IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

In re: Guidant Defibrillators Products Liability Litigation	Court File No. 05-md-1708 (DWF/AJB)

This pleading applies to:

ALL ACTIONS

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' CLAIMS RELATED TO THE VENTAK PRIZM 2 DR MODEL 1861 BASED ON FEDERAL PREEMPTION

INTRODUCTION

Defendants are entitled to summary judgment. Defendants moved for summary judgment based upon a statement of just two material facts: (1) the PRIZM 2 was approved by the FDA pursuant to the PMA process; and (2) the FDA has never withdrawn, revoked, or suspended that PMA.[1] Defs. Mem. at 11. Plaintiffs do not and cannot dispute either of these facts.

[1] In contrast, Plaintiffs' 36-page so-called "Statement of Relevant Facts," is both incomplete and riddled with factual inaccuracies. It is also replete with mischaracterizations of actual events and unfounded, improper legal conclusions asserted by "experts." Furthermore, the narrative format in which it is proffered renders an effective response virtually impossible. Defendants therefore object to "Plaintiffs' Statement of Relevant Facts" in its entirety, and, for purposes of this motion, dispute each of the "facts" contained therein. This premature preview of Plaintiffs' entire case theory is entirely immaterial to the present legal motion. Defendants need only demonstrate the two facts above to prevail as a matter of law, and they have met that burden.

Under the controlling precedent of *Brooks v. Howmedica,* 273 F.3d 785 (8th Cir. 2001), *cert. denied,* 533 U.S. 1056, as well as the persuasive authority of six other federal Circuit Courts of Appeal, PMA approval is recognized as creating unique, device-specific federal requirements that give rise to federal preemption of state law claims under 21 U.S.C. §360k(a). *See id.* at 795, 798; *see also Reigel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 228 (6th Cir. 2000) ("it is the totality of the design, manufacturing processes, and labeling – when coupled with the prohibition against modifying them – that represents the specific federal requirement.").

In a desperate attempt to avoid the outcome required by controlling law, and relying on non-binding authorities, Plaintiffs urge this Court to adopt an outlier view of federal preemption that is not supported by §360k(a), Congressional intent, Eighth Circuit precedent, or common sense. In essence, Plaintiffs argue that any medical device recipient plaintiff who can suggest a way to second-guess the FDA's decision-making; or who can articulate any criticism of a manufacturer's post-approval conduct (regardless of whether any regulatory violation was ever recognized by the FDA), ought to be given a green light to unlimited litigation against that manufacturer. Under Plaintiffs' theory, FDA approval – even approval of Class III medical devices – would eventually come to serve only an "advisory" purpose, while state court juries, with their potentially conflicting verdicts, will become the ultimate arbiters of medical device safety and effectiveness. This result is plainly contrary to Congress' intent in enacting the MDA.

In light of the feeble legal authority available to support their response to this motion, Plaintiffs expend a great deal of effort trying to manufacture disputed issues of

fact. Their primary target is the validity of the PRIZM 2 PMA. They incorrectly argue both that the PRIZM 2 approval was a mistake made by a regulatory agency incapable of getting it right, and that a PMA supplement is less significant than an original. Alternatively, Plaintiffs mistakenly argue that after the PRIZM 2 PMA was issued, it was somehow invalidated (unbeknownst, incidentally, to either the FDA or Guidant) by Guidant's alleged violations of federal regulations. Even if these contentions could be proven by record evidence (and they cannot), under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), such facts could not serve as the basis for legal claims against Defendants. *Id.* at 348-52, n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.").

Invocation of federal preemption under §360k(a) will not, as Plaintiffs falsely suggest, grant Defendants "complete immunity" or "deprive consumers of a damage remedy." Defendants readily concede in their moving papers that an individual's claim based on a *true* manufacturing defect – meaning one where evidence will establish that a specific device failed to deliver therapy because it was not manufactured according to FDA-approved manufacturing specifications – is *not* preempted. Defs. Mem. at 31. Here, however, there are *no* such device-specific manufacturing defect claims currently before the Court. Plaintiffs' Master Complaint alleges only that *all* PRIZM 2's were "uniformly defective." *See* Master Compl. ¶ 90. Plaintiffs' claims therefore indisputably attack the *design* of the PRIZM 2, not a true manufacturing defect.

Giving juries the last word on whether a Class III medical device should have received or maintained regulatory approval would completely usurp the FDA's regulatory prerogative and run contrary to the intent behind the express preemption provision. *See Brooks*, 273 F.3d at 797 ("The arguments advanced by [plaintiff] ignore the need for national uniformity in product regulation, one of the *explicit goals* of the MDA") (emphasis added). By including an express preemption provision within the MDA, Congress definitively demonstrated its intent that medical device manufacturers not be subjected to state law requirements at odds with device-specific federal regulation. A perpetual threat that tort liability might attach to federally-approved device design features or labeling would stifle – not promote – development of innovative and potentially life-saving medical devices. Defendants' motion should be granted.

ARGUMENT

A. PMA Approval Creates Device-Specific Federal Requirements

Section 360k(a) provides for preemption of Plaintiffs' state law claims if just two criteria are satisfied, the first of which is a specific federal requirement (or requirements) applicable to the device under the FDCA. *Id.*; *see also* 21 CFR §808.1(d) (2006). As Defendants established in their moving papers, by virtue of the PMA approval of the PRIZM 2, a series of federal requirements was created. Among them was the requirement that the device be manufactured and labeled precisely in accordance with the FDA-approved specifications,[2] and that Guidant satisfy numerous regulatory obligations

[2] In the case of a PMA supplement, those specifications would include those of approved predecessor devices *as modified* by the supplement application.

as set forth in the accompanying conditions of approval. *See* Defs.' Mem. at 15-18. Thus, device-specific federal requirements arise not from the mere fact of a PMA approval, but from the necessary *application* of that approval in the production and marketing of the device.

1. The *Goodlin* opinion is neither binding nor persuasive authority.

Plaintiffs argue in response that because the FDA serves a "gatekeeping" function in its regulatory role of assessing safety and effectiveness, the PMA process cannot possibly impose the specific federal requirements contemplated by 21 U.S.C. §360k(a). Pls. Opp. at 44. In so doing, they rely almost exclusively on the (non-binding and aberrant) decision in *Goodlin*, 167 F.3d 1367 (11th Cir. 1999) to argue that no federal requirements are created by the PMA process because medical device manufacturers are "free to develop and submit any design they wish." Pls. Opp. at 46.

Plaintiffs' position ignores the current, and better-reasoned, legal landscape on this issue. *Goodlin* is the *only* federal circuit court case to date to deny that PMA approval can create federal device-specific requirements. The case is distinctly contrary to the Eighth Circuit's views, as clearly expressed in *Brooks.* In *Brooks*, the Eighth Circuit not only recognized that PMA approval *can* create specific federal requirements, but concluded in that case that it *had*. *Brooks*, 273 F.3d at 798 ("Through its approval of the

PMA application . . . and its continuing series of directives, the [FDA] impose[s] specific federal requirements on [the manufacturer].").[3]

In the seven years since the Eleventh Circuit decided *Goodlin*, no other federal circuit has adopted that court's reasoning. That case now stands completely alone – a minority of one – against a majority of *seven* federal circuit courts that have reached the opposite conclusion based on the plain language of the statute, its purpose and intent, and the policies behind it.[4] Indeed, since Defendants filed their motion, the Second Circuit has become the latest to join the "growing consensus" on the interpretation of §360k(a). *See Reigel v. Medtronic, Inc*., 451 F.3d 104, 105 (2d Cir. 2006) ("[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."). Plaintiffs' exclusive reliance on *Goodlin* only underscores how untenable their arguments are.

2. Plaintiffs' attempt to distinguish contrary authority, including *Brooks*, fails.

Plaintiffs barely bother to acknowledge the overwhelming persuasive authorities directly aligned against them on the issue of specific federal requirements, and offer no legitimate justification for this Court not to follow them. *See* Pls. Opp. at 48, n.31 (noting only factual differences in other circuit court decisions).

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[3] Plaintiffs do not dispute that this MDL transferee court "should apply the law of the circuit in which it is located." *In re Teporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996).

[4] *See* Defs. Mem. at 19 (cataloguing circuit court decisions). At least three states' high courts have also sided with the federal majority view. *Id.*

Plaintiffs' attempt to distinguish the Eighth Circuit's decision in *Brooks*, 273 F.3d 785, simply does not hold up. The sole issue on appeal in *Brooks* was preemption of failure-to-warn claims under §360k(a). The court found that the FDA's role in approving the design and content of the device labels at issue (including "review[ing] every word" on the labels and drafting language for the package insert) had created a federal requirement – namely, that the labeling must follow the PMA-approved specifications. *See id.* at 798.

Plaintiffs imprudently argue that this Court can ignore *Brooks.* They mistakenly claim that while in *Brooks*, the FDA was heavily-involved in the review of the proposed device labeling, this case is different because the FDA allegedly "did not specify any particular insulating material for the leads[5] on the Prizm2." Pls.' Opp. at 48; *see also id.* at 20, quoting Parisian Report at 9-10 (FDA "established no requirements, gave no approval, and set no conditions on the use of [polyimide] in the header of the Prizm2 [sic] device.").

Plaintiffs completely miss the mark. The controlling factor here, as in every case involving medical device preemption, is simply whether the FDA approved the *device itself*.[6] By law, PMA approval by the FDA signals a completed review and approval of

[5] In the context of an implantable cardioverter defibrillator like the PRIZM 2, "leads" are separate medical devices subject to independent FDA approval, and are not the subject of this litigation. Defendants presume that Plaintiffs actually intended here to refer to "feedthrough wires."

[6] Notably, Plaintiffs' overly-restrictive view of *Brooks* utterly fails to acknowledge the decision's obvious impact on their other claims. Many of Plaintiffs' claims (including those labeled "failure-to-warn" and several that are not) are fundamentally founded upon allegations that Guidant knew something more or different about the risks associated with the PRIZM 2 than

every aspect of the design and labeling of a medical device like the PRIZM 2. *See* Sept. 8, 2006 Suppl. Report of Robert L. Sheridan, Ex. A, at 6 ("When FDA approves a device, it approves all the components that make the device, regardless of the information about the specific components contained in the PMA."); *Kemp*, 231 F.3d at 228.

Plaintiffs' suggestion that the FDA could approve some, but not all, of a particular Class III medical device has no basis in law or fact, and defies even the FDA's own stated views:

> [I]t is the *whole* device as it is described in the application that must meet this [PMA] legal standard. The MDA does not include a provision allowing FDA to approve a PMA for one feature of a device described in the application. FDA would violate the law were it to approve a PMA for a device if only part of the device met the "reasonable assurance of safety and effectiveness" standard . . . . Thus, FDA can and does approve a PMA *only when the entire device that is the subject of the submission meets the correct PMA legal standard*. . . . When FDA sends a letter to an applicant telling them that their PMA is approved, the whole device, as it is described in that letter, is PMA-approved.

Murphree Statement of Interest, Ex. D to Defs' Mem, at p. 6 (emphasis added).

Although *Brooks* did not involve a device originally approved through the PMA process, the FDA classification of the *Brooks* device involved the same legal criteria to determine safety and effectiveness as the FDA evaluation of the PRIZM 2. *See e.g. Brooks*, 273 F.3d at 789 (describing post-MDA classification of device at issue as Class III). Plainly, because the FDA's review of the *Brooks* device gave rise to federal

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it communicated to the public. *See* Defs.' Mem. at 23-24. In light of *Brooks*, Plaintiffs cannot possibly dispute that the PMA process for Class III devices like the PRIZM 2 includes scrutiny and approval of all labeling and warnings as particular aspects of the device, thereby giving rise to federal requirements. *See* 21 U.S.C. §360e(c)(1)(B)-(C) (F); 21 U.S.C. §360e(d)(2)(A)-(D) (labeling found to be false or misleading during the PMA process shall result in denial of the PMA application.).

requirements (and, therefore, preemption), the same is true of the PRIZM 2 (and its predecessors). As in *Brooks*, the device at issue in these cases received approval pursuant to the rigorous PMA process. This Court should apply the binding precedent of the Eighth Circuit's decision in *Brooks* with respect to creation of device-specific federal requirements.[7]

3. The Court should give deference to the FDA's view regarding §360k(a).

The FDA believes that "the agency's approval of [a] device through the PMA process *does* impose specific requirements for the product, including requirements for its design, manufacturing, performance, labeling, and use," which invoke federal preemption of state tort claims. *See* Defs. Mem. at 17 (discussing FDA's *amicus* brief submitted in *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004)).

Plaintiffs argue – once again relying primarily on the outlier *Goodlin* case – that the FDA's views should be accorded no deference whatsoever. Their argument, however, is contrary to U.S. Supreme Court precedent. In *Lohr*, a majority of the Supreme Court deferred to the FDA's interpretation of the preemptive effect of certain

[7] Plaintiffs' repeated attempts to rely on *In re St. Jude Med.*, 2004 WL 45503 (D. Minn. Jan. 5, 2004) should be rejected, as that decision is contrary to the Eighth Circuit's controlling decision in *Brooks*. The *St. Jude* court's analysis paved the way for a lay person's challenge to the safety of a device approved by the FDA as safe and effective through the PMA process – precisely what federal preemption is intended to foreclose. In that respect, *St. Jude* court erroneously ignored the analytical framework of *Brooks* and the majority-view cases. *See Baker v. St. Jude Medical, S.C., Inc.*, 178 S.W.3d 127, 134 (Tex. App. 2005) (rejecting *In re St. Jude*'s approach and applying preemption to the same regulatory history). It also disregarded the FDA's own views on the rigors and preemptive impact of its regulatory process and the importance of its regulatory autonomy to the development of safe and effective medical devices. *See Horn amicus* brief, discussed at Defs. Mem. at 17 and available at 2004 WL 1143720 (May 14, 2004).

provisions of the MDA. Although not referring specifically to 21 U.S.C. §360k(a) at the time, the justices noted that:

> [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.

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).

The Third Circuit likewise properly followed the *Lohr* court's lead in deferring to the FDA on matters of medical device preemption:

> While we acknowledge that the FDA's interpretation of statutes that it has been charged by Congress with enforcing is not fully dispositive of the issues here, the Supreme Court has instructed us that the FDA's preemption determinations are significant and should inform our interpretation . . . . Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, and, therefore, whether it should be pre-empted.

Horn, 376 F.3d at 171. This Court too should defer to the FDA in recognizing that the PMA process creates device-specific federal requirements.

The FDA's approval of the PRIZM 2 indisputably created device-specific requirements with respect to the design, manufacture, labeling, and advertising of the

device. Plaintiffs' state law claims, virtually all of which directly conflict with these requirements by asserting that Guidant should have used different design, manufacture, labeling, and advertising than that which was approved by the FDA, are preempted. *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 867 (2000) (explaining that the majority of the *Lohr* court had agreed that common-law tort actions fall within the MDA's preemption clause); *Brooks*, 273 F.3d at 796 (explaining that contrary to the FDA's mandate, "[t]he effect of a jury finding of negligent failure to warn would be that state law would require [defendant] to change the label and package insert" for the device); *Reigel*, 451 F.3d at 122 (explaining that manufacturers would be in an untenable situation if faced with a single jury verdict on state tort claims, as they would remain unable to make the change without FDA approval).[8]

The foregoing authorities make it abundantly clear that Defendants are entitled to summary judgment on *all* claims that challenge the design, manufacturing specifications, labeling, or advertising, regardless of the advertising, regardless of the names affixed to them *See* Defs. Mem. at 20-37.

B. The PRIZM 2 PMA Is Unassailable.

Plaintiffs openly acknowledge that the PRIZM 2 was "approved by the FDA on August 4, 2000 pursuant to Supplement 15 of PMA P960040," Pls. Opp. at 21; and their own expert confirms that it remains approved to this day. *See* Oct. 11, 2006 Parisian

[8] On this point, Plaintiffs mistakenly rely on *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), a case decided under a different statute (FIFRA), and which, unlike the PMA process involved here, did not involve federal agency evaluation or approval of the pesticide label statements at issue.

Depo. Tr., Ex. B, at 148 ("The PMA-approved device remains approved."). Nonetheless, Plaintiffs invite this Court to doubt the validity of that approval. They repeatedly call into question both the capability and reliability of the FDA, despite the fact that the agency is specifically charged by Congress with the authority to regulate all medical devices sold in the United States. None of Plaintiffs' assertions are supported by either law or fact.

1. The PRIZM 2 PMA was properly granted.

Plaintiffs inappropriately question whether the PRIZM 2 PMA should have ever been granted, and mistakenly argue that Guidant withheld information from the FDA that it would have needed to effectively evaluate the application. *See* Pls. Opp. at 59 ("Guidant had this information [about polyimide], or should have had it, and should have provided it to the FDA. It did not; as a result FDA 'was not aware of the risk the [Prizm2] presented.'"). The record, however, establishes that the FDA had thousands of pages of information concerning the PRIZM 2 available in its PMA application, and had previously reviewed many thousands of pages of information in connection with PRIZM 2's predecessor devices – *including* information specifically related to the continuous use of polyimide in device headers dating back to its original FDA approval in 1992.[9] *See* Novak Depo. Tr., Vol. II, Ex. C, at 490-494; Novak Depo. Ex. 369, attached as Exhibit D hereto.

[9] Plaintiffs' opposition to Defendants' motion tries to have it both ways, arguing simultaneously both that the FDA did not have enough information to evaluate the PRIZM 2 application, (Pls. Opp. at 20-21), *and* that it had too much. *Id.* at 20, n.17.

Moreover, through the Real Time Review process under which the PRIZM 2 was evaluated for safety and effectiveness, the FDA literally had a "direct line" with Guidant regulatory personnel available to address any concerns the agency may have had about the application. *See* Novak Dep. Vol. II, Ex. C, at 479-482 (describing real time review process); *see also* 21 U.S.C. 379i(D). There is no record evidence whatsoever to support Plaintiffs' purely speculative (and immaterial) assertion that the FDA was inadequately staffed to handle the PRIZM 2 PMA, or that it "did not review the Prizm 2 PMA Supplement beyond the four corners of the document." Pls. Opp. at 20, n.17.[10] Indeed, the very fact that the PRIZM 2 PMA supplement *was* approved establishes as a matter of law that the FDA had the information it needed to carry out its regulatory mandate. The FDA is required by law to deny a PMA supplement application if it determines that there is any deficiency. *See* 21 C.F.R. § 814.45(b).

Even if it were true that Guidant deliberately withheld necessary information from FDA (which Defendants categorically deny), Plaintiffs still would lack the right to sue based on that fact. *See* 21 U.S.C. § 337(a); *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,

[10] Plaintiffs rely extensively on the report of Suzanne Parisian as evidence of the inner workings of the FDA. Dr. Parisian, however, has no personal knowledge of these workings during the relevant time period. She left the agency years before the PRIZM 2 PMA was submitted, and was not in a position to have evaluated the PMA applications of any Guidant ICD or, for that matter, any device in the cardiac rhythm management industry.

1274 (D. Minn. 1988). A tort cause of action based on any alleged deceit in the PMA process would be impliedly preempted. *Buckman*, 531 U.S. at 349-52.[11]

2. The PMA supplement approval process is no less legally rigorous than an original PMA approval process, and gives rise to the same preemptive effect under § 360k(a).

Plaintiffs also attempt to discredit the PRIZM 2 PMA by insinuating that approval of a Class III medical device through the PMA supplement process or involving a real time review is somehow a "lesser" form of approval or should be treated as such because the process is typically faster. *See* Pls. Opp. at 58. This argument has no merit. By law, PMA supplements are subject to the same legal standards as original PMAs. *See* 21 C.F.R. § 814.39(c) ("All procedures and actions that apply under §814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change."). Additionally, "real time" review does not alter the substantive standard for PMA approval. It simply permits the FDA to conduct the same rigorous review required by federal law by exchanging real time questions and answers with the manufacturer about the pending application. *See* Novak Dep. Vol. II, Ex. C, at 482 (describing a substantively identical review process whether real time or not); *see also* 21 U.S.C. § 379i(D).

[11] Plaintiffs wrongly argue that implied and express preemption cannot co-exist. *See* Pls. Mem. at 53. The United States Supreme Court has made clear that express preemption "does not foreclose (through negative implication) 'any possibility of implied [conflict] preemption.'" *Geier*, 529 U.S. at 869, quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 285 (1995).

This Court should flatly reject, as contrary to law, reason, and policy, Plaintiffs' argument that the use of a PMA supplement or real time review affects the significance or validity of federal regulatory approval; or the device-specific requirements it creates.

3. The PRIZM 2 PMA is not self-invalidating, and has never been withdrawn by the FDA.

In a last-ditch effort to question the validity of the PRIZM 2 approval, Plaintiffs wrongly argue that Guidant's supposed failure to comply with post-approval requirements[12] rendered the PRIZM 2 approval invalid. *See* Pls. Opp. at 62. A PMA, however, is not self-invalidating. Federal regulations are clear that such an approval cannot be and is not withdrawn without a noticed hearing, followed by prescribed statutory formalities. *See* 21 C.F.R. §§ 814.46, *et seq*. It is undisputed that no such notice or proceeding was commenced here. *See* Novak Dep. Vol. II, Ex. C, at 486 (confirming that the 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).

Plaintiffs' suggestion that FDA somehow impliedly revoked its PMA approval of the PRIZM 2 without formal action, (Pls. Opp. at 61), is utterly without basis in fact or law. There is no evidence indicating an FDA withdrawal of the PRIZM 2 PMA. Nor is

[12] Plaintiffs' only "evidence" of these alleged PMA-invalidating "violations" are their own expert's opinions – opinions which are themselves improper legal conclusions. Plaintiffs simply cannot be permitted to avoid a statutory preemption provision by unilaterally "declaring" a violation of the FDCA. *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 the argument that alleged failure to report to the FDA circumvents preemption as an impermissible attempt to "bootstrap" a "fraud-on-the-FDA" claim into a liability theory).

there evidence that the FDA has ever taken any *other* action to prevent distribution of the PRIZM 2, such as ordering removal of the device from the market or seeking restraining orders, injunctions, or seizures, although there are also regulatory processes available for doing so. Guidant's voluntary recall had no effect on the validity of the PRIZM 2, and even Plaintiffs' own expert acknowledges as much. *See* Parisian Depo Tr., Ex. B, at 120:10-18 (indicating that both recalled and non-recalled PRIZM 2 devices remain PMA-approved). If it did, such a result would be contrary to the letter and spirit of the FDCA as it would deter manufacturers from taking any action in response to early reports of device failures.

Finally, the FDA has plainly continued to recognize the validity of the PRIZM 2 PMA, even following the June 2005 voluntary recall, by approving additional supplements to the PRIZM 2 PMA. *See* Parisian Depo. Tr., Ex. B, at 122, 145 (acknowledging P960040/S77); and by continuing to require regulatory filings for the device, including annual reports. *See* Novak Dep., Vol. II, Ex. C, at 487.

The PRIZM 2 was thus validly approved through the PMA process, and remains so today. The Court should not allow Plaintiffs to circumvent and challenge the device-specific requirements created by the approval of the PRIZM 2 by the FDA.

C. Only True Manufacturing Defect Claims Survive Preemption.

Plaintiffs argue vigorously in their opposition that manufacturing defect claims are not preempted by §360k(a). Pls. Opp. at 53-55. Defendants agree, and openly conceded this point in their moving papers. *See* Defs. Mem. at 31. Plaintiffs, however, are not content to accept a rational application of this narrow exception to express preemption

under §360k(a). They go on to argue that *all* their claims are "predicated" on a manufacturing defect, and that as a result, *none* are subject to preemption: "[T]here is substantial evidence that a manufacturing defect is at the heart of the product defect at issue in this litigation. This alone *removes preemption as an issue* in this litigation." Pls. Opp. at 18; 53.

Plaintiffs' approach has no basis in law, and threatens to completely undermine the express preemption provision of the FDCA by creating an "exception" that entirely "swallows the rule." Only a true manufacturing defect claim – one in which a plaintiff alleges a injury from his own device's failure to deliver therapy, and where that failure was caused by a provable deviation from the PMA-approved manufacturing specification – may avoid preemption under §360k(a).

Plaintiffs' Master Complaint, however, does not assert *even one* such claim. Plaintiffs allege only that *all* PRIZM 2's were "uniformly defective," Master Compl. ¶90; *see e.g.* Pls. Opp. at 25 (Dr. Parisian repeatedly referring to a universal "defect in the Prizm2 device.").[13] These sorts of so-called "manufacturing defect" allegations indisputably attack not the manufacture of an individual device, but the very *design* of the PRIZM 2 model. As such they are preempted. *See Reigel*, 451 F.3d at 122 (claims for which "the liability-creating premise" was "that the [device] itself, in its present PMA-approved form, is in some way defective and therefore requires modification" are

[13] Defendants deny any suggestion that *all* PRIZM 2 devices are "defective." Notwithstanding the discrete set of known arcing failures, the PRIZM 2 continues to this day to *exceed* the reliability predictions contained in its PMA application. *See* Sept. 12, 2006 Renold Russie Depo. Exs. 408 and 410, attached hereto as Exhibits E and F, respectively.

preempted). Plaintiffs' attempt to save their myriad other claims by claiming that they are "predicated" on a manufacturing defect they *did not even plead* plainly fails as a matter of law and must be rejected.

CONCLUSION

The statutory criteria for preemption of Plaintiffs' various claims and controlling legal authorities are absolutely clear, and they are satisfied here. The FDA approved the PRIZM 2 pursuant to the rigorous PMA process. Under the Eighth Circuit's decision in *Brooks*, as well as the consistent holdings of six other federal circuit courts, the FDA approval created device-specific requirements for the design, manufacture, labeling, and advertising characteristics of the product. Any state law claim that threatens liability based on the sale of a device that meets those requirements – regardless of what it may be titled – creates an unconstitutional conflict, and is expressly preempted.

The simple fact is that the vast majority of both the Device Recipient and Third-Party Payor Plaintiffs' state law claims (with the noted and limited exception of true manufacturing defect claims) are expressly preempted. The remainder are subject to implied preemption principles. They cannot be saved by Plaintiffs' desperate attempts to cloak them in a false manufacturing defect "predicate," or to bury them in a mountain of disputed but immaterial facts. Allowing juries the last word on whether a Class III medical device is safe and effective would usurp the FDA's regulatory prerogative and contradict Congressional intent.

Defendants are entitled to summary judgment, and respectfully request that it be granted in their favor.

Respectfully submitted,

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