UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Guidant Corp. Implantable Defibrillator Product Liability Litigation	Multidistrict Litigation No. 05-1708 (DWF/AJB)
HOLLY GRANT; NATHAN STEIN; by and through his surviving spouse and, Executrix, ESTHER STEIN; DERYL FEIMESTER; and BILLY SMITH, by and through his surviving spouse, wrongful death trustee and estate administrator, DOROTHY SMITH, Plaintiffs -v- GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC. and BOSTON SCIENTIFIC CORPORATION, Defendants.	Civil Case No. 07-1252 (DWF/AJB) **First Amended Complaint and Jury Demand**

Plaintiffs (hereafter "Plaintiffs"), by undersigned counsel, against Defendants Guidant Corporation, Guidant Sales Corporation, Cardiac Pacemakers, Inc. and Boston Scientific Corporation (hereafter "Guidant"), in this Complaint and Jury Trial Demand, make the following allegations based upon information and belief, as well as upon their attorneys' investigative efforts, as to Guidant's actions and misconduct, and allege as follows:

INTRODUCTION

1.

This suit involves the same parties Defendant and the same generic factual and legal issues as those contained in the proceedings entitled: "In Re: Guidant Corp. Implantable Defibrillators Products Liability Litigation", MDL No. 05-1708, USDC, Minnesota, Third Division, Honorable Donovan W. Frank. Judge Frank entered Pretrial Order No. 10 in said MDL permitting attorneys, who are not admitted to regular practice before this Court, to file cases related to the aforementioned litigation directly into this Court without the necessity of associating local counsel admitted before this Court. The requisite "List of United States Federal Courts to which Counsel for Plaintiff is Admitted" is attached hereto.

2.

On January 30, 2007, Judge Frank entered Pretrial Order 27 that allowed multiple Plaintiffs to file their actions as a single complaint.

3.

At all times material hereto, Guidant designed, manufactured, tested, marketed, distributed, promoted and/or sold Implantable Cardioverter Defibrillators ("ICDs"), Implantable Cardiac Resynchronization Therapy Devices ("CRT-D") and pacemakers (collectively "ICDs") including the model implanted in Plaintiffs (hereinafter referred to as "Device" or "Guidant's Defective Device").

4.

Plaintiffs are all residents of the state of North Carolina. Each one has previously had one of Guidant's Defective Devices implanted in his/her chest. Each one of these Devices was subject to a recall. As a result of the device being defective and/or the recall, each Plaintiff, as a direct and proximate result, suffered damages. Plaintiffs incorporate by reference the Master

Complaint in MDL No. 05-1708, its causes of action, allegations and damages asserted.

5.

Guidant's Defective Device is an implantable defibrillator which is designed to detect and treat abnormal heart rhythms (tachycardia) that could result in sudden cardiac death. An implantable defibrillator is designed to be inserted under the skin with wires or "leads" placed into the heart to shock the heart back into a normal rhythm when it starts beating irregularly.

6.

On or about June 23, 2005, Guidant issued a public notice that it was initiating a recall of Guidant's Defective Device which said recall is formally known under the U.S. Food and Drug Administration Recall. This includes the Device implanted in Plaintiffs' chests.

7.

For a period of over three years, Guidant concealed from doctors and defibrillator recipients that certain of its defibrillators, currently implanted in an estimated 24,000 people, contained a flaw that caused at least 26 malfunctions and the death of one defibrillator recipient. Additionally, Guidant changed its manufacturing processes twice in 2004 (April and November) to address this defect but concealed these facts from doctors and defibrillator recipients and continued to sell the defective defibrillators out of existing inventory.

8.

Though Guidant knew, or should have known, about the defective and life-threatening nature of its Device, it was not until on or about June 17, 2005, through September 22, 2005, that Guidant advised doctors about safety problems with some of its defibrillator models, including its Ventak Prizm 2 DR (Model 1861), Contak Renewal (Model H135), Contak Renewal 2 (Model H155), Ventak Prizm AVT (Model 1900), Vitality AVT, and Renewal 3 and 4 AVT, as

well as Contak Renewal 3 HE (Model H179), Contak Renewal 3 (Model H175), Pulsar and Pulsar Max (Model 1270), Insignia I Ultra DR (Model 1290) and Insignia I Plus SR (Model 1194), with the defects involving a series of different problems, each detailed in one of numerous FDA Recall Notices.

9.

On or about June 24, 2005, Guidant advised doctors about safety problems with its CRT-D devices named Contak Renewal 3 and 4, Renewal 3 and 4 AVT, Renewal RF, and Models H179, H175 and implantable cardioverter defibrillators ("ICDs"), and did likewise in September 2005 for Models 1270, 1290 and 1194.

10.

At the time Guidant's Defective Device was implanted into Plaintiffs, Guidant knew, or should have known, about the defective and life-threatening nature of its product and should have advised doctors about safety problems with its Device, but failed to do so.

11.

Guidant placed its products, including Plaintiffs' Device, into the stream of worldwide commerce and interstate commerce in the United States. Guidant did this without adequately testing the Device and with no warning that the Device was defective, inherently dangerous and unfit for its intended use as described herein.

JURISDICTION AND VENUE

12.

Defendant, Cardiac Pacemakers, Inc., is a wholly owned subsidiary of Guidant Corporation existing under the laws of Indiana with its principal place of business located at 4100 Hamline Avenue North, St. Paul, Minnesota. CPI developed Guidant's ICDs and

pacemakers and was merged into Guidant in or about September 1994.

13.

Defendant, Guidant Sales Corporation, is a wholly owned subsidiary of Guidant Corporation existing under the laws of Indiana with its principal place of business located at 111 Monument Circle, 29th Floor, Indianapolis, Indiana. Guidant and Guidant Sales marketed the Device under the trade name Contak Renewal. Guidant sells its ICDs, CRT-Ds and pacemakers through Guidant Sales.

14.

Plaintiffs are residents of North Carolina.

15.

Defendant, Boston Scientific Corporation, is a corporation existing under the laws of Massachusetts with its principal place of business located at One Boston Scientific Place, Natick, Massachusetts.

16.

Guidant Corporation is a wholly owned subsidiary of Boston Scientific Corporation, and Boston Scientific is responsible for all acts, omissions, misrepresentations, failure to warn, failure to test, defective products and/or torts of Guidant. Additionally, in April 2006, Guidant's shareholders approved its acquisition by Defendant, Boston Scientific. On April 21, 2006, Boston Scientific's acquisition of Guidant was completed. Through the acquisition, Boston Scientific assumed all the liabilities of Guidant in connection with this litigation and will henceforth be liable for the wrongdoing of Guidant as it existed prior to the close of that acquisition.

17.

This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because Plaintiffs allege that the amount in controversy exceeds seventy-five thousand dollars ($75,000), exclusive of interest and costs.

18.

Guidant is incorporated and has its principal places of business in states other than the state where Plaintiffs reside.

19.

Venue in this Court is proper pursuant to 28 U.S.C. §1391 in that a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, and Guidant is subject to personal jurisdiction in this District and as the result of the Order of Judge Frank.

BACKGROUND FACTS

20.

In January 2002, Guidant's Defective Device was surgically installed inside Plaintiffs' bodies and was designed to shock or pace the heart into normal rhythm in the event Plaintiffs suffered a rapid, life-threatening heart rhythm disturbance. These heart rhythm disturbances can lead to sudden cardiac arrest. The Device provides electrical pulses to the heart in the event of heart failure symptoms.

21.

In June 2005, Guidant disclosed to physicians and to the Food and Drug Administration the existence of, but not the magnitude of, the said defective aspects of the Device, a condition of which they were aware for a long period of time.

22.

At all times relevant to this action, Guidant knew, and/or had reason to know, that the Devices were not safe for the patients for whom they were prescribed and implanted. This includes the Device implanted in Plaintiffs.

23.

As a result of the defective design and manufacture, Guidant's Device can cause serious physical trauma, injury and/or death. Guidant knew, or had reason to know, of this tendency and the resulting risk of injury and death preventing the Plaintiffs and their health care providers from making informed choices about the implantation of the Device.

24.

Cardiovascular disease is the leading cause of death for both men and women in the United States and claims more lives each year than the next five leading causes of death combined. To treat cardiovascular disease, Guidant designs, develops, manufactures, distributes and markets products that focus on the treatment of cardiac arrhythmia, heart failure and coronary and peripheral disease. Guidant also designed, manufactured and supplied implantable defibrillators which include the Ventak Prizm AVT Model 1900, Ventak Prizm VR Model 1850, Ventak Prizm DR Model 1851, Ventak Prizm VR HE Model 1852, Ventak Prizm DR HE Model 1853, Ventak Prizm VR HE Model 1857 and Ventak Prizm DR HE Model 1858. Ventak Prizm defibrillators accounted for 47 percent of Guidant's 2004 worldwide sales ($1.7635 billion). Guidant also manufactures models numbered A155, A135, H179, H175, 1270, 1290 and 1194.

25.

The implantable defibrillators ("ICDs") designed, manufactured and distributed into the stream of commerce by Guidant consist of three components: (1) a small rectangular generator,

approximately two inches wide, which is implanted under the skin just below the collarbone; (2) insulated wires, or leads, which are attached to the generator and threaded through a vein to the heart to carry the electric current from the generator; and (3) two electrodes, located at the tip of each lead, which deliver an electric shock to the heart.

26.

The purpose of the ICD is to correct abnormal heart rhythm. The ICD can generate a series of precisely timed, low-intensity, electrical pulses to reset the heart to normal rhythm when the heart beats dangerously fast (tachycardia), or the ICD can deliver sudden shocks to the heart to stop potentially fatal heart quivering (ventricular fibrillation). In addition, the ICD may be programmed as a pacemaker to send small electric signals if the heart beats too slowly (bradycardia).

27.

Implantable CRT-D devices are medical devices that treat heart failure by helping the lower chamber (ventricles) pump synchronously with the upper chambers (atria) while preventing the heart from beating too slowly (bradycardia) and shocking or "over-drive pacing" of heartbeat rhythms that are too fast (a process by which the CRT-D is paced briefly at a rhythm faster than the desired rhythm in order to recapture control of the heartbeat).

28.

All ICDs function as both pacemakers and defibrillators. The ICD can detect and correct both fast and slow heart rates. The ICD corrects the slow rates and can "over-drive pace" rapid rates, and it also can administer shocks to treat ventricular tachycardia and ventricular fibrillation.

29.

ICDs are used in individuals who have arrhythmias or irregular heartbeats that are considered life-threatening. These can include individuals with ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), ventricular tachycardia (excessively rapid heartbeat) that is poorly controlled by medication or significant thickening of the heart muscle resulting in arrhythmia. Such conditions can result in the loss of consciousness or death unless the affected individual receives therapy from an appropriate device to put the heart back into a normal cardiac rhythm. Pacemakers are used in individuals who have bradycardia that is uncontrolled by medicine alone.

30.

If an implanted ICD operates properly, it can save an individual's life. If it fails to operate properly, the individual could die within minutes.

31.

Since 1958, pacemakers have been sold for implantation in individuals who have had certain spontaneous and/or inducible life-threatening arrhythmias, bradycardia, heart block and congestive heart failure and those who are at high risk of developing bradycardia, heart block or arrhythmias. Pacemakers are used to manage disorders that disrupt the heart's normal electrical conduction system.

32.

Pacemakers are designed to be implanted under the skin of the chest wall. The device's power source (pulse generator) is implanted in a pouch formed under the collarbone, just under the skin, usually on the upper left chest. Wires, called leads, are inserted through a blood vessel and attached directly into the heart. These wires, which are connected to the pacemaker or pulse

generator, are capable of both sensing a problematic heart rate and stimulating a more appropriate heart rate.

33.

Some individuals are very dependent on pacemakers to maintain an adequate heart rate, and therefore, cardiac output. For these individuals, failure of the cardiac pacemaker to provide pacing can cause sudden faintness, or loss of consciousness, and can result in death.

34.

At all times relevant, Guidant misrepresented the safety of its ICDs and pacemakers and negligently manufactured, marketed, advertised, promoted, sold and distributed those ICDs and pacemakers as safe devices to be used for treatment of individuals with prior myocardial infarction arrhythmias and individuals who are at high risk for developing such arrhythmias.

35.

Implanted defibrillators have been one of the most popular and fastest growing types of medical devices. In 2005 alone, over 200,000 patients received such defibrillators. In 2001, Vice President Dick Cheney received a defibrillator manufactured by Guidant's competitor. Implanted defibrillators have been Guidant's fastest growing products for at least the last three years. Between 2002 and 2004, Guidant's revenues from these sales skyrocketed by more than 80 percent, from $499.2 million to $1.786 billion.

36.

In its public disclosures, Guidant has represented that its ICDs are essential for saving lives. For example, in its 2002 Annual Report, Guidant describes them as "Lifesaving Therapy for Sudden Cardiac Death (SCD)." Further touting the technology, Guidant states that "About the size of three stacked silver dollars, Guidant's ICD's have 20 million transistors and more

computing power than the original Apollo spacecraft." Similarly in its 2003 Annual Report, Guidant characterized itself as a "pioneer in the development of implantable Defibrillator technologies..." and that "[s]uperior engineering spurred the launch of a new implantable Defibrillator in every quarter of the past year."

37.

Guidant described its manufacturing facilities as "Exceptional." In Guidant's 2003 Annual Report, it states "Experienced technicians—supported by continued investment in state of the art automated manufacturing equipment and expansion—have streamlined manufacturing processes to reduce cost, improve quality, increase out-put and shorten the product development and manufacturing cycle, speeding the delivery of lifesaving therapies to physicians and patients worldwide." Further expounding on "quality," Guidant emphasized in its 2003 Annual Report that it has an "unrelenting focus on quality in everything" it does. Indeed, Guidant proclaims, "Quality is essential; lives depend on us. We pledge together to build the most reliable products and services. We work every day to drive Quality into everything that is Guidant."

38.

Guidant also publicly claimed to be an open provider of information to patients and physicians. In its 2003 Annual Report, it stated that "information for patients, physicians, and the public is available around the clock through Guidant's dedicated customer and technical service representatives, as well as its comprehensive web site (www.guidant.com)."

39.

The FDA approved various implantable defibrillators designed, manufactured and supplied by Guidant, including Plaintiffs' Device.

40.

In marked contrast to these assurances, at some point prior to April 2002, Guidant learned that certain Guidant devices were short-circuiting.

41.

Not until June 17, 2005, did Guidant initiate a so-called "Worldwide Physician Communication" regarding important safety information and corrective action about the Guidant devices Ventak Prizm 2 DR (Model 1861), Contak Renewal (Model H135), Contak Renewal 2 (Model H155), Ventak Prizm AVT (Model 1900), Vitality AVT and Renewal 3 and 4 AVT.

42.

On or about June 24, 2005, Guidant finally began advising doctors about safety problems with additional defibrillator models, including the Contak Renewal 3 and 4, Renewal 3 and 4 AVT and Renewal RF ICD.

43.

Guidant knew, or should have known, that Plaintiffs' Device was defective prior to its implantation on or about January 31, 2002. Plaintiffs had no idea that their defibrillator possessed any defect—much less the serious life-threatening defect described above—until learning of it as a result of Guidant informing the public as described herein regarding the defective nature of its Device. Moreover, Plaintiffs and Plaintiffs' physicians had no way of knowing of the defect.

44.

Guidant is estopped from relying on any statutes of limitation by virtue of its acts of fraudulent concealment, which include Guidant's intentional misleading representations to the FDA, Plaintiffs, the public and the medical community and intentional cover-up of reports of death and injury from use of the Guidant defibrillators. Guidant's acts of fraudulent concealment include, but are not limited to, failing to disclose and failing to warn that Guidant defibrillators

were unsafe, defective and dangerous. Through such acts or omissions, Guidant was able to conceal from the public the truth concerning the Guidant defibrillators.

45.

From implantation until a date after the FDA recall, Plaintiffs had no knowledge that the Device was defective, unsafe and dangerous because Plaintiffs had no reasonable way to discover this defect beforehand.

46.

Information concerning the undisclosed, inherently dangerous characteristics of the Device was concealed from Plaintiffs. Guidant was under a duty to disclose that Plaintiffs' Device was defective, unsafe and inherently dangerous for its intended use, and failed to do so.

VIOLATIONS OF FEDERAL LAW AND REGULATIONS

47.

As part of the conditions of approval for the Devices, Guidant must ensure that no changes be made to the Device that would affect its safety or effectiveness without submission of a Pre-Market Approval ("PMA") supplement for review and approval, and that a PMA supplement must be submitted when a device failure necessitates a labeling, manufacturing or device modification. Violation of such conditions voids their approval.

48.

The removal of devices from the market and other corrective actions taken by Guidant have been classified as Class I or Class II recalls under federal regulations – the highest levels of such recalls.

49.

Under federal regulation "[r]ecall means a firm's removal or correction of a marketed

product that the Food and Drug Administration ("FDA") considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. § 7.3(g) (2006).

50.

The classification of a recall as Class I, II or III "indicate[s] the relative degree of health hazard presented by the product being recalled." Id. § 7.3(m). "Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." Id. § 7.3(m)(1). "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." Id. § 7.3(m)(2).

51.

A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requlations. See 21 U.S.C. § 351(2006). The defective Device is adulterated.

52.

A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352. The defective Device is misbranded.

53.

Manufacturers are required to comply with the FDA regulation of medical devices,

including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. § 360i. This Guidant has failed to do.

54.

Adverse events associated with a medical device must be reported to the FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing or other evaluation of the device and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event and must evaluate the cause of the adverse event. See 21 C.F.R. § 803.50. This Guidant has failed to do.

55.

Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event and whether the remedial action was reported to the FDA as a removal or correction of the device. See 21 C.F.R. § 803.52.

This Guidant has failed to do.

56.

Manufacturers must report to the FDA in five business days after becoming aware of any reportable medical device reporting ("MDR"). MDR events require the manufacturer to conduct a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. See 21 C.F.R. § 803.53. This Guidant has failed to do.

57.

Device manufacturers must report promptly to the FDA any device corrections and removals and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. See 21 C.F.R. § 806.10. This Guidant has failed to do.

58.

Manufacturers must comply with quality system regulations that require manufacturers to meet design-control requirements including, but not limited to, conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and

maintain procedures for implementing corrective actions and preventive actions and investigate the cause of nonconforming product and take corrective action to prevent recurrence. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See generally 21 C.F.R. § 820. This Guidant has failed to do.

59.

A manufacturer must report to the FDA, through a PMA supplement, any new indications for use of a device, labeling changes or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. A manufacturer may implement changes to a device that enhance the safety of the device prior to obtaining FDA approval if the manufacturer submits a special report entitled: "Special PMA Supplement - Changes Being Effected" and provides a full explanation of any labeling changes or changes in quality control or manufacturing process that add a new specification of test method or otherwise provide additional assurance of purity, strength or reliability of the device. This Guidant has failed to do.

60.

Federal regulations require that "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." Conditions of Approval at 1, attached to FDA Approval Letter from Daniel G. Schultz, Deputy Director for Clinical Policy, FDA, to Kaye Anderson, Senior U.S. Regulatory Affairs Associate, Guidant Corporation (July 18, 2002). See 21 C.F.R. § 814.39. This Guidant has failed to do.

61.

Guidant's failure to meet federal regulations applicable to medical devices and Guidant's other acts and omissions as described herein directly and proximately caused the Device to be in violation of federal law and unfit for sale and proximately caused harm and injury to Plaintiffs. Plaintiffs' state law claims are based on parallel state law provisions that do not conflict with federal law.

GUIDANT'S FAILURE TO MEET BASIC MANUFACTURING AND REGULATORY STANDARDS

62.

The FDA conducted an inspection of Guidant's facilities during the time period of August 22, 2005, to September 1, 2005. At the conclusion of the inspection, the FDA issued a 483 Inspection Report ("FDA 483") in which it detailed violations of federal regulations by Guidant. See FDA 483 Inspection Report (Sept. 1, 2005) ("Sept. 1 FDA 483").

63.

The stated purpose of the FDA 483 is "to assist the firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration." FDA 483 Inspection Report at 2 (Feb. 8, 2006) ("Feb. 8 FDA 483").

64.

Included in the Sept. 1, 2005, FDA 483 for Guidant were the following 15 observations of violations noted by FDA:

(a) procedures for conducting quality audits were incomplete;

(b) "[n]ot all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified;"

(c) procedures were not completed and implemented for monitoring and controlling of process parameters for validated processes;

(d) "[a] process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures;"

(e) "[p]rocedures to ensure that equipment is routinely maintained were not established;"

(f) "[d]uring production, component and device characteristics are not fully monitored and controlled;"

(g) "[p]rocedures for changes to methods were not complete;"

(h) management with executive responsibility has not ensured that an adequate and effective quality system has been implemented and maintained at all levels of the organization;

(i) "[s]oftware used as part of production and the quality system has not been fully validated for its intended use according to an established protocol," and electronic records which are used do not have requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records;

(j) "appropriate sources of quality data are not adequately analyzed to identify existing and potential causes of nonconforming product and other quality problems;"

(k) processes have not been approved, and electronic records do not meet employee

accountability/responsibility policy and signature manifestation requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records;

(l) "[t]he document control procedures do not designate an individual to review documents for adequacy and approve them prior to issuance;"

(m) "[r]ework and reevaluation activities have not been documented in the device history records;"

(n) "[d]ocument control procedures are not complete;" and

(o) the device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record. Feb. 8 FDA 483 at 1-6.

65.

The findings of the FDA inspection of August and September 2005 confirm that Guidant was violating federal and state law in manufacturing the Devices and that the same are defective.

66.

From December 2005 to February 2006, the FDA again inspected Guidant's manufacturing facilities and found further egregious violations of basic manufacturing standards fundamental to federal and state law. See Feb. 8 FDA 483. Specifically, the FDA found that Guidant had failed to disclose certain AVT device defects that it had known about since May 2002 and had attempted to correct through revised software implemented by May 2004. See id.

67.

The FDA's inspections led to recalls of at least some of the Guidant Devices at issue in this litigation and specifically criticized Guidant's manufacturing and disclosure processes

stating that Guidant had failed to establish adequate procedures in violation of federal regulations.

68.

Moreover, with respect to each of the Guidant Devices at issue in this litigation, Guidant failed to comply with FDA regulations and the Conditions of Approval relating to relevant PMA and PMA Supplements.

69.

The claims alleged herein set forth sufficient facts to establish manufacturing defects with respect to the Guidant Devices. Additionally, the Guidant Devices as listed in the Complaint were unreasonably dangerous and defective because:

a. The manufacturing processes for the defibrillators and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the Devices;

b. The failure of the manufacturing processes for the defibrillators and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the Devices resulted in unreasonably dangerous manufacturing defects; and

c. Guidant failed to warn of the unreasonable risks created by these manufacturing defects.

70.

No claims alleged herein are preempted under any provisions of the Medical Device Act or FDA regulations.

71.

Guidant's failure to meet federal regulations applicable to medical devices and Guidant's other acts and omissions as described herein directly and proximately caused the Devices to be in violation of federal and state law, and proximately caused harm and injury to Plaintiffs.

72.

At all times relevant to this action, Guidant knew, and had reason to know, that the Device was not safe for the individuals for whom they were prescribed and implanted because the Device is subject to being short circuited and otherwise malfunction and, therefore, failed to operate in a safe and continuous manner causing serious medical problems and, in some individuals, catastrophic injuries and deaths.

73.

As a result of defects in both the design and the manufacture of the Device, Guidant knew, and had reason to know, that the Device would fail to function properly and have a significantly decreased life expectancy which was concealed from the FDA, the medical community and the individuals in whom the Devices were implanted.

74.

Further, Guidant knew, and had reason to know, that the life expectancy of the Device was significantly shorter than that which Guidant represented to the FDA, the medical community and those in whom the Device was implanted. Guidant affirmatively concealed and suppressed the true information about the life expectancy and reliability of the Devices.

GENERAL ALLEGATIONS

CAUSES OF ACTION AND CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION AND CLAIM FOR RELIEF

NEGLIGENCE

75. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein.

76. Guidant was careless in designing, testing, manufacturing, marketing, warning, distributing and selling the defibrillators with defects.

77. Guidant had knowledge of the defects, yet Guidant failed in its duties to recall these devices or to adequately alert or warn physicians and users of the defects and the need to either remove or carefully monitor the devices. Further, Plaintiffs were foreseeable victims of these defects.

78. Guidant owed Plaintiffs a duty to exercise reasonable care in the manufacture, design, warning, testing, inspection, marketing and distribution of these devices.

79. Guidant breached its duty of care to Plaintiffs.

80. This breach of duty was negligent.

81. As a proximate result of the aforementioned negligence of Guidant, Plaintiffs suffered damages.

82. The conduct of Guidant was so willful, wanton, malicious, reckless and in such disregard for the consequences as to reveal a conscious indifference to the clear risk of death or serious bodily injury and merits the imposition of punitive damages.

SECOND CAUSE OF ACTION AND CLAIM FOR RELIEF

NEGLIGENCE *PER SE*

83. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein.

84. Guidant was careless in designing, testing, inspecting, manufacturing, marketing, warning, distributing and selling the defibrillators with defects.

85. Plaintiffs were a foreseeable user, and Guidant owed a number of duties to Plaintiffs based on federal regulations, some of which are set forth above. Plaintiffs were in the

class of individuals these regulations were designed to protect, and the type of harm suffered by Plaintiffs is the type of harm the regulations were designed to protect against.

86. Guidant breached its duty of care to Plaintiffs by failing to comply with these federal regulations.

87. This breach of duty was negligent.

88. As a proximate result of the aforementioned negligence of Guidant, Plaintiffs suffered damages, economic and non-economic.

89. The conduct of Guidant was so willful, wanton, malicious, reckless and in such disregard for the consequences as to reveal a conscious indifference to the clear risk of death or serious bodily injury and merits the imposition of punitive damages.

THIRD CAUSE OF ACTION AND CLAIM FOR RELIEF

PRODUCTS LIABILITY (DESIGN DEFECT)

90. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein.

91. Guidant designed, marketed, distributed and sold the subject Devices in a condition which rendered them unreasonably dangerous due to their propensity to fail without warning while safer alternative designs could have reasonably been used.

92. The aforementioned defects existed when Guidant placed the subject defibrillators into the stream of commerce.

93. Guidant's product was unreasonably dangerous due to a defect in the design.

94. Plaintiffs' injuries were a direct and proximate result of one or more of the defibrillators' defects.

95. By engaging in the aforesaid conduct, Guidant is strictly liable to Plaintiffs.

FOURTH CAUSE OF ACTION AND CLAIM FOR RELIEF

PRODUCTS LIABILITY (MANUFACTURING DEFECT)

96. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein.

97. Guidant manufactured, marketed, distributed, designed and sold the subject Devices in a condition which rendered them unreasonably dangerous due to their propensity to fail without warning.

98. The aforementioned defects existed when Guidant placed the subject defibrillators into the stream of commerce.

99. Guidant's product was unreasonably dangerous due to a defect in the manufacturing, testing and/or inspection of the defibrillators.

100. Plaintiffs' injuries were a proximate result of one or more of the defibrillators' defects.

101. By engaging in the aforesaid conduct, Guidant is strictly liable to Plaintiffs.

FIFTH CAUSE OF ACTION AND CLAIM FOR RELIEF

PRODUCTS LIABILITY (FAILURE TO WARN)

102. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein.

103. The Guidant Device in question was defective due to lack of warning or instruction, because, after Guidant knew, or should have known, of the risk of serious bodily harm and death from the use of the defibrillator, it failed to provide an adequate warning of the product to consumers, including Plaintiffs and their physicians, knowing the product could cause serious injury and death.

104. The failure to warn made the defibrillators unreasonably dangerous.

105. By engaging in the aforesaid conduct, Guidant is strictly liable to Plaintiffs.

SIXTH CAUSE OF ACTION AND CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY

106. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein.

107. Plaintiffs purchased the defibrillator from Guidant.

108. Guidant impliedly warranted that the defibrillator was of merchantable quality and safe and fit for the use for which it was intended.

109. Plaintiffs relied on the skill and judgment and implied warranty of Guidant that the defibrillator was of merchantable quality and safe and fit for the use for which it was intended.

110. The defibrillator was not of merchantable quality and not safe nor fit for the use for which it was intended in that it had dangerous propensities when put to its intended use and would cause severe injuries to the users, including Plaintiffs.

111. As a result of the breach of implied warranty by Guidant, Plaintiffs suffered, and will continue to suffer, injuries, damages and losses.

SEVENTH CAUSE OF ACTION AND CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

112. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein..

113. Plaintiffs purchased a defibrillator from Guidant.

114. Guidant expressly warranted that the defibrillator was safe, effective, fit and proper for the use for which it was intended.

115. Plaintiffs relied on the skill and judgment and express warranties of Guidant that the defibrillator was of safe, effective, fit and proper for the use for which it was intended.

116. The express warranties were untrue, false and inaccurate in that the defibrillator was not safe, effective, fit nor proper for the use for which it was intended.

117. As a result of the breach of express warranty by Guidant, Plaintiffs suffered, and will continue to suffer, injuries, damages and losses.

EIGHTH CAUSE OF ACTION AND CLAIM FOR RELIEF

MISREPRESENTATION

118. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein.

119. Guidant misrepresented the safety of its defibrillators and fraudulently, intentionally, recklessly or negligently concealed material adverse information regarding the safety of the defibrillators when it had a duty to disclose such information to the FDA and to the consuming public, including Plaintiffs.

120. Guidant made false or misleading statements and omissions about the safety of the defibrillators in its labeling, advertising, promotional materials and other marketing materials.

121. Guidant further made misrepresentations in its February 2005 letter by downplaying the risks associated with continuing to use these devices and downplaying the need to have them removed. In addition, Guidant failed to offer to pay for the costs of removing and replacing the defective defibrillators.

122. Guidant made these misrepresentations and actively concealed adverse information at a time when it knew, or should have known, because it was in a superior position to know, that the Devices had defects, dangers and characteristics that were other than what Guidant had represented to the FDA, the medical profession and the public, including the Plaintiffs. Alternatively, Guidant made statements with reckless disregard for their truth or falsity.

123. The facts misrepresented or not fully disclosed were material.

124. Guidant made these misrepresentations and actively concealed this information

with the intention that Plaintiffs, their physicians and the consuming public would rely on the misrepresentations or omissions in selecting the defibrillators for purchase and use.

125. Guidant should have reasonably foreseen that Plaintiffs and persons similarly situated were likely to rely on the facts misrepresented or not disclosed.

126. Plaintiffs and installing physicians reasonably relied on and were induced by Guidant's misrepresentations and/or active concealment in selecting and using the devices.

127. Plaintiffs sustained injuries and losses as a direct and proximate result of Guidant's misrepresentations or active concealment of information.

128. The conduct of Guidant was so willful, wanton, malicious, reckless and in such disregard for the consequences as to reveal a conscious indifference to the clear risk of death or serious bodily injury and merits the imposition of punitive damages.

NINTH CAUSE OF ACTION AND CLAIM FOR RELIEF

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS/FEAR OF MALFUNCTION

129. Plaintiffs repeat and reallege the foregoing paragraphs as if fully stated herein.

130. Plaintiffs were in the zone of danger created by the defect in Guidant's Device and suffered severe emotional distress from the fear that the defibrillator malfunction causing them physical harm or suffering.

131. The severe emotional distress was the direct and proximate result of the actions of Guidant described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter judgment against Guidant and in favor of Plaintiffs and award the following relief:

a. Compensatory damages against Guidant including all economic and noneconomic losses, medical monitoring, pain, suffering, distress, impairment, survivorship losses and wrongful death losses;

b. Punitive damages against Guidant;

c. Pre-judgment and post-judgment interest on all damages;

d. Costs, including expert fees and attorneys' fees incurred in the prosecution of this action; and

e. Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury in this case.

Respectfully submitted,

Dated: Englewood, CO
March 16, 2007

BURG SIMPSON
ELDREDGE HERSH & JARDINE, P.C.

s/Seth A. Katz
Seth A. Katz
David P. Hersh
40 Inverness Drive East
Englewood, CO 80112
Tel: (303) 792-5595
Fax: (303) 708-0527

ATTORNEYS FOR PLAINTIFF

LIST OF UNITED STATES DISTRICT COURTS TO WHICH
COUNSEL FOR PLAINTIFF IS ADMITTED

Pursuant to Pretrial Order No. 10, MDL No. 05-1708 (DWF/AJB), Seth A. Katz is admitted to practice in the following United States District Courts:

U.S. District Court, Eastern District of New York
U.S. District Court, Southern District of New York
U.S. District Court, District of Colorado

I hereby certify that I am admitted to the preceding United States District Courts and that I have not been disbarred or suspended from practice before any of these Courts or any other United States District Courts.

Seth A. Katz