expressly preempted.

b. Federal law preempts Dr. Clasby's claims based on an alleged failure to provide more or different information about the risks associated with the PRIZM 2.

The majority of claims asserted by Dr. Clasby are founded upon allegations that Guidant somehow knew something more or different about the risks associated with the PRIZM 2 than it communicated to him or his physician prior to his PRIZM 2 implant. *See* Compl. by Adoption at ¶211. For instance, Dr. Clasby asserts an independent cause of action for "Strict Liability – Failure to Warn." *Id.* at ¶¶ 271-277. His negligence claims also allege a breach of a duty to "warn" of the allegedly "defective nature of Defendants' devices," *id.* at ¶288-290, and a breach of an obligation not to "violate the law in the . . . warning of risks and dangers" of the PRIZM 2. *Id.* at ¶ 294.[14] Dr. Clasby's fraud and constructive-fraud claims are likewise founded on the mistaken notion that Guidant "omitted material facts regarding the safety and effectiveness" of the PRIZM 2. *Id.* at ¶¶ 305-306; 312-313. Dr. Clasby's trade practice claims assert that Guidant made fraudulent representations and material omissions in its communications to him and his physicians. *See id.* at ¶¶ 319; 349. Even his emotional distress claims are based upon an alleged failure to warn. *Id.* at ¶ 341.

[14] In *Lohr*, the Supreme Court held that claims of negligence based on a manufacturer's failure to follow federal requirements (i.e., negligence *per se*) are not automatically expressly preempted under § 360k because they may not impose a legal standard "different from, or in addition to" federal requirements. 518 U.S. at 494-95. In this case, however, Dr. Clasby's allegations that Guidant violated the FDCA are in substance failure-to-warn claims. As such, they are not only expressly preempted, but also impliedly preempted. *See* discussion at section III.C., *infra.*

(1) Federal law preempts Dr. Clasby's failure-to-warn claims.

Each of Dr. Clasby's warnings-related claims – whether asserted in negligence, strict liability, or fraud – at its core challenges the sufficiency of the FDA-approved labeling and warnings that accompanied every PRIZM 2 into the marketplace. *See* 21 U.S.C. § 360e(c)(1)(B)-(C) (F) (PMA process for Class III devices includes FDA scrutiny and approval of all labeling and warnings as particular aspects of the device); *see* 21 U.S.C. § 360e(d)(2)(A)-(D) (proposed labeling found to be false or misleading during the PMA process shall result in denial of the PMA application); Sheridan Aff. (MDL Dkt. #262) at ¶ 18.

Under Florida law, for instance, Dr. Clasby's claim for strict-liability failure-to-warn requires him to prove that Guidant failed to warn *adequately* of a danger that the manufacturer knew or reasonably should have known. *See Ferayorni v. Hyundai Motor Co.*, 711 So.2d 1167, 1172 (Fla. 4th DCA 1998). By definition, however, the FDA-approved labeling *is adequate* to inform the physician (and, by virtue of the learned intermediary doctrine, his or her patient) of all information the FDA considers material to the prescribing physician's decision. Representations of safety, effectiveness, conditions of use, hazards, or other information are considered part of labeling and cannot include any information inconsistent with the approved label. *See* Novak Aff. at ¶ 32. The FDA even approves the exact wording, punctuation, type of information, location of information, typeface, and font size of a product label. Thus, Dr. Clasby's claims plainly

demand something different from, and in addition to, the federal requirement – namely, a different label or labeling scheme. *See, e.g., Brooks*, 273 F.3d at 796.

In *Brooks*, the Eighth Circuit found that the MDA preempted plaintiff's state-law claim for failure to warn of the risk of occupational asthma associated with vapors emitted from mixing PMA-approved bone cement. As the Eighth Circuit noted, "[t]he failure to warn claim asserted by [plaintiff] would interfere or conflict with the specific federal requirements imposed during the regulation of [the product]." The Eighth Circuit emphasized that the bone cement at issue in that case had undergone the rigorous PMA process and that the "FDA drafted or approved every word of the [product's] label, and any changes were subject to close FDA scrutiny," just as the agency did with respect to the PRIZM 2 here. *Id*. The court explained that "[t]he effect of a jury finding of negligent failure to warn would be that state law would require [a defendant] to change the label and package insert for [the product], but [a defendant] may not unilaterally make such changes under federal law." *Id*.

The Eighth Circuit also discussed the FDA's comprehensive regulation of device labeling as follows:

> A device may not be labeled in a manner inconsistent with any conditions specified in its PMA. A manufacturer must submit a Supplemental PMA for any proposed labeling changes that affect the safety of the device. [Plaintiff] points out that the regulations permit manufacturers to make temporary changes in the interest of safety, but such changes are valid only after the manufacturer has submitted a Supplemental PMA and only during the pendency of that application. Once the Supplemental PMA has been approved, modified, or denied, the manufacturer must comply with the FDA's decision.

Brooks, 273 F.3d at 796 (citations omitted).

The overwhelming majority of circuit courts confronting this same issue have agreed with the Eighth Circuit's view as expressed in *Brooks*. The Seventh Circuit, for instance, concluded that a claim alleging inadequate warnings:

> would be based on the assertion that the manufacturer should have provided a different warning than the one approved by the FDA. Such a state-law claim would impose a requirement that was different from, or in addition to the applicable federal requirements and would be preempted.

McMullen, 421 F.3d at 488, *see also Cupek*, 405 F.3d at 424 ("Any claim, under state law, . . . that Defendant failed to warn patients beyond warnings required by the FDA . . . would constitute state requirements 'different from' or 'in addition to" the requirements of the federal PMA application and supplement process."); *Papike*, 107 F.3d at 738 (failure to warn claim preempted under § 360k(a)). Other district courts considering failure-to-warn claims involving Guidant have followed suit. *See Clement v. Kaiser Found. Health Plan, Inc.*, No. CV04-704 MJR(MCX), 2004 WL 3049753 (C.D. Cal. Dec. 13, 2004) (failure to warn and unintentional tort claims preempted); *Betterton v. Evans*, 351 F. Supp.2d 529 (N.D. Miss. 2004) (state law tort claims challenging design, labeling, manufacturing, safety, and effectiveness of PMA-approved device preempted).

In *Kallas v. Pfizer*, No. 2:04CV0998 PGC (D. Utah Sept. 15, 2005), the FDA responded to the district court's call for the agency's guidance on a similar labeling issue, albeit in the prescription drug context. Plaintiffs in that case argued that the manufacturer of a pharmaceutical product should be held liable under state law for using

only the labeling approved by the FDA, and *not* warning of additional potential risks. *See* U.S. Amicus Brief at p. 4 (Dkt. # 1430, Ex. G). It was the FDA's stated position that to hold the defendant liable – through legislation or tort judgments – for adhering to the FDA approved warnings, and not warning of additional potential risks, would be *contrary to federal law*. *Id*.) at 2-3 (emphasis added).

(2) Federal law preempts Dr. Clasby's fraud-based claims.

The foundation of Dr. Clasby's fraud claim is his allegation that Guidant "misrepresented that the Devices were safe and effective for their intended use by affirmative misrepresentation." Compl. by Adoption at ¶305. Under Florida law, Dr. Clasby must prove that Guidant's statements regarding safety and effectiveness were not only material, but intentionally false. *See Lance v. Wade*, 457 So.2d 1008 (Fla. 1984). Here, representations related to safety or effectiveness (and Dr. Clasby has not pled precisely which representations he contends were false, who made them, or when), were necessarily tempered by the FDA-approved labeling. That labeling specifically warned of the risk of component failure and even patient mortality. *See supra* Part II at 5-6.

The MDA expressly preempt Dr. Clasby's fraud and misrepresentation claims because those claims relate exclusively to FDA-regulated labeling, advertising, or promotional materials. As the Seventh Circuit explained in *Mitchell*:

> To the extent that [a claim of fraud through misrepresentations about the product] is based on the labeling of the product in conformity with the PMA requirements of the FDA, the claim is preempted for the same reasons that similar misbranding and mislabeling claims are preempted.

> The sufficiency of this information has been approved explicitly by the FDA.

126 F.3d at 914. The Seventh Circuit also noted that a fraud claim that encompasses allegations of fraud in advertising and promotional materials, which are also subject to FDA regulation, "would survive only to the degree that they allege that the material did not conform to the specifications of the PMA." *Id.* Here, Dr. Clasby has made no such allegations.

(3) Express preemption bars Dr. Clasby's emotional-distress claims.

The MDA expressly preempt Dr. Clasby's emotional-distress claims because those claims rest primarily upon allegations that he suffered distress as a result of having received *inadequate information* from Guidant about the risks associated with implantation of the PRIZM 2. *See, e.g.*, Compl. by Adoption at ¶341; *see also Talbott v C.R. Bard, Inc.*, 865 F. Supp. 37, 52 (D. Mass. 1994), *aff'd*, 63 F.3d 25 (1st Cir. 1995) (concluding that state law claims for negligent infliction of emotional distress brought by survivors of patient in whose angioplasty an allegedly defective Class III, PMA approved heart catheter was used were preempted, even where manufacturer had admitted willfully ignoring FDA requirements relating to those catheters).

(4) Federal law also preempts Dr. Clasby's consumer-protection claims.

Although he adopted the MDL Master Complaint as his own, and with it the statutory consumer-protection claim, to date Dr. Clasby has never bothered to

articulate the precise contours of his consumer-protection claim.[15] To whatever extent such a claim is based on alleged deficiencies in the safety or effectiveness of the design, warnings, or labeling of the PRIZM 2, however, federal law preempts it for the reasons cited above. *See, e.g.*, *Martin*, 254 F.3d at 575. The allegations under this Count of the Complaint by Adoption largely mirror the allegations that compose Dr. Clasby's failure-to-warn, fraud, and misrepresentation claims, which, as discussed above, are preempted.

Any state-law claims—regardless of their titles—asserted by Dr. Clasby and based upon an alleged failure or deficiency in the PRIZM 2's warnings, written marketing materials, or instructions, including any claims that would require Guidant to have communicated *anything* more or different about the risks posed by the PRIZM 2 than approved by the FDA, are expressly preempted by the MDA.[16] *See Mitchell*, 126 F.3d at 913-14; *Horn*, 376 F.3d at 177 n.22, *Martin*, 254 F.3d at 584-85; *Kemp*, 231 F.3d at 236-37; *see also Worthy*, 967 S.W.2d at 371.

c. The MDA expressly preempt Dr. Clasby's claims that take issue with the FDA-approved PRIZM 2 manufacturing process.

Despite the fact that his PRIZM 2 has never malfunctioned and *has not been recalled*, *see supra*, Part II at 28. Dr. Clasby makes liberal use of the term

[15] Dr. Clasby's original complaint included no such claim. The Complaint by Adoption does not specify which provisions of the Florida Deceptive and Unfair Trade Practices Act provisions Dr. Clasby contends apply to his claim under the Act. Guidant contends any such claim is also barred on non-preemption grounds. *See infra*, Part VII.

[16] This would include Dr. Clasby's unjust enrichment claim, to the extent it hinges upon a finding that retention of the conferred benefit would be inequitable because of conduct for which liability is preempted.

"manufacturing defect" throughout his adopted Amended Master Complaint. *See, e.g.*, First Am. Master Complaint at ¶¶ 83, 177, 282. To the extent Dr. Clasby intends to take issue with the manufacturing processes used to construct his device, those claims would impose requirements different from or in addition to those created by the PRIZM 2's PMA approval. The FDA evaluated and specifically approved the manufacturing process for the PRIZM 2, including a description of controls, which were detailed in the PRIZM 2's PMA application. *See* Novak Aff. at ¶¶ 25, 29. Once the FDA had issued its PMA approval for the PRIZM 2, Guidant was subject to stringent Quality Systems Regulation, including frequent inspections. Sheridan Aff. (Dkt. #262) at ¶ 32. Thus, the PRIZM 2 PMA approval created specific requirements related to the manufacturing processes to be used in constructing the device.

Numerous courts have held or otherwise noted that claims based on an alleged defect in the manufacturing process of a medical device are preempted under the MDA. *See, e.g., Easterling v. Cardiac Pacemakers, Inc.*, 986 F. Supp. 366, 375 (E.D. La. 1997) (holding that plaintiff's defective manufacture claim "can only be based on deviations from manufacturing specifications and standards approved in the PMA process"); *see also Horn*, 376 F.3d at 179; *Martin*, 254 F.3d at 584-85; *Mitchell*, 126 F.3d at 913; *In re Medtronic*, 96 F. Supp. 2d 568, 571 (E.D. Tex. 1999); *Baker v. St. Jude Medical, S.C., Inc.*, 178 S.W.3d 127, 137 (Tex. App. 2005); *Moore v. Sulzer Orthopedics*, 337 F. Supp. 2d 1002, 1011-12 (N.D. Ohio 2004); *Isbell v. Medtronic*, 97 F. Supp. 2d 849, 859 (W.D. Tenn. 1998).

To the extent Dr. Clasby intends to assert that his PRIZM 2 did not conform to FDA-approved manufacturing specifications, such a "true" manufacturing defect claim is admittedly *not* expressly preempted under the MDA because the state law claim would assert merely parallel, rather that different or additional requirements.[17] Such a claim, however, can only be resolved with the individual device history record, and here there is *no* evidence of a manufacturing defect in Dr. Clasby's PRIZM 2. Dr. Clasby's PRIZM 2 has not been recalled or explanted. Moreover, Dr. Clasby has produced *no* expert report in support of such a claim.

d. Federal law preempts Dr. Clasby's warranty and consumer protection claims.

Dr. Clasby restates many of his failure-to-warn and design-related allegations verbatim in attempts to assert warranty, consumer protection, and unjust enrichment claims. *See, e.g.,* Compl. by Adoption, Counts V, VII, IX, XVIII, XIX, XXI, XXIV. These alternative headings, however, do not alter the underlying basis of such claims – namely, that Dr. Clasby's PRIZM 2 is allegedly not safe and effective. Such claims therefore run counter to the FDA's conclusions about the PRIZM 2's safety and efficacy for its intended use, and as such are expressly preempted by the MDA. *See, e.g.*, *Martin*, 254 F.3d 573 (warranty claims preempted; claims under Texas deceptive trade practices act preempted); *see also Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir. 1995), *vacated for reconsideration in light of Lohr*, 518 U.S. 470 (1996) (implied warranty of fitness and merchantability claims preempted because they "by necessity

[17] This logical exception to express preemption is narrow, and does not extend to any and all claims that allege a criticism of the manufacture of a particular device.

depend . . . upon the accepted standards for the design and manufacture of products in the state of Pennsylvania" and those standards "may deviate from the FDA's determinations in the PMA process"); *Mitchell*, 126 F.3d at 911-915 (fraud, implied-warranty, and misbranding claims preempted); *Worthy*, 967 S.W.2d at 376-77 (claims under Texas Deceptive Trade Practices – Consumer Protection Act claims that "are similar to common law claims for negligence, breach of warranty, and products liability" are preempted).

The FDA's own views on this issue once again underscore the point that regulatory determinations of medical device safety and effectiveness are the optimal form of "consumer protection," and are within the Agency's exclusive domain:

> Congress enacted the MDA and vested in FDA the authority to implement its provisions, including making a determination whether Class III devices meet the PMA approval standard of a "reasonable assurance of safety and effectiveness." . . . It is within FDA's discretion to determine the quantity and quality of data necessary to meet this standard . . . and it is a scientific task for which FDA is uniquely qualified.

Statement of Interest of the United States of America at 9, *Murphree v. Pacesetter, Inc*., Civil No. CT-005429-00-3 (Tenn. Cir. Ct. Dec. 12, 2003) (citations omitted) (Dkt. # 1430, Ex. H). The FDA reiterated its position more recently via formal rule-making with respect to prescription drugs. *See* 71 Fed. Reg. 3911, 3934-36, 3967 (2006) (providing examples of how state law tort claims conflict with the FDA's federal law pronouncements, explaining why the FDA permits only scientifically valid warnings and discourages over-warning, and noting that its requirements constitute "both a 'floor; and a 'ceiling'").

The FDA has also explained that "[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling" because they do not involve "centralized expert evaluation of device regulatory issues." *Horn* Amicus Brief, Ex. C, 2004 WL 1143720, at *25-26. Instead, state tort actions "encourage, and in fact require, law judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of the FDA – sometimes on behalf of a single individual or group of individuals." *Id.*; *see also* 71 Fed. Reg., 3922, 3935.

In vesting the FDA with exclusive regulatory and enforcement authority and also enacting the preemption provision, Congress knew that Class III medical devices, by definition, involve substantial risk and require complex safety calculations that are best suited to expert evaluation. *See* Sheridan Aff. (Dkt. #262) at ¶ 21-22. No doubt Congress was well aware that Class III medical devices are inherently complex and some will fail, that scientific knowledge is never perfect, and that the FDA is not infallible. Nonetheless, Congress determined that device innovation is essential and that the risks are best managed by uniform federal regulation – not litigation in which juries are invited to revisit FDA decisions.

To the extent Dr. Clasby may argue in response to this Motion that the FDA's agency's views with respect to the applicability of preemption can be ignored, the Supreme Court has stated otherwise:

> [I]n most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.' Because the FDA is the federal agency to

> which Congress has delegated its authority to implement the provisions of the [FDCA], the agency is uniquely qualified to determine whether a particular form of state law. . .should be pre-empted.

Lohr, 518 U.S. at 495-96 (Stevens, J. plurality); *accord id.* at 505 ("[I]n the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect.") (Breyer, J. concurring). Indeed, the Supreme Court itself has recently *sought out* the views of the government with respect to the issue of federal preemption. *See Reigel,* 127 S. Ct. at 575.

C. Dr. Clasby's claims involving allegations that Guidant failed to report information to the FDA are impliedly preempted.

Dr. Clasby's fraud and negligence-based claims are preempted for additional reasons. He makes blanket allegations that Guidant has a "history" of withholding information regarding its devices from the FDA. *See, e.g.*, First Am. Master Complaint at ¶ 211. The FDA, however, has never notified Guidant that it believes the company withheld information from the FDA concerning the PRIZM 2 in violation of the conditions of approval. Dr. Clasby's adopted Master Complaint also asserts that Guidant failed to satisfy the post-market requirements of the FDCA with respect to the PRIZM 2, *see*, *e.g.*, *id.* at ¶¶ 95-96, when in fact it plainly has. *See* Novak Aff. at ¶¶ 33, 34.

Although the FDA has never suggested or made such a finding, Dr. Clasby contends that Guidant violated the FDCA (21 U.S.C. §§ 331(a) and 333(a)(2)), and that these violations are actionable in their civil lawsuit. *See* First Am. Master Complaint ¶ 74 (alleging Guidant's "failure to meet federal regulations applicable to medical

devices"), and ¶ 176 (alleging failure to "comply with FDA regulations and the Conditions of Approval relating to relevant PMA and PMA Supplements"). Dr. Clasby, however, does not have authority to police Guidant's compliance with the MDA. Congress assigned the FDA, not tort litigants, the responsibility and obligation to apply and enforce the MDA.

As the Seventh Circuit has observed, the MDA's express preemption provision is simply a manifestation of Congress' view that *all* regulatory authority rests with the FDA. *See Mitchell v. Collagen Corp.*, 67 F.3d at 1283. The provision therefore "does not permit such a searching state inquiry into the inner workings of FDA procedures.'" *Id.* (quoting *Michael v. Shiley*, 46 F.3d at 1329). Pursuant to the Supreme Court's decision in *Buckman*, 531 U.S. at 352, any attempts by Dr. Clasby to usurp the FDA's regulatory role are impliedly preempted.

In *Buckman*, the plaintiffs alleged that the defendant made misrepresentations to the FDA to secure PMA approval for its product, and that, but for those misrepresentations, the FDA would not have approved the product. *See Buckman*, 531 U.S. at 343. The Supreme Court found that "policing fraud against federal agencies is hardly 'a field which the states have traditionally occupied,'" and went on to hold that plaintiffs' claims arising out of misrepresentations made to the FDA were "impliedly preempted." *Id.* at 347, 348. The Court also found that such claims "inevitably conflict with FDA's responsibility to police fraud consistently with the Administration's judgments and objectives." *Id*. at 350.

Consistent with *Buckman's* reasoning and holding, policing compliance with the MDA is exclusively within the FDA's purview. Examining the FDCA, the Supreme Court found that the FDA "has at its disposal a variety of enforcement options that allow it to take a measured response to suspected fraud upon the Administration." *Buckman*, 531 U.S. at 349. The flexibility inherent in the various enforcement methods available to the FDA "is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Id.* at 349. Likewise, the First Circuit has noted: "Centrally situated and with the requisite expertise, the FDA is in the best position to determine whether the provisions of the MDA have in fact been violated and to ensure that the law is applied in a uniform manner." *Talbott*, 63 F.3d at 29-30; *accord*, *Reeves v. Acromed Corp*., 44 F.3d 300, 307 (5th Cir.), *cert. denied*, 513 U.S. 1104 (1995); *see also Caraballo v Intermedics*, 886 F. Supp. 974 (D.P.R. 1995) (FDA responsible for enforcement of its own regulations).

Under these standards, Dr. Clasby's negligence *per se* claims are also impliedly preempted to the extent that they allege that Guidant failed to comply with the FDA's conditions of approval. Such claims are nothing more than "disguised fraud on the FDA claim[s]" and as such are preempted under *Buckman*. *See Cupek*, 405 F.3d at 424. Similarly, Dr. Clasby's fraud and misrepresentation claims (which are expressly preempted as labeling claims, *see supra*, Section III.B.), are also impliedly preempted. They too are simply "disguised fraud on the FDA" claims:

> [The fraud count] of plaintiffs' original complaint does not explicitly allege that [defendant] fraudulently obtained approval of the [device] by presenting false information to the

> FDA. Rather, plaintiffs merely claim that [defendant] misrepresented the [device] to plaintiffs and their physicians. To prove the falsity of [defendant's] representation as required [to prove the state law claim], however, plaintiffs must establish that the [device] was falsely represented to be safe and effective – the very determination made by the FDA in granting PMA approval. Consequently, although plaintiffs' fraud claim does not expressly allege 'fraud on the FDA," such a claim is necessarily implied in plaintiffs' allegations.

Kemp, 231 F.3d at 234 n. 14 (emphasis added). In this case, any claim that Guidant misrepresented (or somehow failed to represent) the risks of the PRIZM 2 to Dr. Clasby's physicians is, in effect, a claim that Guidant first misrepresented the risks of the PRIZM 2 to the FDA.

D. Public policy supports preemption of claims against manufacturers of medical devices.

The FDA's grant of PMA approval memorialized the Agency's conclusion that the PRIZM 2 was both safe and effective. This is clearly:

> a case which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how these competing considerations should be resolved * * *, and implemented that conclusion via a specific mandate on [the] manufacturer[].

Lohr, 518 U.S. at 501; *accord Mitchell*, 126 F.3d at 911 (stating that the PMA process fits this description).

Moreover, individual litigation of the adequacy of warnings jeopardizes uniform regulation, as the Eighth Circuit has recognized:

> [T]he need for national uniformity in product regulation [is] one of the explicit goals of the MDA. The legislative history

> indicates that this was the reason the preemption provision was included within the MDA. H.R.Rep. No. 853, 45 (1976) ("[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.").

Brooks, 231 F.3d at 797. Indeed, in another cardiac device case, the FDA itself has noted:

> For state courts to determine that the scope of such PMA approvals is subject to second-guessing by a jury would severely disrupt the carefully constructed, comprehensive regulatory scheme Congress put in place for medical devices. Indeed, the prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged the FDA with implementing.

Murphree Statement of Interest at p. 8.

Claims like Dr. Clasby's therefore present an "'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Worthy*, 967 S.W.2d at 377 (quoting *Medtronic*, 518 U.S. at 507 (Breyer, J., concurring)). The express preemption provision of the MDA, was intentionally inserted to *preserve* the purposes and objectives of Congress. As the Texas Supreme Court noted in *Worthy*, if Congress had intended for FDA approval to serve only as a prerequisite to marketing a device, there would be no need for a preemption provision in the MDA. *See id.*

Federal law both expressly and impliedly preempts Plaintiff Eugene Clasby's claims. Guidant therefore respectfully requests that summary judgment be granted in its favor, and that the Court dismiss such claims accordingly.

IV. FLORIDA LAW GOVERNS DR. CLASBY'S CLAIMS

A proper choice-of-law analysis dictates that Florida law applies to each of Dr. Clasby's claims. Because this diversity case was filed in and transferred from the United States District Court for the Southern District of Florida, Florida's choice-of-law rules control, and this Court must apply the "significant relationships test" in the Restatement (Second) of Conflict of Laws. Discovery has revealed that Florida has by far the most significant connections with this case. Considering those vast Florida connections and the policy considerations underlying the substantive claims at issue, the Court should easily conclude that Florida has the most significant interests in the application of its substantive laws to Dr. Clasby's claims.

A. As the forum state, Florida's choice-of-law rules apply.

"Federal courts sitting in diversity are required to look to the choice-of-law principles of the forum state . . . and then apply the same law to the case as the forum state would." *PVI, Inc. v. Ratiopharm GmbH*, 253 F.3d 320, 329 (8th Cir. 2001) (citing *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496-98 (1941)). Here, the forum state is Florida, where Dr. Clasby filed his lawsuit against Defendants. *See In re: Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D. La. 2006) ("In MDL cases, the forum state is typically the state in which the action was initially filed before being transferred to the MDL court."); *In re Ski Train Fire in Kaprun, Austria on Nov. 11, 2000*, 257 F. Supp. 2d 717, 723 (S.D.N.Y. 2003) (same); *In re: Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 140 (E.D. La. 2002) (same). Hence, Florida's choice-of-law rules apply.

That this case was subsequently transferred to this Minnesota court for consolidated proceedings pursuant to 28 U.S.C. § 1407 does not change the fact that this is a Florida diversity case. The inter-district transfer did not make Minnesota the forum state. *See Van Dusen v. Barrack*, 376 U.S. 612, 639 (1964) ("[I]n cases such as the present, where the defendants seek transfer, the transferee district court must be obligated to apply the state law that would have been applied if there had been no change of venue."); *In re: Vioxx*, 239 F.R.D. at 454; *In re Ski Train Fire*, 257 F. Supp. 2d at 723; *In re: Propulsid*, 208 F.R.D. at 140. Indeed, the transferee court applies the law that would have applied in the transferor court "regardless of which party initiated the change in venue." *Thorn v. Int'l Bus. Machines, Inc.*, 101 F.3d 70, 72-73 (8th Cir. 1995).

Dr. Clasby's subsequent adoption of portions of the MDL Master Complaint, filed in this Court, likewise, does not change the "forum state" for choice-of-law purposes from Florida to Minnesota. When deciding which state's choice-of-law principles to apply, "the master complaint should not be given the same effect as an ordinary complaint. Instead, it should be considered as only an administrative device to aid efficiency and economy." *In re: Propulsid*, 208 F.R.D. at 142; *see also* First Am. Master Compl. at ¶ 2 (stating the Master Complaint was submitted pursuant to the Case Management Order "to serve only the administrative functions of efficiency and economy of presenting certain common claims and common questions of fact and law").

Nor does Guidant's agreement to try Dr. Clasby's claims in this Court make Minnesota the "forum state" for choice-of-law purposes. First, that Guidant agreed to a trial here is irrelevant to this pretrial summary judgment proceeding. The case law

discussed above was all decided in the context of similar MDL pretrial motion practice and fully supports finding Florida to be the "forum state." Second, Guidant has not found any cases finding the "forum state" changes when the parties agree to trial in the MDL court. The case cited by the plaintiff in the *Duron* case, *In re Bridgestone/Firestone Inc. ATX, ATX II & Wilderness Tires Prods. Liab. Litig.*, 155 F. Supp. 2d 1069 (S.D. Ind. 2001), does not support the proposition that agreeing to trial in the MDL court makes the state in which the MDL court sits the "forum state." The Indiana district court presiding over the *Bridgestone/Firestone* MDL applied Indiana choice-of-law principles only because the parties agreed that the Indiana court "should be treated as the forum court." *Id.* at 1078. In fact, the *Bridgestone/Firestone* court recognized the controlling law -- absent the parties' agreement -- that "[i]n MDL proceedings, the forum state generally is the state in which the transferor court of each individual action sits." *Id.*

In the end, only a superficial analysis would dictate that Minnesota choice-of-law principles would apply. *See Van Dusen*, 376 U.S. at 637-38. Although many decisions provide, as a general matter, that a district court sitting in diversity should apply the choice-of-law principles of the state in which it sits, those decisions do not involve transferred cases in a MDL setting. Applying the choice-of-law principles of the state where the transferee court sits would, in the words of the Supreme Court, "directly contradict[] the fundamental *Erie* doctrine" because it would result in the application of a different substantive law in a federal diversity case than if the same action had been filed in a state court down the street. *Van Dusen*, 376 U.S. at 638.

As this Court has previously found, "[i]n multidistrict litigation that has been transferred to a central forum for coordinated or consolidated pretrial proceedings, the transferee federal district court must apply the substantive state law of the transferor district, including its choice of law rules." *McCord v. Minn. Mut. Life Ins. Co.*, 138 F. Supp. 2d 1180, 1186 (D. Minn. 2001) (quoting Charles Allan Wright & Arthur R. Miller, Federal Practice and Procedure, § 112.07(2)(b) (3d ed. 1990)). Thus, here, the Court must apply Florida's choice-of-law rules.

B. Florida uses the "significant relationships test" to determine which state's substantive law applies.

The "significant relationships test" in the Restatement (Second) of Conflict of Laws controls choice-of-law determinations in Florida.[18] *See Cortes v. Am. Airlines*, 177 F.3d 1272, 1296 n.19 (11th Cir. 1999) ("Florida's conflict-of-laws rules are the same as federal common-law conflict-of-laws rules, because both have adopted the Restatement (Second) of Conflict of Laws."); *Trumpet Vine Invs., N.V. v. Union Capital Partners I., Inc.*, 92 F.3d 1110, 1115 (11th Cir. 1996); *Bishop v. Fla. Specialty Paint Co.*, 389 So. 2d 999, 1001 (Fla. 1980). A proper application of that test dictates that Florida substantive law applies to each of Dr. Clasby's claims.

To determine which state has the most "significant relationship," the Restatement instructs to (1) use the "contacts"[19] in section 145 to determine which states

[18] "The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6." Restatement (Second) of Conflict of Laws § 145(1).

[19] The "contacts" to consider are: "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence,

have connections with the case and (2) use the "principles"[20] in section 6 to determine which of those states' interests are the most significant. *See In Re: Am. Airlines, Inc. Flight 869 Turbulence Incident of January 17, 1996*, 128 F. Supp. 2d 1367, 1370 (S.D. Fla. 2001); *Peoples Bank & Trust Co. v. Piper Aircraft Corp.*, 598 F. Supp. 377, 380 (S.D. Fla. 1984). Not only does Florida have more connections with this case than any other state, Florida also has the most significant interest in the application of its laws. Florida law thus applies to Dr. Clasby's claims.

1. Florida has the most significant contacts with this case.

Florida's connections with this case are overwhelming. Dr. Clasby filed his lawsuit in Florida, where he has resided for forty years. *See supra* Part II at 38. Dr. Clasby's Florida doctors prescribed an implantable defibrillator, received representations about Guidant's Prizm 2 device, recommended that device to his wife, and implanted the device in him based on his wife's consent—all in Florida. *Id.* A pamphlet prepared by Guidant was provided to Dr. Clasby in Florida by the Florida hospital where the implantation occurred. *Id*. Dr. Clasby also received similar information in Florida from his Florida doctor. *Id*.

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nationality, place of incorporation and place of business of the parties, and, (d) the place where the relationship, if any, between the parties is centered." Restatement (Second) of Conflict of Laws § 145(2).

[20] The "principles" to consider are: "(a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied." Restatement (Second) of Conflict of Laws § 6(2).

Dr. Clasby experienced an incident, in Florida, where his device allegedly shocked him. He was treated for that incident at a Florida hospital and then subsequently treated for the alleged effects of that incident by a Florida psychiatrist and psychologist. *Id.* at 39. Dr. Clasby spoke with Guidant's representative only once, and that occurred in Florida after the alleged shocking incident. *Id.*

Dr. Clasby had his device monitored at Florida hospitals and learned of potential problems with the device while reading the New York Times, as he does every day in Florida where he resides. *Id.* The device was then explanted in a Florida hospital by a Florida surgeon based on a decision made by Dr. Clasby in Florida after consultation with his Florida doctor. *Id*.

In short, Florida has substantial "contacts" with this case. The foregoing undisputed facts show that Florida is the place where the injury occurred, the place where the conduct causing the injury occurred, and the place where the relationship between the parties is centered. *See Blain v. Smithkline Beecham Corp*., 240 F.R.D. 179, 193 (E.D. Pa. 2007) (concluding plaintiff's home state had most significant contacts because it was where the product was "delivered, marketed and taken" and thus where the conduct causing injury occurred and where the parties' relationship was centered).

Dr. Clasby's vain invocation of Minnesota law is based on an unsupported assumption that all key events took place in Minnesota. Minnesota is connected to this case only because Defendant Cardiac Pacemakers, Inc. ("CPI") is a Minnesota company, and CPI designed and manufactured the Prizm 2 device. However, part of that manufacturing did not even occur in Minnesota; it occurred in Ireland. *See* Device

History Report at 23-36 (Ex. 10). The assumption that all of the manufacturing and material corporate conduct occurred in Minnesota is simply wrong. Indiana is connected to this case because Defendant Guidant Sales Corporation ("GSC") is an Indiana company, allegedly responsible for the marketing and sale of the Prizm 2 device. *See* First Am. Master Complaint at ¶¶ 39, 40.

In spite of the foregoing conduct in Minnesota, Indiana, and Ireland, the Court should still find that the conduct causing Dr. Clasby's alleged injuries occurred in Florida. *See In re Vioxx*, 239 F.R.D. at 458 (rejecting argument that conduct causing the injury occurred where corporate decisions were made; conduct occurred where the product was advertised, marketed, shipped into, prescribed in, sold in, ingested in, and allegedly caused harm in). Ultimately, the Minnesota, Indiana, and Ireland contacts with this case pale in comparison to the vast Florida connections.

This Court must nonetheless determine if, based on the foregoing Minnesota, Indiana, and Ireland connections, which are less significant in the instant choice-of-law analysis, those jurisdictions nevertheless have a greater interest than Florida in the application of their substantive law. As will be shown below, they do not.

2. Florida has the most significant interests in application of its law.

"The presumption borne of the 'significant relationships test' is that the law of the forum where the injury occurred determines the substantive issue." *Emmart v. Piper Aircraft Corp.*, 659 F. Supp. 843, 843 (S.D. Fla. 1987) (emphasis added) (quoting *Peoples Bank & Trust Co.*, 598 F. Supp. at 379); *accord Judge v. Am. Motors Corp.*, 908

F.2d 1565, 1568 (11th Cir. 1990) (noting that state where in jury occurred is decisive under most circumstances). Because Dr. Clasby unquestionably sustained his alleged injuries in Florida, Florida law presumptively applies. Entrenching that presumption, Dr. Clasby has expressly stated his belief that Florida law applies. His Complaint by Adoption cites Florida law as controlling. *See* Device Recipient Pl. Compl. by Adoption at ¶ 8, Count VIII. There is thus an overwhelming presumption, based on location of injury, that Florida has the greatest interests in this case and that Florida law applies.

That overwhelming presumption can be defeated only with substantial evidence that "another state has a more compelling interest in the parties or events." *Emmart*, 659 F. Supp. at 843. There is no such evidence in this case. Indeed, as noted above, Florida is not only the place of injury, it is also the place of where the conduct causing the injury occurred. *See Blain*, 240 F.R.D. at 193; *In re Vioxx*, 239 F.R.D. at 458.

The section 6 compelling interest analysis "turns in large part on the balance of competing interests contemplated by sections 6(2)(b) and 6(2)(c)." *Cortes*, 177 F.3d at 1299; *Judge*, 908 F.2d at 1569; *see also Nelson v. Freightliner, LLC*, 154 Fed. Appx. 98, 104 (11th Cir. 2005) (stating subsections 6(2)(d) and (f) "have little significance because torts, especially unintentional torts, do not occur with predictability"). To balance those competing interests, the court must identify the particular rule of law to be applied by each interested state, identify the purposes or policies underlying those rules, and then analyze how those purposes or policies would be furthered by applying those rules. *See Nelson*, 154 Fed. Appx. at 104; *Cortes*, 177 F.3d

at 1299; *Judge*, 908 F.2d at 1569-70. In the end, "the state whose interests are most deeply affected should have its local law applied." Restatement (Second) Conflict of Laws § 6, cmt. f (emphasis added); *accord Cortes*, 177 F.3d at 1299. Based on the facts of this case, Florida's interests are most deeply affected. Thus, consistent with the overwhelming presumption discussed above, the Court should apply Florida law to each of Dr. Clasby's claims.

a. Florida law governs Dr. Clasby's personal injury claims (Counts I-IV, X-XII).

Section 146 of the Restatement applies to personal injury tort claims and provides, consistent with the general presumption, that:

> In an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in § 6 to the occurrence and the parties, in which event the local law of the other state will be applied.

(Emphasis added). Neither Minnesota, nor Indiana or Ireland, have a superior interest in the application of their personal injury tort law than Florida, especially an interest sufficient to overcome the strong Florida law presumption.

Dr. Clasby's personal injury claims are founded predominantly on products liability theories. The purpose/policy underlying the products liability law of the respective jurisdictions is basically the same: to protect the public from an unreasonable risk of harm by imposing duties to not develop, manufacture, and market defective products. *See generally West v. Caterpillar Tractor Co.*, 336 So. 2d 80 (Fla. 1976) (discussing Florida products liability law and expressly recognizing strict liability as a

cognizable tort in Florida); *Porter v. Rosenberg*, 650 So. 2d 79, 81 (Fla. Dist. Ct. App. 1995). Although Minnesota, Indiana, and Ireland have an interest in deterring tortious conduct allegedly emanating from within their borders, that conduct also occurred in Florida. *See Blain*, 240 F.R.D. at 193; *In re Vioxx*, 239 F.R.D. at 458. Florida thus has a similar and more powerful interest in deterring allegedly tortious conduct that both occurs within its borders and causes harm within its borders. *See Fla. Steel Corp. v. Whiting Corp.*, 677 F. Supp. 1140, 1141 (M.D. Fla. 1988) (applying Florida law because Florida was location of injury and where parties' relationship was formed; discounting Illinois, where the conduct causing the injury occurred, as "not significant in strict products liability case").

Indeed, the court in *In re Vioxx*, 239 F.R.D. at 458, found that even though the defendant corporation's conduct may have originated from its headquarters, it was effectuated and felt by plaintiffs where they resided. Hence, the court concluded that "the substantive law of each plaintiff's home jurisdiction must be applied to his or her respective claims." *Id.* Similarly, here, Florida law applies because Florida's interests (in protecting its residents and regulating harmful conduct) are most deeply affected. *See Fla. Steel Corp.*, 677 F. Supp. at 1141; *see also Blain*, 240 F.R.D. at 193-94 (concluding state where plaintiff resides has a greater interest in application of its tort law because "fixing liability for tortious harm caused within its boundaries goes to its interests in protecting its citizens and regulating conduct there," while state where defendant resides only has an interest in regulating the portion of defendant's conduct that originates there).

b. Florida law governs Dr. Clasby's fraud and deceit claims (Counts VI-IX).

Section 148 of the Restatement applies to torts involving fraud and misrepresentation and provides that:

> When the plaintiff has suffered pecuniary harm on account of his reliance on the defendant's false representations and when the plaintiff's action in reliance took place in the state where the false representations were made and received, the local law of this state determines the rights and liabilities of the parties unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in § 6 to the occurrence and the parties, in which event the local law of the other state will be applied.

(Emphasis added). Here, the representations and omissions at issue were made, received, and supposedly relied on in Florida -- where the device was marketed, purchased, and implanted -- not in Minnesota, Indiana, or Ireland where Defendants may have originally conceived the marketing material. *See Ilah Coffee Merriman v. Convergent Bus. Sys., Inc.*, Case No. 90-30138-LAC, 1993 U.S. Dist. LEXIS 10528, *28 n.7 (N.D. Fla. June 23, 1993) ("alleged fraudulent conduct occurred where CPAS employees actually made the misrepresentations and omissions"). Because Guidant's representations and omissions allegedly induced implantation of the device in Dr. Clasby in Florida, Florida law applies. *See id.* at *29 (applying Florida law because fraud and deceit claims were in the nature of fraud in the inducement claims and the inducement occurred in Florida, even though injury occurred in Texas where the plaintiff was located).

Analyzing the substantially similar policies underlying the fraud and deceit law in the respective jurisdictions does not change this result. Florida has a more

compelling interest in ensuring representations made in Florida and relied upon by Florida residents are not false or misleading and do not result in pecuniary harm in Florida. Dr. Clasby fully agrees, evidenced by his Complaint by Adoption, which selected Florida law as controlling Count VIII, his statutory deceit claim.

c. Florida law governs Dr. Clasby's remaining claims (Counts V and XVII).

Dr. Clasby has also alleged claims for breach of implied warranty and unjust enrichment. Florida law applies to these claims, as well, for similar reasons. Florida has the most significant connections with the parties and the subject matter of this case and the most significant interests in having its law applied to protect a Florida consumer. Minnesota, Indiana, and Ireland do not have a more compelling interest in the application of their implied warranty and unjust enrichment law sufficient to overcome the overwhelming presumption in favor of Florida law. Dr. Clasby simply had no expectation that Minnesota, Indiana, or Ireland law would apply. *See, e.g.*, *In re Vioxx*, 239 F.R.D. at 458 (stating it "unlikely" that a plaintiff would even know the defendant who made and distributed the product and "even more doubtful" that the plaintiff would know where the defendant was incorporated and operated its business).

In summary, the proper Florida choice-of-law analysis dictates that Florida law applies to all of Dr. Clasby's claims. Florida was where the product was prescribed, marketed, recommended, and implanted. Florida was also where Dr. Clasby learned about the product, sustained all of his alleged injuries, and brought his lawsuit. These vast Florida connections, and the significant Florida interests they create, dwarf those of

any other state. Ultimately, no other state has any interests in this case remotely significant enough to overcome the crushing presumption in favor of Florida law.

V. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT BASED ON LACK OF INJURY CAUSED BY MALFUNCTION

Dr. Clasby's PRIZM 2 never malfunctioned. It never short-circuited. Nor was it ever recalled. To the contrary, Dr. Clasby's device worked appropriately during the entire time it was in his body. Nevertheless, Dr. Clasby is seeking damages under strict liability, negligence, warranty, and emotional distress theories although he has no evidence that a defect manifested in his device causing him physical injury.[21]

Florida law, however, does not permit recovery based on the mere *risk* that a product might malfunction in the future. Rather, Florida law expressly requires evidence that there is actually something wrong with the product used, regardless of the ground of liability asserted, to recover for harm allegedly caused by a defective product. *E.R. Squibb & Sons, Inc. v. Jordan*, 254 So.2d 17, 20 (Fla. Dist. Ct. App. 1971). In short, a plaintiff must prove a manifest defect. Thus, Dr. Clasby cannot recover for his alleged injuries, including emotional distress, inappropriate shocks, or injury surrounding his explant surgery because he cannot establish a causal nexus between those injuries and a manifest malfunction in his device. Accordingly, the Court should dismiss the following claims:

[21] Dr. Clasby has also made a claim for medical monitoring, but has confirmed that he do not assert medical monitoring as a separate cause of action, but merely as an element of potential consequential damages in the form of future medical expenses.

- Strict Liability – Failure to Warn (Count I – First Amended Master Complaint)
- Strict Liability Design and Manufacturing Defect (Count II – First Amended Master Complaint)
- Negligence (Count III – First Amended Master Complaint)
- Negligence Per Se (Count IV – First Amended Master Complaint)
- Breach of Implied Warranty (Count V – First Amended Master Complaint)
- Fraud (Count VI – First Amended Master Complaint)
- Constructive Fraud (Count VII – First Amended Master Complaint)
- Negligent Infliction of Emotional Distress (Count X – First Amended Master Complaint)
- Intentional Infliction of Emotional Distress (Count XI – First Amended Master Complaint)

Dr. Clasby's claims fail as a matter of law because his device never manifested a defect. Under Florida law, for a "manufacturer to be held liable for harm allegedly caused by a product, regardless of the ground of liability asserted, it is necessary that it be shown that there was actually something wrong with the product used . . . ." *E.R. Squibb & Sons, Inc., v. Jordan*, 254 So. 2d 17, 20 (Fla. Dist. Ct. App. 1971).

In *E.R. Squibb & Sons, Inc., v. Jordan*, plaintiffs brought claims against the manufacturer of an animal bone product used in certain human surgeries. 254 So. 2d 17. Evidence adduced at trial indicated that plaintiff's physician "had over a 90 percent failure rate with some 50 other patients" using the animal bone product. *Id*. at 19. Moreover, "[o]ther testimony was presented [by plaintiffs] as to the ineffectiveness of

[the product's use] by other medical personnel." *Id.* The jury returned a verdict for plaintiffs.

On appeal, the manufacturer argued that "the jury should have been instructed, as requested, that it was incumbent upon the [plaintiffs] to show a defect in the [product] *actually used*." *Id*. at 19. (emphasis added). The Court of Appeal of Florida agreed with the manufacturer and ordered a new trial.

In so holding, the court explained that "whatever form of liability is pursued, whether it be warranty, negligence or strict liability, the [plaintiff's] injury must have been caused by some defect in the product." *Id*. at 20 (citing *Royal v. Black and Decker Manufacturing Co*., 205 So. 2d 307 (Fla. Dist. Ct. App. 1967)). The testimony adduced at trial regarding other instances of product failure was, in the court's words, "not felt to be pertinent." *Id*. at 19. Accordingly, *Jordan* forecloses all strict-liability, negligence, warranty and emotional distress claims in the absence of a manifest product defect.

Florida courts are not alone in requiring manifest defects in cases such as this. In the medical-device context, federal and state courts throughout the country have consistently rejected claims by individuals who cannot show a physical injury attributable to a manifest defect in a medical device. As New York's highest court explained:

> [a]n implanted or inserted device intended to perform a continuing function . . . causes no injury until the product malfunctions. Until that time the recipient . . . has no cause to complain. If through malfunction the product is thought to have caused harm, it can in most cases be removed and

> examined to ascertain whether in fact it malfunctioned and, if so, whether that was the cause of the harm.[22]

Numerous courts considering such medical-device cases have followed this logic to dismiss a variety of product-liability claims, including those based on warranty, tort, strict liability, fraud and consumer-protection statutes:

- *Pfizer v. Farsian*, 682 So. 2d 405, 407 (Ala. 1996) (in case involving allegedly defective heart valve, holding plaintiff's belief that a product could fail in the future is not, without more, a legal injury sufficient to support plaintiff's fraud claim).

- *Willett v. Baxter Int'l, Inc*., 929 F.2d 1094, 1097 (5th Cir. 1991) (applying Louisiana law and precluding claims where plaintiffs, whose heart valves carried a 0.08% failure rate, "provided no evidence that their particular [heart] valves . . . were not performing as designed").

- *Spuhl v. Shiley, Inc.*, 795 S.W.2d 573, 580 (Mo. App. 1990) (in a case involving an allegedly defective heart valve with 0.02% failure rate, holding that product malfunction or failure is an essential element of a claim for negligent- or strict-liability-based failure to warn).

- *Bravman v. Baxter Healthcare Corp.*, 794 F. Supp. 96, 100 (S.D.N.Y. 1992) (in case involving heart valve with 0.1% failure rate, "New York generally does not recognize a cause of action for a faulty heart valve until the valve actually fails and causes a physical harm"), *aff'd in part and rev'd in part*, 984 F.2d 71 (2d Cir.1993).

- *Rall v. Medtronic, Inc*., 1986 WL 22271 at * 2 (D. Nev. Oct. 15, 1986) (noting that "plaintiff's contention that the mere presence of a polyurethane lead in the body, with or without any malfunction, establishes a basis for liability, and a question common to all members, defies reality" and denying class certification).

- *Walus v. Pfizer, Inc*., 812 F. Supp. 41, 44 (D.N.J. 1993) (in case involving allegedly defective heart valve, noting that "[n]o provision in [New Jersey's

[22] *Martin v. Edwards Labs*, 457 N.E.2d 1150, 1155 (N.Y. 1983) (emphasis added) (superceded on unrelated grounds by N.Y. C.P.L.R. 214-c(2), which provides that the statute of limitations in toxic-exposure cases begins to run on date of discovery of latent injury, not on date of "impact" with toxic substance).

product liability statute] authorizes a cause of action based on a claim that a normally functioning product might fail at some unknown time").

- *Keath v. Shiley, Inc*., 1991 U.S. Dist. LEXIS 21872, at *7 (N.D. Ohio 1991) (in case involving allegedly defective heart valve and strict liability, negligence, and warranty claims, noting that "[a] product is considered defective only if it causes an injury; it cannot be considered defective simply because it is capable of producing injury").

- *Lauterbach v. Shiley, Inc*., No. CIV. A H-87-3208, 1991 WL 148137, at *9 (S.D. Tex. March 29, 1991) (in case involving allegedly defective heart valve and claims based on strict liability, negligence, warranty, fraud, and intentional infliction of emotional distress, noting that "[t]here is no cause of action under Texas law where a plaintiff's product is and has been functioning without incident. Texas law does not recognize a claim seeking to recover for alleged concern or anxiety that a functioning product might fail at some future unknown time").

- *Murphy v. Shiley, Inc*., 1991 U.S. App. LEXIS 17190, at *1 (9th Cir. 1991) (holding that Washington Product Liability Act law does not allow recovery "absent product failure, malfunction, or product-caused accident").

- *Kahn v. Shiley*, 266 Cal. Rptr. 106, 110 (Cal. App. 1990) (holding that "[n]o matter which theory is utilized, where a plaintiff alleges that a product is defective, proof that the product has malfunctioned is essential to establish liability for an injury caused by the defect).

In this case, Dr. Clasby alleges injuries arising from inappropriate shocks, learning of the recall and his explant surgery, and he seeks to recover under various malfunction-dependant theories, including strict liability, negligence, warranty, fraud, and negligent and intentional infliction of emotional distress. Dr. Clasby, however, has no evidence that his device ever malfunctioned while implanted. To the contrary, Dr. Clasby testified that no physician or Guidant representative ever told him that his device was defective or had manifested a defect. *See supra* Part II, at 29-30. Furthermore, a visual inspection of the device after it was explanted revealed it had never short-circuited.

See supra Part II, at 31. Thus, Dr. Clasby's device functioned normally and exhibited no defect during the almost three-and-one-half years that it was implanted in him.

Without a manifest defect, there can be no causal nexus between Dr. Clasby's claimed injuries and the alleged defect in his device. The April 1, 2003 shocks Dr. Clasby complains of were due to neither an arcing defect nor any other manifest defect. Instead, the incident is evidence that his device worked in accordance with its programmed parameters. Even Dr. Clasby conceded that this event was not a malfunction. *See supra* Part II, at 29-30. Moreover, no physician ever told Dr. Clasby that the device had fired inappropriately. *Id*. To the contrary, medical records indicate that these shocks were appropriately within the present parameters of Dr. Clasby's Device. *See* JMH-00276-279 (medical records).

Likewise, Dr. Clasby's alleged injuries surrounding his voluntary explant surgery and emotional distress from learning of the recall are not caused by a manifest defect in Dr. Clasby's device, but rather his fear that his device *may* fail. *Jordan clearly* forecloses recovery for such broad claims. *See* 254 So. 2d at 19. Instead, Dr. Clasby must prove that these alleged injuries were caused by a defect in *his* specific device. 254 So. 2d at 20. Dr. Clasby is simply unable to meet this burden. As such, the causal link between Dr. Clasby's alleged injuries and a manifest defect is wholly absent in this case. Under *Jordan*, each of Dr. Clasby's malfunction-dependant theories must be dismissed.

Guidant is entitled to summary judgment as a matter of law because Dr. Clasby has failed to produce any evidence that his injuries were caused by a manifest

defect in his device. Thus, Guidant respectfully requests that the Court grant its Motion and dismiss the aforementioned claims with prejudice.

VI. DEFENDANTS' MEMORANDUM IN SUPPORT OF SUMMARY JUDGMENT ON DR. CLASBY'S FAILURE-TO-WARN CLAIMS

The Court should grant summary judgment in favor of Guidant on Dr. Clasby's failure-to-warn claims. Under Florida law, Guidant is not liable for failure to warn if Guidant adequately warned Dr. Clasby's physicians of the possibility that his PRIZM 2 could cause the injuries he alleges here. Dr. Clasby alleges that his PRIZM 2 inappropriately shocked him on April 1, 2003, as he was playing a "vigorous" game of tennis despite Dr. Myerburg's express orders. He also alleges that he suffered anxiety and depression based on his fear that his PRIZM 2 might inappropriately shock him or fail to defibrillate or pace when needed. Guidant specifically warned Dr. Clasby's physician that the PRIZM 2, like all such devices, involved the risk of "inappropriate shocks" and "potential mortality due to inability to defibrillate or pace" and that patients might suffer "depression" and "fear of shocking while conscious." Because these warnings encompass all of Dr. Clasby's alleged injuries, the Court should dismiss Dr. Clasby's failure-to-warn claims.

Setting aside the warnings that Guidant provided Dr. Clasby's physicians, this Court should also dismiss Dr. Clasby's failure-to-warn claims because he cannot establish causation. It is well known in the electrophysiology community, including amongst Dr. Clasby's physicians, that implantable cardioverter defibrillators ("ICDs") carry certain risks, including inappropriate shocks, failure to provide therapy, and patient

depression and fear of shocking. Under the learned-intermediary doctrine, the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had substantially the same knowledge as an adequate warning from the manufacturer should have communicated to him. These facts make it impossible for Dr. Clasby to prove causation essential to his failure-to-warn claims.

Accordingly, based on the adequacy of Guidant's warning and the lack of causation, this Court should dismiss Dr. Clasby's failure-to-warn claims, including the following:

- Strict Product Liability Failure to Warn (Count I – First Amended Master Complaint)
- Fraud (Count VI – First Amended Master Complaint)
- Constructive Fraud (Count VII - First Amended Master Complaint)
- Unfair and Deceptive Trade Practices Under Florida Statute § 501.201 et seq. (Count VIII – First Amended Master Complaint)

A. The learned-intermediary doctrine applies.

Dr. Clasby cannot establish that Guidant's warnings to his physician were inadequate. At the outset, the learned-intermediary doctrine applies in this case. Under the learned-intermediary doctrine, "manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of a product." *Baker v. Danek Medical*, 35 F. Supp. 2d 875, 881 (N.D. Fla. 1998). Such information may be provided to the physician through the manufacturer's package insert. *Baker*, 35 F.Supp.2d at 881; *Cornelius v. Cain*, 2004 WL 48102, at *2 (Fla. Cir. Ct. 2004). "When the package insert for the prescription [product] adequately warns the

physician about the risks associated with its [product], the manufacturer cannot be liable for failure to warn." *Cornelius*, 2004 WL 48102, at *2. "Whether the physician in fact reads the warning, or passes its contents along to the recipient of the [product] is irrelevant." *E.R. Squibb and Sons, Inc. v. Farnes*, 697 So. 2d 825, 827 (Fla. 1997).

The learned-intermediary doctrine has long been recognized in Florida and is based on sound policy considerations. First, medical ethics and practice dictate that the doctor must be an intervening and independent party between the patient and drug manufacturer. *Amore v. G.D. Searle & Co., Inc*., 748 F. Supp. 845, 849 (S.D. Fla. 1990) (quoting *Hill v. Searle Laboratories*, 884 F.2d 1064, 1070 (8th Cir. 1989)). Second, the information regarding risks is often too technical for a patient to make a reasonable choice. *Id*. Third, it is virtually impossible in many cases for a manufacturer to directly warn each patient. *Id*.

B. Guidant adequately warned of the possibility of Dr. Clasby's alleged injuries.

"In determining the adequacy of the warning, the critical inquiry is whether it was adequate to warn the physician of the possibility that the [product] caused the injury alleged by the plaintiff." *Paparo v. Ortho McNeil Pharmaceutical*, 2007 WL 121149, at *3 (S.D. Fla. Jan. 11, 2007) (citing *Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990)) (emphasis added). Moreover, "manufacturers are not required to warn of every risk which might be remotely suggested by any obscure tidbit of available knowledge, but only of those risks which are known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of

manufacture and distribution." *Griffin v. Kia Motors Corp*., 843 So. 2d 336, 339 (Fla. App. 2003); *Marzullo v. Crosman Corp*., 289 F. Supp. 2d 1337, 1347 (M.D. Fla. 2003); *Ferayorni v. Hyundai Motor Co*., 711 So. 2d 1167, 1172 (Fla. App. 1998). In the case of an implantable ICD, the relevant knowledge to consider is the available scientific knowledge at the time of implantation, at the latest.

Guidant adequately warned Dr. Clasby's physicians about the potential for his alleged injuries – *i.e*., anxiety and inappropriate shocking. Guidant warned that the PRIZM 2, like all ICDs, carried the risk of "inappropriate shocks" and "potential mortality due to inability to defibrillate or pace" and that patients might suffer "depression" and "fear of shocking while conscious":

5.1. Potential Adverse Events

Based on the literature and AICD implant experience, the following alphabetical list includes possible adverse events associated with implantation of an AICD system:

- Acceleration of arrhythmias, Air embolism, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Fluid accumulation, Formation of hematomas or cysts, Inappropriate shocks, Infection, Keloid formation, Lead abrasion, Lead discontinuity, Lead migration/dislodgement, Myocardial damage, Pneumothorax, Potential mortality due to inability to defibrillate or pace, Shunting current or insulating myocardium during defibrillation with internal or external paddles, Thromboemboli, Venous occlusion, Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychologic intolerance to an AICD system that may include the following:

- Dependency, Depression, Fear of premature battery depletion, Fear of shocking while conscious, Fear that shocking capability may be lost, Imagined shocking

Physicians Technical Manual at 4.

Dr. Clasby alleges that he suffered anxiety and depression following the implantation of his PRIZM 2 in December 2002. Guidant warned the risk of

"depression." Further, Dr. Clasby alleges that, after the April 2003 tennis incident, he suffered anxiety based on his fear that his device would inappropriately shock him. Eugene Clasby Dep. Tr. at 47:12-21. Guidant warned of the risk of "inappropriate shocks," even though in this case, there is no evidence that Dr. Clasby's device inappropriately shocked him. *See supra* Part II at 30-31. Thus, Guidant discharged its duty by warning Dr. Clasby's physicians about the potential for each of his alleged injuries.

C. Dr. Myerburg had independent knowledge of the possibility of Dr. Clasby's alleged injuries.

Moreover, even if Guidant issued no such warnings to Dr. Clasby's physicians, his failure-to-warn claims fail since his physicians had independent knowledge of the potential for his alleged injuries. As a result, Dr. Clasby cannot establish the essential element of causation. "[T]he causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." *Christopher v. Cutter Laboratories*, 53 F.3d 1184, 1192 (11th Cir. 1995). Thus, "the failure of the manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." *Id.* (citing *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1517 (S.D. Fla.1990)).

Here, the potential for each of Dr. Clasby's alleged injuries – *i.e.*, anxiety and "inappropriate" shock – were risks well known to his physicians. Each of these risks has been generally known in the electrophysiology community for over twenty years. *See* Affidavit of Steven L. Higgins at ¶ 11. Thus, Dr. Clasby's physicians knew that an ICD may deliver a shock when a patient's heart rate exceeds the ICD detection rate, and also that an ICD may deliver inappropriate shocks. Dr. Clasby's physicians were aware of the risk of anxiety and depression based on his independent medical knowledge and experience. In fact, Dr. Myerburg had a "lengthy discussion" with Dr. Clasby "about the natural history of anxiety after ICD implants." RBM-00008 (medical records). Accordingly, there is no evidence sufficient to create a genuine dispute of material fact on the issue of causation.

D. Guidant had no duty to warn of a non-existent defect.

Finally, Dr. Clasby asserts that Guidant failed to warn him that his device was defective. Guidant owed him no such warning. Dr. Clasby's device was not defective. It was not even recalled by the FDA. He has no evidence that he suffered any injury as a result of Guidant's failure to warn of an alleged defect.

Axiomatically, Guidant had no duty to warn of a non-existent defect. For a manufacturer to be held liable under a failure to warn claim or for any other claim, "it is necessary that it be shown that there was actually something wrong with the product used." *E.R. Squibb & Sons, Inc. v. Jordan*, 254 So. 2d 17, 20 (Fla. Dist. Ct. App. 1971). Here, Dr. Clasby has no evidence of any defect in his device.

Dr. Clasby testified that none of his physicians notified him that his device was defective. *See supra* Part II, at 29-30. He also testified that none of his physicians ever told him that his device inappropriately shocked him. *Id.* at 31. Dr. Clasby testified that at his regular three-month checkups, no one has ever identified his device as having malfunctioned or as being defective. *Id.* at 30. Even after he was shocked while playing tennis, Dr. Clasby stated that none of his physicians told him that his device was defective or malfunctioned. *Id.* at 31. Further, both his final interrogation, taken on the day of his explant, and the post-explant visual inspection illustrates that Dr. Clasby's device was functioning appropriately. *See id.* Therefore, Dr. Clasby cannot possibly show that his device was defective.

Dr. Clasby's device was not recalled. His device was manufactured after April 16, 2002 and has not been recalled by the FDA. *See supra* Part II, at 27-28. Further, 877 devices manufactured from April to November of 2002, were returned to Guidant and tested. Those test results produced no malfunctions. *See id.* at 28. In fact, of the 11,000 devices manufactured during that same period, only one malfunction is known to have occurred, representing an occurrence rate of 0.009%. *Id.* His physicians correctly did not tell him that his device was affected by the FDA recall. *Id.*

Without a defect in Dr. Clasby's device, Guidant cannot possibly be burdened with a duty of warn of a non-existent defect. Accordingly, Dr. Clasby's failure-to-warn claims fail and should be dismissed as a matter of law.

For the reasons set forth above, Guidant respectfully requests that the Court issue an Order dismissing Dr. Clasby's failure-to-warn claims with prejudice and grant such other relief as the Court may deem just and proper.

VII. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON FDUPTA CLAIMS

Count VIII of Dr. Clasby's Complaint by Adoption alleges a violation of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"). The only damages alleged with that claim are the cost of the device, "related medical costs," and "other damages." First Am. Master Compl. at ¶¶ 318, 320, 321, 323, 325-26. None of those allegations support a viable FDUTPA claim because Dr. Clasby cannot recover the cost of the device on the undisputed facts of this case, and the remaining damages are either (A) consequential damages or (B) damages stemming from purported personal injuries, neither of which are recoverable under the FDUTPA.

A. Dr. Clasby cannot recover the cost of his device with his FDUTPA claim.

The FDUTPA provides relief in the form of "actual damages" when a plaintiff has suffered a loss. *See* Fla. Stat. § 501.211(2) ("In any individual action brought by a consumer who has suffered a loss as a result of a violation of this part, such individual may recover actual damages."); *Montgomery v. New Piper Aircraft, Inc.*, 209 F.R.D. 221, 230 (S.D. Fla. 2001) ("Proof of damages is required for recovery under FDUTPA."). "Actual damages" are calculated by the difference between the value of a product as delivered and the value of the product as represented. *See Collins v. DaimlerChrysler Corp.*, 894 So. 2d 988, 990 (Fla. Dist. Ct. App. 2004) (citing cases);

Montgomery, 209 F.R.D. at 230 ("[R]ecoverable damages are limited to the market value diminution caused by the deceptive trade practice."); *Delgado v. J.W. Courtesy Pontiac GMC-Truck, Inc.*, 693 So. 2d 602, 605 (Fla. Dist. Ct. App. 1997).

Here, Dr. Clasby cannot recover for the cost of his device because, when Dr. Clasby had his Guidant device explanted, Defendants paid for the replacement device. *See supra* Part II, at 27. In fact, even if the device had not been explanted, Dr. Clasby would still not have suffered any actual damages because his device functioned properly and thus never had a diminished value. Further, as stated above, the shocks about which Mr. Clasby complains are actually proof that the device was functioning as programmed. Consequently, Dr. Clasby has not suffered any "actual damages" in the form of owning a product whose value has allegedly been diminished by a deceptive or unfair practice or act.

B. Dr. Clasby cannot recover his "related medical costs" under the FDUTPA.

Although a FDUTPA plaintiff can recover "actual damages" in the form of diminished product value, special or consequential damages are not recoverable under the FDUTPA. *See Urling v. Helms Exterminators, Inc.*, 468 So. 2d 451, 454 (Fla. Dist. Ct. App. 1985). Dr. Clasby's alleged "related medical costs" are plainly consequential damages and therefore cannot support a viable FDUTPA claim. *See id.*

C. Dr. Clasby cannot recover his "other damages" under the FDUTPA.

The only damages that could possibly save Dr. Clasby's FDUTPA claim are the unspecified "other damages." Since Dr. Clasby's Complaint did not define these

"other damages," Guidant asked Dr. Clasby what his alleged damages were during discovery. In every context, Dr. Clasby stated he seeks to recover damages for alleged personal injuries:

> **Dr. Clasby's Fact Sheet:** Dr. Clasby seeks damages for bodily injury, in the form of depression and anxiety, purportedly caused by implantation of the device, an alleged shocking incident, and learning of the alleged defective nature of the device. *See* Pl.'s Fact Sheet at I(C), VII(A).
>
> **Dr. Clasby's Deposition:** When asked what injuries he sustained as a result of being implanted with the device, Dr. Clasby testified: "I suffered from increased anxiety and some depression as a result of the information that I encountered in approximately May of last year relating to the possibility of failure by Guidant devices." Dep. Tr. of Eugene Clasby at 14:5-8. He also testified that he suffered pain and anxiety after allegedly being shocked by the device. *See id.* at 40:5-21, 47:12-21.
>
> **Dr. Clasby's Interrogatory Responses:** Dr. Clasby identified the following categories of damages: "physical, emotional, and financial damages incurred as a result of two explant surgeries and the resulting complications associated with said explant surgeries. Plaintiff further seeks damages for the mental anguish and stress associated with the conduct described in the Plaintiff's Complaint." Pl.'s Verified Resp. to Defs.' First Set of Interrogs. at Answer to Interrog. No. 4 (Ex. 17).

Damages for such personal injury claims -- in the form of fear, anguish, or emotional distress damages -- cannot be recovered under the FDUTPA because the statute expressly prohibits such a claim. *See* Fla. Stat. § 501.212 ("This part does not apply to: . . . (3) A claim for personal injury."); *Delgado*, 693 So. 2d at 605 (noting the statute "specifically exlude[s] claims for personal injury or death or damage to other property"). Indeed, courts have repeatedly and consistently dismissed FDUTPA claims

predicated on personal injuries. *See, e.g., Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 315, 328-29 (S.D.N.Y. 2006) (dismissing FDUTPA claim where the "thrust" of the plaintiff's complaint was that he would not have used the defendant's product and sustained physical and emotional distress but-for the defendant's unfair and deceptive acts); *T.W.M. v. Am. Med. Sys., Inc.*, 886 F. Supp. 842 (N.D. Fla. 1995) (dismissing FDUTPA claim; recipient of allegedly defective penile implant could not maintain FDUTPA claim against manufacturer for personal injury damages); *Barrow v. Bristol-Myers Squibb Co.*, No. 96-689-CIV-ORL-19B, 1998 U.S. Dist. LEXIS 23187 at *234-36, 1998 WL 812318 at *46 (M.D. Fla. Oct. 29, 1998) (dismissing FDUTPA claim for physical injuries from defective silicone breast implants), *aff'd*, 190 F.3d 541 (11th Cir. 1999) (table).

Because the only damages Dr. Clasby allegedly sustained are not recoverable under the FDUTPA, the Court should enter judgment for Guidant on Count VIII. The Court should likewise enter judgment for Guidant on Dr. Clasby's Senior Citizen FDUTPA claim (Count IX).[23] Section 501.2077, Florida Statutes, provides for a civil penalty (paid to the Florida Department of Legal Affairs) when willful and intentional conduct violating the FDUTPA victimizes those over 60 years of age. Since the undisputed facts cannot sustain Dr. Clasby's underlying FDUTPA claim, his Senior Citizen FDUTPA claim similarly fails as derivative of that claim.

[23] Based on Defendants' choice of law argument, Dr. Clasby's senior citizen consumer protection claim arises under the FDUTPA and not under Minnesota Senior Citizen and Handicapped Person Consumer Fraud Act.

VIII. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON WARRANTY CLAIMS

Guidant is entitled to summary judgment as a matter of law on Dr. Clasby's warranty claims because Dr. Clasby has failed to produce any evidence that Guidant breached either an implied or an express warranty. Dr. Clasby's implied-warranty claim fails as a matter of law because there is no privity of contract between Dr. Clasby and Guidant; Dr. Clasby's doctor selected his device, not Dr. Clasby. Moreover, his device never manifested a defect. Dr. Clasby's express warranty claim fails as a matter of law because there is simply no evidence that Guidant made and breached an express warranty.

A. Implied warranty.

1. Dr. Clasby's implied-warranty claim fails for lack of privity.

Dr. Clasby's implied-warranty claim fails because there is no privity of contract between Dr. Clasby and Guidant. In Florida, the doctrine of strict liability has subsumed implied-warranty claims for personal injury that lack privity. *See Kramer v. Piper Aircraft Corp.*, 520 So. 2d 37, 39 (Fla. 1988). Thus, Florida courts require "privity between the manufacturer and the consumer of the product in order for the consumer to assert an implied warranty claim." *Baker v. Danek Medical*, 35 F. Supp. 2d 875, 878 (N.D. Fla. 1998) (interpreting Florida law).

Here, there is no privity of contract between Dr. Clasby and Guidant because Dr. Clasby's doctor selected the device, not Dr. Clasby. In fact, Dr. Clasby played no role whatsoever in selecting his device. Dr. Clasby testified that he does not

remember anything in between when he experienced ventricular fibrillation on the tennis court and when he woke up in the hospital after he had already received his PRIZM 2. *See* Eugene Clasby Dep. Tr. 136:4-23; 138:12-22. As such, privity of contract does not exist, and Dr. Clasby's implied warranty claim fails as a matter of law. *See Wilson v. Danek Medical, Inc.*, No. 96-2460-CIV-T-17B, 1999 WL 1062129, at *7 (M.D. Fla. Mar. 29, 1999) (interpreting Florida law) (dismissing implied warranty claims where "plaintiff's doctors and not Plaintiff selected the [medical device] used on Plaintiff"); *see also Bailey v. Janssen Pharma. Inc.*, No. 06-80702-CIV-RYSKAMP/VITUNAC, 2006 WL 3665417, at * (S.D. Fla. Nov. 14, 2006) (interpreting Florida law) (holding that privity did not exist where the doctor "prescribed [the product] for relief of post-surgical pain to the decedent"); *Timmons v. Purdue Pharma Co.*, No. 8:04-CV-1479-T-26MAP, 2006 WL 263602, at * 5 (M.D. Fla. Feb. 2, 2006) (interpreting Florida law) (holding that "there [was] no evidence to suggest that any privity exists" where plaintiff's doctors had prescribed the drug at issue).

Moreover, there is no privity because "it is undisputed that the product used in plaintiff's surgery was purchased by the hospital first, and then implanted into the plaintiff." *Baker*, 35 F. Supp. 2d at 879 (holding that "[t]he recipient of an implant is not in privity with the manufacturer when the implant is purchased by the plaintiff's medical provider"). The invoice for Dr. Clasby's Device establishes that Jackson Memorial Hospital purchased the device *first*. *See* CPI 176 00100853 (Invoice for Device of Eugene Clasby, Dec. 10, 2003) (Ex. 18). As such, Dr. Clasby's implied warranty claim fails for lack of privity.

2. Dr. Clasby's implied warranty claim fails absent manifest defect.

Even if privity did exist, Dr. Clasby's implied warranty claim would fail as a matter of law because his device never manifested a defect. *See E.R. Squibb & Sons, Inc. v. Jordan*, 254 So. 2d 17 (Fl. Dist. Ct. App. 1973). In *Jordan*, plaintiffs brought an implied warranty claim, among others, against the manufacturer of an animal bone product used in certain human surgeries. On appeal, the manufacturer argued that "the jury should have been instructed, as requested, that it was incumbent upon the [plaintiffs] to show a defect in the [product] *actually used*." *Id.* at 19 (emphasis added). The Court of Appeal of Florida agreed with the manufacturer and ordered a new trial.

In so holding, the court noted that "in a case for damages for a breach of an implied warranty, the plaintiff must show that the product was transferred from the manufacturer's possession while in a Defective state, and as a result of the Defect, the plaintiff was injured." *Id.* at 20. Moreover, "for a drug manufacturer to be held liable for harm allegedly caused by a product, regardless of the ground of liability asserted, it is necessary that it be shown that there was actually something wrong with the product used . . . ." *Id.*

Here, there is simply no evidence that "there was actually something wrong" with Dr. Clasby's device. To the contrary, Dr. Clasby's device performed flawlessly throughout its useful life. *See supra*, Part II, at 29-31. As such, even if Dr. Clasby could establish privity, his implied warranty claim fails absent a manifest defect in his device.

B. Express warranty.

Dr. Clasby's express-warranty claim fails as a matter of law because there is no evidence that Guidant breached an express warranty. In Florida, express warranties are created and breached when, as part of the basis of a bargain, a seller: 1) makes an "affirmation of fact or promise . . . which relates to the goods" and the goods fail to "conform to the affirmation or promise"; 2) gives a "description of the goods" and the goods fail to "conform to the description"; or 3) displays a "sample or model" and the goods fail to "conform to the sample or model." FLA. STAT. ANN. § 672.313 (West 2007). There is simply no evidence that Dr. Clasby's device failed to conform to any alleged affirmation or promise. As discussed above, Dr. Clasby's device never manifested a defect throughout the life of the device.

Guidant has always offered a limited warranty on the package insert of the PRIZM 2. This limited warranty is available if the device "fails to function within normal tolerances due to defects in materials, workmanship, or design during the first 6 years (72 months) after date of implantation." Limited Warranty, VENTAK PRIZM 2 Models 1860/1861, attached as Ex. 19. The limited warranty specifically disclaims any express or implied warranties other than those contained on the package insert. *Id.* Absent any evidence that Dr. Clasby's device manifested a defect, however, Guidant cannot have breached a warranty conditioned on defects.

Moreover, there is no evidence that Guidant made and breached any other express warranty. As noted, Dr. Clasby has no memory of the time period between losing consciousness on the tennis court and receiving his device. There is simply no

evidence of communication -- verbal or written -- between Dr. Clasby and Guidant before he received his device, and accordingly, there is no evidence that any express warranty was part of the basis of the bargain. Absent any evidence that Guidant made and breached an express warranty, Dr. Clasby's express warranty claim fails as a matter of law.[24]

Guidant is entitled to summary judgment as a matter of law because Dr. Clasby has failed to produce any evidence that Guidant breached either an implied or an express warranty. Thus, Guidant respectfully requests that the Court grant its Motion and dismiss the aforementioned claims with prejudice.

IX. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON NEGLIGENCE CLAIMS

At all times relevant to this litigation, Dr. Clasby's device performed adequately and in conformance with its design and settings. It was never and is not now part of an FDA recall. Moreover, it never malfunctioned and never demonstrated a defect. These facts are fatal to Dr. Clasby's negligence claim.

To establish a claim for negligence under Florida law, a plaintiff must demonstrate all of the following: 1) the existence of a duty toward him; 2) a breach of that duty; and 3) that his injuries were actually and proximately caused by that breach. *See Rupp v. Bryant*, 417 So. 2d 658, 668 n.27 (Fla. 1982). In the context of products liability, a plaintiff cannot demonstrate a breach of duty without proof of a defect in the

[24] In any event, Guidant provided Dr. Clasby with a replacement device at no cost. *See supra* Part II at 27. And Guidant offered to pay Dr. Clasby's unreimbursed medical expenses up to $2500 as part of their voluntary, supplemental warranty program following the recall.

product. *See Humphreys v. General Motors Corp.*, 839 F. Supp. 822, 829 (N.D. Fla. 1993). Here, as demonstrated below, Dr. Clasby is unable to establish a defect in his device. Moreover, Dr. Clasby's allegations regarding breach are starkly at odds with the facts. Therefore, Guidant is entitled to summary judgment in its favor because Dr. Clasby cannot show a breach of duty.

A. Dr. Clasby's negligence claim fails because he cannot demonstrate that his device was defective.

As a threshold matter, Florida law regarding negligence in the products liability context requires proof of some defect in the product. *See Barrow v. Bristol-Myers Squibb Co.*, No. 96-689-CIV-ORL-19B, 1998 WL 812318, at *27 (M.D. Fla. Oct. 29, 1998); *Edgar v. Danek Med., Inc.*, No. 96-2451-CIV-T-24A, 1999 WL 1054864 (M.D. Fla. Mar. 31, 1999). Here, Dr. Clasby is unable to demonstrate that his device was defective. Therefore, Guidant is entitled to summary judgment in its favor.

1. Dr. Clasby cannot demonstrate a design defect in his device.

At the outset, it is important to restate that Dr. Clasby's device was never, and is not now, the subject of any FDA recall. Although a PRIZM 2 DR, Model 1861, his device falls outside of the recall population. The FDA recall regarding PRIZM 2 DR, Model 1861 devices was explicitly limited to those manufactured on or before April 16, 2002. *See supra* Part II at 28. The manufacture of Dr. Clasby's device, however, did not begin until May 2002. *Id.* Therefore, his device is outside the recall population.

The reliability of the population into which Dr. Clasby's device falls is well-established. On April 16, 2002, Engineering Change Order (ECO) 40773 made

changes to the design and manufacturing process of the PRIZM 2 DR, Model 1861. *See supra* Part II at 28. These changes distinguished new devices from the pre-change, recalled population. At the time of the FDA recall regarding PRIZM 2 DR, Model 1861 devices, no devices manufactured after April 2002 had demonstrated any malfunction or failure associated with arcing. *Id*. Since then, only one such malfunction has occurred in Dr. Clasby's device population. *Id.* Out of a total of approximately 11,000 devices in this population, a single malfunction represents a occurrence rate of 0.009%. *Id.* Furthermore, testing of 877 returned devices did not provoke a single malfunction. *Id.* Here, Dr. Clasby is unable to demonstrate that his device suffered from a design defect. Because Florida law requires proof of a defect, Guidant is entitled to summary judgment in its favor.

2. Dr. Clasby cannot demonstrate a manufacturing defect in his device.

Dr. Clasby's device has never manifested a defect. There is, therefore, no basis for concluding that his device suffered from a manufacturing defect. In fact, Dr. Clasby's own testimony demonstrates a lack of defect. Dr. Clasby testified on more than one occasion that no physician ever told him that his device was defective or had manifested a defect. *See supra* Part II at 29-31. Furthermore, a visual inspection of the device after it was explanted revealed it had never short-circuited. *Id.* at 31. None of Dr. Clasby's expert witnesses opine that his specific device suffers from a manufacturing defect. Moreover, the mere possibility of future failure is insufficient to establish that a product is defective. *E.R. Squibb & Sons, Inc. v. Stickney*, 274 So. 2d 898, 906 (Fla. Ct.

App. 1973). Here, Dr. Clasby is unable to present a genuine issue of fact regarding whether his device suffered from a manufacturing defect. Because Florida law requires proof of defect, Guidant is entitled to summary judgment in its favor.

B. Dr. Clasby's negligence claim fails because he cannot demonstrate that Guidant breached a duty owed to him.

With respect to Dr. Clasby's allegations regarding breach, an analysis of each is instructive. First, Dr. Clasby alleges that Guidant breached a duty by "incorporating a defect into the design of the Devices." First Am. Master Compl. at ¶ 288. The facts do not support this allegation. Despite the wording of the Master Complaint, the relevant inquiry here is whether a duty was breached with respect to Dr. Clasby. As set forth above, it is undisputed that Dr. Clasby's device never failed and was never recalled. None of Dr. Clasby's expert witnesses tested his device and claim otherwise. Furthermore, the occurrence rate of malfunction for Dr. Clasby's device population is a mere 0.009%. Therefore, there is no genuine issue of material fact regarding the existence of a design defect in the relevant device population.

Second, Dr. Clasby alleges that Guidant breached a duty by "manufacturing and assembling the Devices in such a manner that they could short circuit and/or otherwise fail to operate and malfunction." First Am. Master Compl. at ¶ 289. The facts do not support this allegation. Despite the wording of the Master Complaint, the relevant inquiry here is whether a duty was breached with respect to Dr. Clasby. As set forth above, Dr. Clasby's device never manifested a defect. Dr. Clasby's own testimony indicates that his physicians never advised him of such a defect. Therefore, there is no

genuine issue of material fact regarding the existence of a manufacturing defect in Dr. Clasby's device.

Third, Dr. Clasby alleges that Guidant breached a duty by "failing to notify and warn the FDA, [his] treating physicians, [him] and the public at the earliest possible date of known design or manufacturing defects in the Devices." First Am. Master Compl. at ¶ 290. The facts do not support this allegation. Despite the wording of the Master Complaint, the relevant inquiry here is whether a duty was breached with respect to Dr. Clasby. As set forth above, Dr. Clasby's device was manufactured after the implementation of certain changes to the design and manufacturing process of PRIZM 2 DR, Model 1861 devices. At the date of the FDA recall regarding certain PRIZM 2 DR, Model 1861 devices, there were no reported malfunctions in devices manufactured after that initial ECO. *See supra* Part II at 28. Only after the FDA recall was there any report of a single malfunction in this device population. This malfunction took place years after the implant of Dr. Clasby's device. Therefore, even if one malfunction was sufficient to trigger a duty to warn (which it is not), there is no genuine issue of material fact regarding whether Guidant breached a duty to warn prior to Dr. Clasby's implant.

In addition, when the malfunction was discovered, Guidant included it as part of an Advisory Update for VENTAK PRIZM 2 DR, Model 1861, which was issued on December 20, 2005. There is no reason to believe that this information could have been communicated at an earlier date. Furthermore, this information was made publicly available by the Advisory Update. Therefore, there is no genuine issue of material fact regarding whether Guidant breached a duty to warn in a timely fashion.

Fourth, Dr. Clasby alleges that Guidant breached a duty by "failing to exercise due care under the circumstances." First Am. Master Compl. at ¶ 291. The facts do not support this allegation. Considering that Dr. Clasby's device population has never been part of a recall and that his device never manifested a defect, the basis for alleging a failure to exercise due care is unclear. In fact, Guidant exercised due care by providing Dr. Clasby with an FDA-approved device that never manifested a defect. If providing such a device is not sufficient due care, it is difficult to imagine what is.

None of Dr. Clasby's allegations regarding breach of duty are supported by the facts. Guidant did not breach any duty to Dr. Clasby. Instead, it provided him with a fully-approved and fully-functional device. Because there is no genuine issue of material fact regarding a breach of duty, Dr. Clasby's negligence claims fails. Therefore, Guidant is entitled to summary judgment in its favor.

X. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON NEGLIGENCE PER SE CLAIMS

Dr. Clasby asserts that Guidant is liable to him for damages based on a theory of negligence per se. *See* Complaint by Adoption ¶ 8. Specifically, Dr. Clasby alleges that Guidant's acts "constitute an adulteration, misbranding, or both, as defined by the federal FDCA §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom and from parallel state law requirements, under theories of negligence per se." First Am. Master Compl. ¶ 295. However, there is one glaring problem with Plaintiff's contention – Florida law does not recognize negligence per se claims based on violations of the Federal Food Drug and

Cosmetic Act ("FDCA"). *See Blinn v. Smith & Nephew Richards,* 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) (a plaintiff "cannot use a negligence per se claim to create a private cause of action for Defendant's violation of the FDCA").[25]

Under Florida law, violations of regulatory and/or penal statutes cannot constitute negligence per se unless the statute allegedly violated contains an express right of private action for its violation. *See Murthy v. N. Sinha Corp.,* 644 So. 2d 983, 986 (Fla. 1994) ("a statute that does not purport to establish civil liability but merely makes provisions to secure the safety or welfare of the public entity, will not be construed as establishing a civil liability"); *Jupiter Inlet Corp. v. Brocard,* 546 So. 2d 1, 2-3 (Fla. 4th DCA 1988) (violations of OSHA not negligence per se because that statute does not provide a "private right of action"); *Stevens v. Danek Medical, Inc.,* Case No. 95-14293, 1999 U.S. Dist. LEXIS 22397, *19 (S.D. Fla. April 16, 1999) (Paine, J.) ("Florida courts have refused to recognize a private right of action for negligence per se based on an alleged violation of a federal statute that does not provide for a private right of action"). The FDCA does not provide for a private right of action. In fact, the language of the Act itself expressly prohibits a private cause of action for its violation. *See* 21 U.S.C. § 337(a). *See also Merrell Dow Pharmaceuticals Inc. v. Thompson,* 478 U.S. 814-817 (1986) (holding that the FDCA does not provide for a private cause of action). As such, Dr. Clasby's negligence per se claims must fail.

[25] The VENTAK PRIZM II DR 1861 model was FDA-approved at all times that it was marketed by GSC. In fact, FDA approval was never revoked. *See supra* Part II at 10.

Indeed, in *Blinn* the plaintiffs alleged that the defendant, a manufacturer of bone screws, was liable for negligence per se based on its alleged violations of various FDA regulations regarding informed consent, marketing and promotion. 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999). In granting summary judgment in favor of the defendant medical device manufacturer, the Court stated:

> Under Florida law, whether there is civil liability for violation of a statute depends on legislative intent. In the absence of a legislative intent to create a private cause of action, violation of a statute creates no civil liability. The FDCA expressly prohibits private claims for violations of that statute, 21 U.S.C. § 337(a), strongly evidencing a legislative intent not to create a private cause of action. Under Florida law, therefore, Plaintiffs cannot use a negligence per se claim to create a private cause of action for Defendant's alleged violation of the FDCA.

Id.

Similarly, in *Stevens* the plaintiff sued the manufacturer of medical devices used during surgical procedures. 1999 U.S. Dist. LEXIS 22397, *2 (S.D. Fla. 1999). Plaintiff pled a negligence per se claim against the manufacturer based on alleged violations of the FDCA. *Id.* In entering summary judgment in favor of the defendant on plaintiff's negligence per se claims, the court held that because the FDCA does not provide for a private cause of action, a violation of that statute could not constitute negligence per se under Florida law. *Id.* at 19.

Like the plaintiffs' claims in *Blinn* and *Stevens*, Dr. Clasby's negligence per se claims must fail as a matter of law because, under Florida law, the FDCA does not provide for a private cause of action and, therefore, its violation cannot constitute

negligence per se.[26] Summary judgment in favor of Guidant on Plaintiff's negligence per se claims is mandated.

Thus, Guidant respectfully requests that the Court enter an Order awarding summary judgment in its favor on Dr. Clasby's negligence per se claims.

XI. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON GROSS NEGLIGENCE CLAIMS

Dr. Clasby's gross negligence/malice claim is actually one for exemplary or punitive damages. *See* First Am. Master Compl. at ¶ 350. To recover such damages, he must demonstrate two things. First, he must demonstrate that Guidant is liable to him for damages. Second, he must show aggravated circumstances that warrant imposing an extraordinary punishment. Here, Dr. Clasby cannot demonstrate either.

A. Dr. Clasby's gross negligence/malice claim fails because he cannot demonstrate any underlying liability.

The purpose of exemplary or punitive damages is to punish the offender and deter others from acting similarly. *See Am. Cyanamid Co. v. Bryant*, 498 So. 2d 859, 861 (Fla. 1987). Here, there is no punishable offense. As set forth in this Motion, each of Dr. Clasby's claims against Defendants fail. Absent some underlying liability, exemplary damages are unwarranted and inappropriate. There is no genuine issue of fact

[26] It is unclear whether Dr. Clasby asserts a negligence per se claim based on alleged violations of the Florida Drug and Cosmetic Act, Fla. Stat. §§ 499.01, et seq., the state counterpart to the FDCA. To the extent that he is making such claims, those claims similarly fail because that statute also does not provide for a private cause of action and, therefore, cannot be the basis for a negligence per se claim. *See T.M.W. v. American Medical Syst.*, 886 F. Supp. 842 (N.D. Fla. 1995) (holding that the Florida Drug and Cosmetic Act does not expressly or impliedly provide a private cause of action); *Barrow v. Bristol-Myers Squibb Co.*, Case No. 96-689, 1998 U.S. Dist. LEXIS 23187, *235 (M.D. Fla. October 29, 2998) (Fawsett, J.) (holding that the Florida Drug and Cosmetic Act does not provide for a private right of action).

regarding whether Dr. Clasby is entitled to exemplary damages. As such, Guidant is entitled to summary judgment in its favor with respect to the gross negligence/malice claim.

B. Dr. Clasby's gross negligence/malice claim fails because he cannot demonstrate the circumstances necessary to impose exemplary damages.

Under Florida law, exemplary damages are appropriate where gross negligence is "established by facts evincing a reckless disregard of human life or rights which is equivalent to an intentional act or a conscious indifference to the consequences of an act." *Rupp v. Bryant*, 417 So. 2d 658, 670 (Fla. 1982). Here, no such showing of gross negligence is possible. At all times relevant to this litigation, Dr. Clasby's device performed adequately and in conformance with its design and settings. It has never been part of an FDA recall. Moreover, it never malfunctioned and never demonstrated a defect. Guidant provided Dr. Clasby with a fully-functional, FDA-approved device. Therefore, there is no basis for finding that Guidant acted with the type of gross negligence required to justify the imposition of exemplary damages. As such, Guidant is entitled to summary judgment in its favor with respect to the gross negligence/malice claim.

Given that Dr. Clasby cannot establish that Guidant acted reprehensibly towards him, he can be expected to rely on evidence of Guidant's conduct toward others. This Court, however, may only consider conduct by Guidant that was directed toward Dr. Clasby in Florida or other similar conduct. *See Philip Morris USA v. Williams*, 127 S. Ct. 1057, 1063 (2007) (stating that the Constitution's Due Process Clause forbids punishing a

defendant for "injury that it inflicts upon nonparties") ; *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003); *Honda Motor Co. v. Oberg*, 512 U.S. 415, 420 (1994) ("A decision to punish a tortfeasor by means of an exaction of exemplary damages is an exercise of state power that must comply with the Due Process Clause of the Fourteenth Amendment."). Here, no evidence of Guidant's conduct toward others is sufficiently related factually and legally to the conduct allegedly injuring Dr. Clasby to serve as evidence of alleged reprehensibility. Therefore, evidence of Guidant's alleged conduct toward others may not be considered in this case to justify the imposition of punitive damages.

Under Florida law, exemplary damages are not available absent a showing of "reckless disregard of human life or rights." *See id*. Here, Dr. Clasby cannot demonstrate either underlying liability or the type of aggravated circumstances required for exemplary damages. Therefore, Guidant is entitled to summary judgment in its favor with respect to the gross negligence/malice claims.

XII. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON UNJUST ENRICHMENT CLAIMS

Dr. Clasby never pled an unjust enrichment claim when he filed his original Complaint in the United States District Court for the Southern District of Florida. And for good reason: Florida law does not recognize a cause of action for unjust enrichment where a plaintiff has adequate remedies at law. Moreover, Dr. Clasby is entirely incapable of establishing that Guidant was unjustly enriched. Nevertheless, when Dr. Clasby filed his Complaint by Adoption in this Court, he adopted a number of claims in

the Master Complaint, including a claim for unjust enrichment. *See* Complaint by Adoption ¶ 8. The Court should dismiss this inappropriately pled claim.

A. Dr. Clasby's equitable unjust enrichment claim is precluded by the existence of adequate remedies at law.

Dr. Clasby's unjust enrichment claim must fail as a matter of law because he has pled a number of adequate legal remedies. Florida law provides that "[l]ack of an adequate remedy at law is a prerequisite for equitable relief." *Liza Danielle, Inc. v. Jamko, Inc.*, 408 So. 2d 735, 738 (Fla. 3d DCA 1982). Indeed, "[i]t is blackletter law that the theory of unjust enrichment is equitable in nature and is, therefore, not available where there is an adequate legal remedy." *In re Managed Care Litig.*, 185 F. Supp. 2d 1310, 1337 (S.D. Fla. 2003) (dismissing unjust enrichment claims because lack of adequate remedy at law not specifically pleaded). *See also Bowleg v. Bowe*, 502 So. 2d 71, 72 (Fla. 3d DCA 1987) ("unjust enrichment is equitable in nature and is, therefore, not available when there is an adequate legal remedy."); *Gary v. D. Agustine & Asociados*, 865 F. Supp. 818, 827 (S.D. Fla. 1994) (same).[27]

Furthermore, in order to maintain a claim for unjust enrichment, a plaintiff must make clear from the face of the complaint that no adequate legal remedy exists.

[27] Contrary to the substantial amount of case law holding otherwise, there is case law from Florida state and federal courts that indicate a plaintiff may pursue an equitable claim for unjust enrichment even when he/she has adequate remedies at law. *See Williams v. Bear Stearns & Co.*, 725 So. 2d 397, 400 (Fla. 5th DCA 1998); *ThunderWave v. Pan American Bank of Orlando*, 387 F. Supp. 1562, 1566-1567. However, the Florida Supreme Court has not ruled on this issue, and the majority of the case law from Florida and elsewhere holds that a plaintiff cannot recover for unjust enrichment, like any other equitable remedy, when they fail to plead that an adequate remedy at law is not available or when adequate remedies at law are, in fact, available. *See cases cited infra.*

Martinez v. Weyerhauser Mort. Co., 959 F. Supp. 1511, 1518-1519 (S.D. Fla. 1996) (dismissing unjust enrichment claim "because Plaintiff [failed] to allege that an adequate remedy at law does not exist, and the Court [was] not convinced that this was clear from the face of the Amended Complaint"). *See also H2Ocean, Inc. v. Schmitt,* Case No. 05-387, 2006 U.S. Dist. LEXIS 44734, *8-9 (N.D. Fla. June 30, 2006)(Vinson, J.); *American Honda Motor Co. v. Motorcycle Information Network, Inc.*, 390 F. Supp. 2d 1170 (M.D. Fla. 2005). Dr. Clasby did not allege in his original complaint or his Complaint by Adoption that he lacked an adequate legal remedy. Moreover, neither the Master Complaint nor the Amended Master Complaint makes such an allegation. In this case, it is clear that Dr. Clasby has adequate remedies at law as he pleads ten (10) different legal theories of recovery in his Complaint by Adoption.

In fact, Dr. Clasby has pled causes of action at law under which, if successful, he would be entitled to recover the same damages as he would under his unjust enrichment claim. Most notably, Dr. Clasby alleges that he is entitled to damages due to Guidant's alleged violation of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.201, et seq. *See* Complaint by Adoption ¶ 8. The only damages available for private actions stemming from violations of FDUTPA are actual damages, which in this case would be the cost of Dr. Clasby's cardiac medical device(s) – the same damages available under his unjust enrichment claim. *See* Fla. Stat. § 501.211; *Rollins, Inc. v. Heller,* 454 So. 2d 580, 585 (Fla. 3d DCA 1984). Dr. Clasby should therefore not be permitted to proceed with his unjust enrichment claim.

Moreover, a plaintiff's inability to prove his legal claims does not demonstrate an inadequate remedy at law. If that were the case, any plaintiff who failed to meet the elements of a legal remedy could always fall back on a claim for unjust enrichment or other equitable remedies. *See J.C. Penny Co. v. United States Treasury Dep't,* 439 F. 2d 63, 68 (2d Cir. 1971) ("The mere fact more desirable remedies are unavailable does not mean that existing remedies are inadequate."); *cf. Rambo Associates, Inc. v. South Tama County Community School Dist.*, 414 F. Supp. 2d 887, 899 (N.D. Iowa 2006) (noting that one element of unjust enrichment is that "there is no at-law remedy that can be appropriately address the claim"); *Coastal Masonry, Inc. v. Reliance Ins. Co.*, 297 B.R. 34, 41 (E.D. Va. 2003) ("Equitable remedies are designed to give relief where justice demands, but law fails to so provide. That is not the situation before the court. Coastal had an available remedy through the Miller Act, but it waived that right. Coastal had an available remedy through the Miller Act, but it waived that right. Coastal cannot now circumvent the very waiver that deprives it of that remedy through an appeal to the equitable powers of this court.").

In this case, Dr. Clasby has pled numerous legal remedies in his Complaint by Adoption, including strict liability, negligence, fraud, warranty, and consumer protection claims. These are adequate legal remedies that foreclose the availability of equitable remedies, including Dr. Clasby's claims for unjust enrichment. This is consistent with much of the law in Florida and a substantial number of other jurisdictions throughout the country. *See, e.g., Brown v. Sandimo Materials*, 250 F.3d 120 (2d Cir. 2001); *Adamson v. Ortho McNeil Pharmaceutical, Inc.*, 463 F. Supp. 2d 496 (D.N.J.

2006); *Underwriters Ins. Co. v. Offshore Marine Contractors, Inc.*, 442 F. Supp. 2d 325 (E.D. La. 2006); *Brumbelow v. Law Offices of Bennett and Delaney, P.C.*, 372 F. Supp. 2d 615 (D. Utah 2005); *Ethypharm S.A. France v. Bentley Pharmaceuticals, Inc.*, 388 F.Supp.2d 426 (D. Del. 2005); *Harold ex rel. Harold v. McGann*, 406 F. Supp. 2d 562 (E.D. Pa. 2005); *Taylor Woodrow Blitman Constr. Corp. v. Southfield Gardens Co.*, 534 F.Supp 340 (D. Mass 1982); *Farmers Nat'l Bank v. Wickham Pipeline Constr.*, 759 P.2d 71 (Idaho 1988); *Guinn v. Hoskins Chevrolet*, 836 N.E.2d 681 (Ill. App. 1st Dist. 2005); *Baker v. MacClay Properties Co.*, 648 So.2d 888 (La. 1995); *Santagate v. Tower*, 833 N.E.2d 171 (Mass. App. Ct. 2005); *Robinson v. Southerland*, 123 P.3d 35 (Okla. Civ. App. Div. 3 2005). Thus, based on the foregoing, Guidant is entitled to summary judgment on Plaintiff's unjust enrichment claims.

B. Dr. Clasby has failed to demonstrate that Guidant has been "unjustly" enriched.

Even if the Court finds that Dr. Clasby does not have adequate remedies at law, his unjust enrichment claims must still fail because Dr. Clasby cannot demonstrate that any alleged enrichment is "unjust." As one court found, "to succeed on…the unjust enrichment…claims, Plaintiffs would have to demonstrate that they were either injured by [a prescription drug], or that [it] did not provide them any health benefits." *In re Baycol Prods. Liab. Litig.*, 218 F.R.D. 197, 213-14 (D. Minn. 2003). *See also Lewis v. Bayer*, 66 Pa. D. & C4th 470, 504 (Pa. Ct. Com. Pl. 2004) ("If an individual consumed an effective cholesterol-reducing medication which was "unsafe" because of inadequate warnings or because of increased exposure to serious injury and has a chance and fate

provided in fact suffers no injury, no equitable claim for unjust enrichment can lie."); *Albertson v. Wyeth, Inc.*, 63 Pa. D. & C4th 514, 536 (Pa. Ct. Com. Pl. 2003) (dismissing unjust enrichment claim because "plaintiffs did receive the product they sought, a hormone replacement therapy. Plaintiffs merely allege that Prempro was not safe, and that Wyeth knew it was unsafe but promoted the drug anyway. These allegations are insufficient to state a claim for unjust enrichment.").

Here, Dr. Clasby's device never malfunctioned. It never caused him any harm while implanted.[28] Dr. Clasby received exactly what he thought he was purchasing – a fully-functioning device. Thus, Plaintiff cannot demonstrate that any alleged enrichment is "unjust."

In addition to receiving the benefits of an appropriately- functioning device, Dr. Clasby also incurred no out-of-pocket costs from his explant surgery. And as for the allegedly ill-gotten "profits" associated with the sale of Dr. Clasby's PRIZM 2, those do not lend any support to Dr. Clasby's unjust enrichment claim: Guidant issued a $17735 credit for Dr. Clasby's first device. *See supra* Part II at 27. There is no evidence whatsoever that Guidant profited from the sale of Dr. Clasby's device, justly or otherwise.

[28] Although Dr. Clasby claims that his PRIZM 2 delivered inappropriate shocks in April 2003, which Guidant denies, he did not request that the device be explanted until more than three years later. *See supra* Part II at 27-30. As a result, this alleged "defect" cannot be the basis for Dr. Clasby's unjust enrichment claims. *See, e.g.*, *Prohias v. Pfizer, Inc.*, No. 05-22658, 2007 U.S. Dist. LEXIS 33162, *15 (S.D. Fla. April 24, 2007) (Jordan, J.) (dismissing unjust enrichment claim because Plaintiffs continued to use the product after their knowledge of the alleged "defect" and/or after they became aware of the allegedly actionable conduct by the defendant).

Because Dr. Clasby has an adequate remedy at law, and he cannot establish that Guidant was unjustly enriched, Dr. Clasby's unjust enrichment claims must fail. Thus, Guidant respectfully requests that the Court enter an Order awarding summary judgment in its favor on Dr. Clasby's unjust enrichment claims.

XIII. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON CONSTRUCTIVE FRAUD CLAIMS

In Count VII of the Master Complaint, Dr. Clasby asserts a claim for constructive fraud, alleging Guidant "took unconscionable advantage of [its] dominant position of knowledge" concerning the safety and efficacy of Guidant devices. Specifically, Dr. Clasby claims that Guidant had "unique knowledge and expertise regarding the defective nature of the Devices," but "professed to Plaintiffs that they were in possession of facts demonstrating that the Devices were safe and effective for their intended use and were not defective." Dr. Clasby contends that these statements were made "to induce Plaintiffs to purchase the Devices," and that he suffered damages as a result.

The court should grant summary judgment on this claim. The key elements in a claim for constructive fraud are the existence and breach of a fiduciary or confidential relationship between the parties. Dr. Clasby cannot establish either in this case. Plaintiff's constructive fraud claim is also barred by the learned intermediary doctrine.

A. Dr. Clasby can show no evidence of a fiduciary duty.

"Under Florida Law, constructive fraud occurs when a duty under a confidential or fiduciary relationship has been abused or where an unconscionable advantage has been taken." *Am. Honda Motor Co., Inc. v. Motorcycle Information Network, Inc.*, 390 F. Supp. 2d 1170, 1179 (M.D. Fla. 2005) (citation omitted).

> The essential difference between actual and constructive fraud lies with intent. In contrast to actual fraud, which relies on the existence of a positive misrepresentation or nondisclosure of a material fact, constructive fraud is based on a presumption of fraud, without the showing of intent, because of the fiduciary of confidential relationship between the parties.

Harbaugh v. Greslin, No. 03-61674, 2004 U.S. DIST. LEXIS 28598, at *17 (S.D. Fla. Dec. 13, 2004). A claim for constructive fraud is equivalent to a claim for breach of fiduciary duty based on misrepresentation or concealment. *Amoco Oil Co. v. Gomez*, 125 F. Supp. 2d 492, 509 (S.D. Fla. 2000).

This is an extremely high standard under Florida law. "Fiduciary duty, the highest standard of duty implied by law, is the duty to act for someone else's benefit, while subordinating one's personal interest to that of the other person." *FDIC v. Stahl*, 854 F. Supp. 1565, 1572 (S.D. Fla. 1994) (citations omitted). "The fact that one party places trust or confidence in the other does not create a confidential relationship in the absence of some recognition, acceptance or undertaking of the duties of a fiduciary on the part of the other party." *Am. Honda*, 390 F. Supp. 2d at 1179.

Dr. Clasby has not alleged or demonstrated in any way that he is owed a fiduciary duty by Guidant. Consequently, his claim for constructive fraud cannot stand.

See Am. Honda, 390 F. Supp. 2d at 1179 (holding plaintiff failed to state a claim for constructive fraud where no confidential or fiduciary relationship existed); *Saglio v. Chrysler First Commercial Corp.*, 839 F. Supp. 830, 833 (M.D. Fla. 1993) (finding fiduciary relationship between the parties did not exist as a matter of law, and holding the absence of such a relationship defeated claim for constructive fraud); *McMahan Sec. Co. v. FB Foods, Inc.*, No. 04-CV-1791, 2006 WL 1822985 at *7 (M.D. Fla. June 29, 2006) (dismissing claim for constructive fraud where no fiduciary duty existed). *Compare Doe v. Evans*, 814 So. 2d 370, 375 (Fla. 2002) (holding fiduciary duty existed between clergy member holding himself out to be a marital counselor and counselee, and plaintiff stated cognizable claim for breach of fiduciary duty); *First Union Nat'l Bank v. Turney*, 824 So. 2d 172, 191 (Fla. 1st DCA 2001) (finding trustee's deliberate withholding of information from trust beneficiary in order to defeat beneficiary's rights constituted "more than constructive fraud" and established crime-fraud exception to attorney-client privilege between trustee and trustee's lawyers); *Harrell v. Branson*, 344 So. 2d 604, 606-07 (Fla. 1st DCA 1977) (holding confidential or fiduciary relationship existed between uncle and niece, the breach of which constituted constructive fraud entitling plaintiff to rescission of deed).

Although a manufacturer of medical devices has duties imposed by the FDA to disclose certain information to physicians and patients, there is simply no authority under Florida law for the proposition that such a duty rises to that of a fiduciary. *Cf. Tolen v. A.H. Robins Co.*, 570 F. Supp. 1146, 1152 (S.D. Ind. 1983) (determining fraudulent concealment doctrine did not operate to toll the statute of limitations because

"there is no confidential or fiduciary relationship between the plaintiff, a consumer, and Robins, a manufacturer of pharmaceutical products").

Count VII of Dr. Clasby's complaint does not allege any fiduciary duty at all. Nor can he point to any evidence establishing a fiduciary duty in this case. Dr. Clasby instead apparently bases his constructive fraud claim on Guidant's alleged taking "unconscionable advantage" of him and "superior knowledge" of a purported product defect. Although the cases sometimes describe constructive fraud in terms of one party taking "unconscionable advantage" of another, the inquiry nevertheless turns on the existence of a fiduciary relationship between the parties. *See, e.g.*, *Am. Honda*, 390 F. Supp. 2d at 1179 (stating that constructive fraud occurs when unconscionable advantage has been taken, but dismissing claim because no confidential or fiduciary relationship existed). Moreover, one party's superior knowledge, without more, does not create a fiduciary relationship with the other. *Cf. Taylor Woodrow Homes Fla., Inc. v. 4/46-A Corp.*, 850 So. 2d 536, 541 (Fla. 5th DCA 2003) ("allegations of superior knowledge of a party's financial condition are generally insufficient to transform the creditor-debtor relationship into a fiduciary relationship.").

B. Dr. Clasby can show no evidence of a breach of any fiduciary duty.

Even if a heightened duty existed that was sufficient to maintain an action for constructive fraud in this case, there has been no breach of such duty. The gist of Dr. Clasby's constructive fraud claim is that Guidant failed to warn him of a purported product defect. However, it is unclear what "defect" Dr. Clasby is referring to. It is undisputed that Plaintiff's device was not subject to a recall because it was manufactured

after the April 2002 Engineering Change Order was instituted. *See supra* Part II at 27-28. Thus, even if Guidant devices manufactured before that date were defective (which they are not), Guidant would have no obligation to warn Plaintiff about a purported defect in a device he did not have. *See supra* Part V.

C. Dr. Clasby's claim is barred by the learned-intermediary doctrine.

At bottom, Dr. Clasby's constructive fraud claim is merely a reconstituted version of his failure to warn claim. Thus, the claim should be barred by the learned intermediary doctrine. *See Albertson v. Wyeth, Inc.*, No. 2944 Aug. Term 2002, 2003 WL 21544488 at *12 (Pa. Ct. Com. Pl. July 8, 2003) (finding plaintiffs had no cause of action for breach of fiduciary duty and fraud in light of the learned intermediary doctrine); *see also supra* Part XIII. The practical effect of permitting a constructive fraud claim such as the one asserted here would be to allow an end-run around the learned intermediary defense for what amounts to nothing more than a garden variety failure to warn claim. Such an effort by Dr. Clasby should not be permitted.

XIV. DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF PARTIAL SUMMARY JUDGMENT ON EMOTIONAL DISTRESS CLAIMS

Guidant is entitled to summary judgment as a matter of law on Dr. Clasby's claims for both negligent infliction of emotional distress (NIED) and intentional infliction of emotional distress (IIED).[29] Dr. Clasby essentially claims that he suffered from emotional distress as a result of Guidant's physician advisory relating to the PRIZM 2

[29] Dr. Clasby did not assert claims for NIED or IIED in his Original Complaint. Dr. Clasby first asserted these claims when he adopted the MDL Master Complaint. *See* Compl. by Adoption Exhibit "B"at ¶ 9 (adopting Count X (NIED) and Count XI (IIED) of MDL Master Complaint).

implantable defibrillator. He cannot, however, provide sufficient evidence to support the essential elements of either emotional distress claim under Florida law. Accordingly, these claims should be dismissed as a matter of law.

A. Dr. Clasby's NIED claim fails under Florida law.

Florida "does not recognize the tort of negligent infliction of emotional distress." *Gonzalez-Jimenez de Ruiz v. United States*, 231 F. Supp. 2d 1187, 1200 (M.D. Fla. 2002). In limited circumstances, Florida does permit the recovery of emotional distress as an element of plaintiff's damages but not as an independent claim. To qualify for these damages, Dr. Clasby "must show that he suffered emotional distress caused by a physical impact which manifested itself into some physical injury resulting from another's negligence." *Mistretta v. Volusia Co. Dep't of Corrections*, 61 F. Supp. 2d 1255, 1265-66 (M.D. Fla. 1999). The requisite physical injury must be "demonstrable…such as death, paralysis, muscular impairment, or similarly objectively discernible physical impairment." *Brown v. Cadillac*, 468 So. 2d 903, 904 (Fla. 1985). Dr. Clasby is unable to prove either the underlying cause of negligence or that he had a "demonstrable physical injury" such as those listed above. Therefore, this claim fails.

1. Dr. Clasby cannot prove that Guidant was negligent.

To succeed on his NIED claim, Dr. Clasby must first prove that Guidant committed a negligent act. *See Dalrymple v. United States*, 2005 U.S. Dist. LEXIS 8320, at *36 (S.D. Fla. May 6, 2005). To prove negligence under Florida's product liability laws, he must show that his device was defective. *See Barrow v. Bristol-Myers Squibb*

Co., No. 96-689-CIV-ORL-19B, 1998 WL 812318, at *27 (M.D. Fla. Oct. 29, 1998). As discussed *supra* in Part V, he is unable to do so.

Dr. Clasby's device falls outside of the population of devices for which the FDA has issued a recall. *See supra* Part II at 27-28. While his device was part of a voluntary Guidant advisory, inclusion in such advisory does not denote the presence of a defect. In fact, with approximately 11,000 post-April 2002 devices in circulation, of which Dr. Clasby's device was one, only one malfunction has occurred, representing an occurrence rate of 0.009%. *See id.* at 28. This low occurrence rate, combined with the fact that none of Dr. Clasby's physicians has ever determined that his device malfunctioned or is defective, precludes Dr. Clasby from proving the necessary element of product defect. Further, as previously stated, Dr. Clasby is unable to prove that either Guidant breached a duty or that such alleged breached caused his injuries. *See supra* Part X. Absent such proof, Dr. Clasby's negligence claim fails, and so too does his NIED claim.

2. Dr. Clasby does not have a "demonstrable physical injury" that resulted from his alleged emotional distress.

Dr. Clasby's NIED claim also fails because he is unable to prove an "accompanying physical injury." *See Gracey v. Eaker*, 837 So. 2d 348, 351 (Fla. 2002); *see also Reiser v. Wachovia Corp.*, 935 So. 2d 1236 (Ct. App. Fla. 2006). "Because a claim for emotional distress is intrinsically speculative and difficult to determine, the requirements of physical impact and physical injury are essential to succeed on a cause of action for negligent infliction of emotional distress." *Mistretta*, 61 F. Supp. 2d at 1266.

As he has not asserted, nor did he testify to, any physical injury as a result of his alleged emotional distress, his NIED claim fails.

To succeed on this claim, Dr. Clasby must prove that he had a "demonstrable physical injury such as death, paralysis [or] muscular impairment…" *Brown,* 468 So. 2d at 904. Dr. Clasby is unable to do so. Indeed, both he and his wife discuss how his physical activities, such as tennis and teaching, remained constant.[30] Additionally, his psychiatrist, Dr. Delgadillo testified to Dr. Clasby's physical activities schedule. He stated that Dr. Clasby "[a]ttends gym Tuesday and Thursday with a personal trainer. Monday, Wednesday, and Friday he does his tennis." *See supra* Part II at 36. Further, Dr. Clasby and his wife "spent at least a month in Maine on vacation" less than two months after the May, 2005 advisories. *Id.* Therefore, any alleged physical injury Dr. Clasby might have cannot possibly rise to the requisite degree of injury necessary since he was able to continue teaching, playing tennis and vacationing. Moreover, none of his claimed injuries, including surgical complications, are derivative of his emotional distress, as required to satisfy this element. *See Mistretta*, 61 F. Supp. 2d at 1265-66. Therefore, as it is clear that Dr. Clasby cannot satisfy the requirement of physical injury, Guidant is entitled to summary judgment in its favor.

B. Dr. Clasby fails to satisfy the elements necessary to sustain a claim for intentional infliction of emotional distress.

For an IIED claim to be successful, Florida requires the following elements to be satisfied: "(1) extreme and outrageous conduct by the Defendant; (2) an intent to

[30] Mrs. Clasby testified that Dr. Clasby "still plays tennis. He doesn't miss tennis." *See supra*, Part II at 36. She also stated that he "never misses work." *Id.*

cause, or reckless disregard to the probability of causing, emotional distress; (3) severe emotional distress suffered by Plaintiff; and (4) that the conduct complained of caused the plaintiff's severe emotional distress." *Decius v. Nat'l Serv. Indust., Inc.*, 2001 U.S. Dist. LEXIS 21400, at *3-4 (S.D. Fla. Nov. 1, 2001). These elements are "difficult to satisfy." *Gibbs v. Rep. Tobacco, L.P.*, 119 F. Supp. 2d 1288, 1296 (M.D. Fla. 2000). "It is well settled that a claim which fails to satisfy the prima facie pleading requirements associated with it must be dismissed." *Decius*, 2001 U.S. Dist. LEXIS 21400, at *4. Because Dr. Clasby can offer no evidence illustrating extreme and outrageous conduct by Guidant, demonstrating that his alleged emotional distress is severe, or linking his alleged emotional distress to Guidant's conduct, his claim cannot possibly succeed and should be dismissed as a matter of law.

1. Dr. Clasby is unable to prove Guidant's conduct is negligent, much less extreme and outrageous.

As shown above, Dr. Clasby cannot prove that Guidant was negligent. Lacking proof of at least negligence, Dr. Clasby is clearly unable to meet the higher standard necessary for an IIED claim – "extreme and outrageous conduct."[31] "'Outrageous' conduct is that which is so extreme that it goes beyond all possible bounds of decency." *Williams v. Asplundh Tree Expert Co.*, 2006 U.S. Dist. LEXIS 52197, at *47 (M.D. Fla. July 27, 2006). "The determination of whether conduct is outrageous is a

[31] "Gross negligence…certainly cannot meet the standard to establish the tort of outrageous and reckless conduct." *Williams v. City of Minneola*, 619 So. 2d 983, 987 n.2 (Fla. Dist. Ct. App. 1993).

question of law for this Court to determine." *Tucci v. Smoothie King Franchises, Inc.*, 215 F. Supp. 2d 1295, 1303 (D. Fla. 2002).

Here, Dr. Clasby's device has never malfunctioned. At each of his three-month checkups, the device was shown to be working properly. *See supra* Part II at 30.[32] Further, his device has not been recalled by the FDA. Therefore, Dr. Clasby is unable to prove that Guidant was negligent in its conduct relating to his device. As Dr. Clasby cannot satisfy the lower standard of negligence, he clearly cannot illustrate that Guidant's conduct is "so extreme that it goes beyond all possible bounds of decency." *Williams*, 2006 U.S. Dist. LEXIS 52197, at *47. Therefore, this cause of action should be dismissed as a matter of law.

2. Dr. Clasby cannot establish that he suffered severe emotional distress.

Dr. Clasby's IIED claim also fails because he cannot prove he suffered from "severe" emotional distress. In fact, given his testimony, it is impossible for him to meet this burden. Therefore, this cause of action should be dismissed as a matter of law.

Florida defines "severe" as "of such intensity or duration that no ordinary person should be expected to endure it." *Standard Jury Instructions*, Civil Cases No. 94-1, 645 So.2d 999, 1000 (Fla. 1994). Dr. Clasby specifically testifies that he "was able to control this anxiety to a certain degree…" *See supra* Part II at 35. Further, as to the

[32] His medical records indicate that therapy was given at one point due to a fast ventricular response. *See supra* Part II at 30. However, he was unable to testify that any physician stated that his device malfunctioned.

duration, he stated that he suffered only "[i]ntermittently. It was not, you know, every day…" *Id.* He specifically stated:

> I had not become suicidal, I had not become so I couldn't get out of bed in the morning. I was not in that kind of condition as far as depression was concerned. But I was depressed to the point where a little bit of joy had gone out of life…

Id. at 35-36. As the intensity of his anxiety was such that he could control it, and the duration such that he described it as intermittent, his condition falls short of Florida's definition of "severe."

Further, were his condition such that "no ordinary person should be expected to endure it," it seems unlikely that he would have sought legal advice before seeking medical advice,[33] waited approximately 11 months after learning of the advisory before having his device replaced,[34] or been able to continue his regular schedule – playing tennis, teaching and vacationing.

Additionally, were his anxiety and depression severe enough to satisfy this definition, it seems likely that he would have discussed such with either his psychologist or psychiatrist at one of his regular appointments. However, he waited 10 visits after he learned of the advisories in May, 2005, before discussing such with his psychologist and 14 visits after that before discussing it again. *See supra* Part II at 37. Similarly, he met with his psychiatrist in June, July, August, September, October, January and March before finally discussing such with him at their April, 2006 session. *See id.* Further, he did not even discuss this issue with his cardiologist for nearly six months.

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[33] *See supra* Part II at 36.

[34] Dr. Clasby had his device explanted on May 4, 2006. *See supra* Part II at 27.

Given the facts recited above, Dr. Clasby's alleged emotional distress could not possibly have been "of such intensity or duration that no ordinary person should be expected to endure it." As Dr. Clasby can produce no evidence to the contrary, this cause of action should be dismissed as a matter of law.

3.

[35] *See supra* Part II at 35-38.

XV. CONCLUSION

For the reasons set forth above, this Court should grant Defendants' summary judgment motions and dismiss all Dr. Clasby's claims with prejudice.

[36] *See supra* Part II at 35.

Respectfully submitted,

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