IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

SHERRY ANN WALKER,
Administratrix of the estate
of Arnold Leroy Walker, Jr.,
and SHERRY ANN WALKER,
Individually,

Plaintiff,

v. **CIVIL ACTION NO. 2:07-00317**

MEDTRONIC, INC.,

Defendant.

MEMORANDUM OPINION

By Judgment Order entered September 29, 2010, the court granted defendant's renewed motion for summary judgment. (Doc. No. 138). The reasons for that decision follow.

I. Factual and Procedural Background

On May 18, 2007, plaintiff Sherry Walker filed the instant action, invoking the court's diversity jurisdiction. Plaintiff alleges that her late husband, Arnold Leroy Walker, Jr., died when his internally-implanted Medtronic SynchroMed EL Infusion Pump (hereinafter "the Pump") malfunctioned, on June 9, 2005, by administering a lethal overdose of medication. Amended Complaint ¶ 5. The pump had been implanted more than two years earlier, on or about May 28, 2003. See id. at ¶ 4. Medtronic, Inc. is the manufacturer of the SynchroMed EL Infusion Pump. Id. at ¶ 3. Walker's complaint asserted three causes of action against

Medtronic: negligence (Count One), strict liability (Count Two), and breach of warranty (Count Three). Original Complaint ¶¶ 11-22. Walker sought compensatory and punitive damages, attorney's fees, costs, and pre- and post-judgment interest. Id. at ¶ 25.

On April 21, 2008, after the United States Supreme Court issued its opinion in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), a case addressing federal preemption under the Medical Device Amendments of 1976 ("MDA"), defendant filed a motion for summary judgment arguing that plaintiff's claims were preempted. By Memorandum Opinion and Order entered on September 9, 2008, the court denied defendant's motion without prejudice concluding that "[w]here the key issue of material fact – whether the infusion pump complied with the terms of its premarket approval – has not been fully explored through the discovery process, the court is unable to grant summary judgment." The court further found, however, that the original complaint did not adequately allege the type of claim which might survive Riegel and informed plaintiff that it would entertain a motion to amend the complaint in order to correct this deficiency.

On October 29, 2008, plaintiff filed an amended complaint which, once again, asserted claims for negligence (Count One), strict liability (Count Two), and breach of warranty (Count Three). The amended complaint also alleged that "the pump failed to comply and operate in terms of its Pre-Market Approval from

the Food & Drug Administration" and that "contrary to the terms of its Pre-Market Approval," Medtronic breached its express and implied warranties. Amended Complaint ¶¶ 11, 15, and 20.

On October, 29, 2009, following discovery on whether the Pump complied with the terms of its premarket approval, defendant filed a renewed motion for summary judgment. In its motion, defendant argued that because discovery had shown that Mr. Walker's pump was designed, manufactured, and sold in accordance with the terms of its premarket approval, plaintiff's claims are expressly preempted by 21 U.S.C. § 360k and, therefore, the complaint should be dismissed.

Plaintiff argued that her claims fall within the narrow exception for parallel claims carved out by Riegel and, therefore, are not preempted. Plaintiff argues that the Pump failed to adhere to the "performance standard," upon which PMA was conditioned - - that the amount of medication dispensed by the Pump would be within ± 15% of the programmed dosage. See Plaintiff's Response at 6-10. According to her, because she alleges a failure to comply with this standard, which was specifically set forth in the PMA and supplement(s), her claim parallels the federal requirement.[1]

[1] In her brief, plaintiff also argued that Medtronic's receipt of "warning letters" from the FDA regarding its failure "to comply with the federally mandated conditions associated with the PMA approval," waives "the pre-emptive benefits afforded by

II. Summary Judgment Standard

With respect to summary judgment, Rule 56 of the Federal Rules of Civil Procedure provides that

> [t]he judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.

Fed. R. Civ. P. 56. The moving party has the burden of establishing that there is no genuine issue as to any material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). As was explained in Celotex, "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for

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PMA approval." Plaintiff's Response at 10-11. During oral argument on the motion, held on August 31, 2010, plaintiff withdrew her argument related to Medtronic's receipt of warning letters. The court notes, however, that plaintiff's abandoned argument is without merit as it has been routinely rejected by other courts. See, e.g., Hughes v. Stryker Corp., 2010 WL 2608957, *3 (S.D. Ala. Jun. 28, 2010) ("Fundamentally, plaintiff made no showing on summary judgment, and has made none now, to draw a nexus between the FDA warning letter and the failure of her specific device."); Anthony v. Stryker Corp., 2010 WL 1387790, *4 (D. Ohio Mar. 31, 2010) ("Anthony did allege that Stryker had received two warning letters from the FDA, but several courts have held that the mere mention of the 2007 warning letters is an insufficient factual basis upon which to state a plausible claim."); Covert v. Stryker Corp., 2009 WL 2424559, *12 (M.D.N.C. Aug. 5, 2009) (receipt of two warning letters from the FDA insufficient to show violation of federal regulations where plaintiff could not show device in question "was ever the subject of any FDA action or recall, or that it has ever been found by the FDA to be in violation of any particular regulation, or even that there is an independent reason to believe that his particular system violated a federal regulation in any way.")(emphasis in original).

discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322.

Once the moving party has met this burden, the burden then shifts to the nonmoving party to produce sufficient evidence for a jury to return a verdict for that party.

> The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find, by a preponderance of the evidence, that the plaintiff is entitled to a verdict . . . .

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Id. at 250-51. Significantly, "a party opposing a properly supported motion for summary judgment may not rest upon mere allegation or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." Id. at 256.

III. Analysis

Although the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., had long required Food and Drug Administration ("FDA") approval for the introduction of new drugs, prior to 1976, "the introduction of new medical devices was left largely for the States to supervise as they saw fit." Riegel v.

Medtronic, Inc., 552 U.S. 312, 315 (2008). In 1976, Congress passed the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c et seq., which "imposed a regime of detailed federal oversight" for medical devices. Id. at 316.

Under the MDA, medical devices are subject to varying degrees of oversight which are dependent on the risks presented by the device at issue. Id. Class I devices, such as elastic bandages and examination gloves, are subject "to the lowest level of oversight." Id. A Class II device, like powered wheelchairs or surgical drapes, "cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety of effectiveness of the device." 21 U.S.C. § 360c(a)(1)(B); Riegel, 552 U.S. at 316-17. For this reason, Class II devices are subjected to additional "special controls" such as performance standards and postmarket surveillance. 21 U.S.C. § 360c(a)(1)(B); Riegel, 552 U.S. at 316-17.

Class III devices are subjected to the most federal oversight. Riegel, 552 U.S. at 317. "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is `purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in

preventing impairment of human health,' or `presents a potential unreasonable risk of illness or injury.'" Id. (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

Class III devices are required to obtain premarket approval "to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C).

> Premarket approval is a rigorous process. A manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; 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, such device; samples or device components required by the FDA; and a specimen of the proposed labeling. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, and may request additional data from the manufacturer.
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> The FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a reasonable assurance of the device's safety and effectiveness. The agency must weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives.

Riegel, 552 U.S. at 318 (internal citations and quotations omitted).

The MDA also includes an express preemption provision which states as follows:

> Except as provided in subsection (b) of this section, no 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 chapter 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 chapter.

21 U.S.C. § 360k(a).

In Riegel, the Court considered how the FDCA's express preemption clause impacts medical devices that have received premarket approval. The Riegel court held that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." Riegel, 522 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). According to the Court, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id.

Riegel established a two-step procedure for determining if state-law claims are preempted. First, a court must determine whether "the Federal Government has established requirements applicable to" the particular medical device. Id. at 321. With respect to the first step, claims involving a Class III medical

device with premarket approval automatically qualify because the PMA process establishes specific requirements applicable to a particular device. Id. at 322-23; see also Lewkut v. Stryker Corp., 2010 WL 1544275, *3 (S.D. Tex. Apr. 16, 2010) ("Thus, for all PMA approved devices, this first prong is met.").

As for the second step, a court must determine whether the state law claims are based on requirements "different from or in addition to" the federal requirements relating to safety and effectiveness or any requirement under the MDA. Riegel, 522 U.S. at 323. Riegel held that state common law and statutory duties imposed through litigation are requirements "with respect to devices" as that term is used in Section 360k(a). Id. at 327-28. In so doing, the Court noted that

> [s]tate tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation.

Id. at 325. As to the case before it, the Riegel court held that the plaintiff's claims for negligence, strict liability, and implied warranty were preempted. See id. at 330.

Since Riegel, "courts across the country have applied Section 360k(a) broadly," preempting all types of products

liability claims, including those alleged herein: negligence,[2] strict liability,[3] and breach of warranty.[4] In re Medtronic,

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[2] See, e.g., Steen v. Medtronic, Inc., 2010 WL 2573455, *4 (N.D. Tex. Jun. 25, 2010); Franklin v. Medtronic, Inc., 2010 WL 2543579, *5 (D. Colo. May 12, 2010); Lewkut v. Stryker Corp., 2010 WL 1544275, *7 (S.D. Tex. Apr. 16, 2010); Wheeler v. DePuy Spine, Inc., 2010 WL 1539855, *3-4 (S.D. Fla. Mar. 9, 2010); Heisner v. Genzyme Corp., 2010 WL 894054, *3 (N.D. Ill. Mar. 8, 2010); Funk v. Stryker Corp., 673 F. Supp.2d 522, 531-32 (S.D. Tex. 2009); Williams v. Allergan USA, Inc., 2009 WL 3294873, *4 (D. Ariz. Oct. 14, 2009); Covert v. Stryker Corp., 2009 WL 2424559, *16 (M.D.N.C. Aug. 5, 2009); Wolicki-Gables v. Arrow, Int'l, Inc., 641 F. Supp.2d 1270, 1286 (M.D. Fla. 2009); Miller v. DePuy Spine, Inc., 638 F. Supp.2d 1226, 1229 (D. Nev. 2009); In re Medtronic Inc. Sprint Fidelis Leads Prods. Liability Litig., 592 F. Supp.2d 1147, 1157-63 (D. Minn. 2009), aff'd, 2010 WL 4026802, *1 (8th Cir. Oct. 15, 2010); Bausch v. Stryker Corp., 2008 WL 5157940, *4 (N.D. Ill. Dec. 9, 2008); Link v. Zimmer Holdings, Inc., 604 F. Supp.2d 1174, 1178-80 (N.D. Ill. 2008); Parker v. Stryker Corp., 584 F. Supp.2d 1298, 1303 (D. Colo. 2008); Raleigh v. Alcon Laboratories, Inc., 2010 WL 3172223 (Ill. App. 1 Dist. Aug. 6, 2010); McGuan v. Endovascular Techs., Inc., 106 Cal. Rptr. 3d 277, 285-86 (Cal. Ct. App. Feb. 9, 2010); Blanco v. Baxter Healthcare Corp., 158 Cal. App. 4th 1039, 1055 (2008); Lake v. Kardjian, 874 N.Y.S.2d 751, 754 (N.Y. Sup. Ct. 2008).

[3] See, e.g., Steen v. Medtronic, Inc., 2010 WL 2573455, *4 (N.D. Tex. Jun. 25, 2010); Heisner v. Genzyme Corp., 2010 WL 894054, *3 (N.D. Ill. Mar. 8, 2010); Banner v. Cyberonics, Inc., 2010 WL 455286, *4 (D.N.J. Feb. 4, 1010); Williams v. Allergan USA, Inc., 2009 WL 3294873, *4 (D. Ariz. Oct. 14, 2009); Miller v. DePuy Spine, Inc., 638 F. Supp.2d 1226, 1229 (D. Nev. 2009); Funk v. Stryker Corp., 673 F. Supp.2d 522, 531-32 (S.D. Tex. 2009); In re Medtronic Inc. Sprint Fidelis Leads Prods. Liability Litig., 592 F. Supp.2d 1147, 1157-63 (D. Minn. 2009), aff'd, 2010 WL 4026802, *1 (8th Cir. Oct. 15, 2010); Bausch v. Stryker Corp., 2008 WL 5157940, *6 (N.D. Ill. Dec. 9, 2008); Link v. Zimmer Holdings, Inc., 604 F. Supp.2d 1174, 1178-80 (N.D. Ill. 2008); Raleigh v. Alcon Laboratories, Inc., 2010 WL 3172223 (Ill. App. 1 Dist. Aug. 6, 2010); McGuan v. Endovascular Techs., Inc., 106 Cal. Rptr. 3d 277, 285-86 (Cal. Ct. App. Feb. 9, 2010); Blanco v. Baxter Healthcare Corp., 158 Cal. App. 4th 1039, 1056-57 (2008); Colombini v. Westchester County Health Care Corp., 2009 WL

Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009), aff'd, 2010 WL 4026802, *1 (8th Cir. Oct. 15, 2010); see also Poole v. Hologic, Inc., 2010 WL 3021528, *5-6 (W.D. La. Jul. 29, 2010) (claims under Louisiana Products Liability Act preempted); Ilarraza v. Medtronic, Inc., 677 F. Supp.2d 582, 589 (E.D.N.Y. 2009) (negligence per se claim preempted).

Plaintiff concedes that the Pump at issue herein was designed, manufactured, and sold in accordance with the terms of its premarket approval. See Transcript of August 31, 2010 Hearing at 23. The Pump's design specifications state that "[t]he flow accuracy of the SynchroMed EL pump, measured at the catheter tip, is within ± 15 percent of the programmed flow

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2170230, *5 (N.Y. Sup. Ct. July 6, 2009).

[4] See, e.g., Steen v. Medtronic, Inc., 2010 WL 2573455, *4 (N.D. Tex. Jun. 25, 2010); Covert v. Stryker Corp., 2009 WL 2424559, *16 (M.D.N.C. Aug. 5, 2009); Bencomo v. Guidant Corp., 2009 WL 1951821, *6 (E.D. La. Jun. 30, 2009); Riley v. Cordis Corp., 625 F. Supp.2d 769, 788-89 (D. Minn. 2009); Miller v. DePuy Spine, Inc., 638 F. Supp.2d 1226, 1229-30 (D. Nev. 2009); In re Medtronic Inc. Sprint Fidelis Leads Prods. Liability Litig., 592 F. Supp.2d 1147,1164 (D. Minn. 2009), aff'd, 2010 WL 4026802, *1 (8th Cir. Oct. 15, 2010); Link v. Zimmer Holdings, Inc., 604 F. Supp.2d 1174, 1178-80 (N.D. Ill. 2008); Parker v. Stryker Corp., 584 F. Supp.2d 1298, 1303 (D. Colo. 2008); Adkins v. Cytyc Corp., 2008 WL 2680474, *2 (W.D. Va. Jul. 3, 2008); McGuan v. Endovascular Techs., Inc., 106 Cal. Rptr. 3d 277, 285-86 (Cal. Ct. App. Feb. 9, 2010); Colombini v. Westchester County Health Care Corp., 2009 WL 2170230, *5 (N.Y. Sup. Ct. Jul. 6, 2009); Mullin v. Guidant Corp., 970 A.2d 733, 739 (Conn. App. Ct. 2009); Lake v. Kardjian, 874 N.Y.S.2d 751, 754 (N.Y. Sup. Ct. 2008).

rate." See PMA Supplement dated March 18, 1999. The specifications go on to the state that "the accuracy of the SynchroMed EL Infusion System depends on how closely procedures are followed. Noncompliance with implant and refill procedures, as well as other human factors, may cause the observed accuracy of the system to vary . . . ." Id. The PMA also acknowledges the possibility of component failure. See PMA at p. 4648.

Plaintiff's theory of the case is that, despite the fact the Pump was designed, manufactured, and sold in accordance with the terms of its premarket approval, it malfunctioned when it overinfused Mr. Walker by approximately 258 percent and this overinfusion was a violation of the terms of the Pump's PMA which required a flow accuracy of ± 15 percent. Defendant contends that the flow accuracy of ± 15 percent was the intended result given a Pump that was designed and manufactured according to the terms of its PMA. In other words, assuming a Pump has been designed and manufactured in accordance with its premarket approval, the expected result is a Pump that has a flow accuracy of ± 15 percent. According to Medtronic, just because a Pump may malfunction and exceed the ± 15 percent flow accuracy, it is not a violation of an FDA requirement. The court agrees.

An alleged deviation from manufacturing performance specifications for a device that has received premarket approval is not the same thing as noncompliance with the FDA or its

regulations. See Anthony v. Stryker Corp., 2010 WL 1387790, * 4 (N.D. Ohio Mar. 31, 2010). To hold otherwise would make a manufacturer an insurer of its product. Indeed, premarket approval does not guarantee that a device is completely safe. Clark v. Medtronic, Inc., 572 F. Supp.2d 1090, 1094 (D. Minn. 2008); see also Rankin v. Boston Scientific Corp., 2010 WL 672135, *3 (E.D. Ky. Feb. 19, 2010) ("[W]hen a medical device undergoes the rigorous premarket approval process and is approved for use, the public is assured that the product is reasonably safe as viewed from the perspective that some risk is always inherent in those medical procedures aimed at `supporting or sustining human life.'") (emphasis added).

> The FDA approves the process by which a Class III device is manufactured, but it does not guarantee that every device manufactured in that process will work. Thus, if the FDA approves a manufacturing process and the defendant-manufacturer conforms with it, a device thereby produced that nevertheless does not function as intended does not give rise to liability. In effect, it is distinctly possible that the FDA-approved process introduced a margin of error wherein a properly manufactured device may nevertheless depart from its intended design. Under Riegel, state law cannot capture this departure and create liability for it because that would, in effect, require the manufacturer to use greater care than required by the FDA. Thus, Plaintiffs' argument that a deice produced in compliance with the FDA-approved process may nevertheless give rise to a state law claim for product liability is incorrect.

Banner v. Cyberonics, 2010 WL 455286, *4 (D.N.J. Feb. 4, 2010); see also Hughes v. Boston Scientific Corp., 669 F. Supp.2d 701, 2009 WL 3817586, *9 (S.D. Miss. 2009) ("[A] manufacturing defect

claim would be preempted if the manufacturer followed the federally approved manufacturing process for a device.").

As discussed below, plaintiff's state law tort claims would impose a higher duty upon Medtronic than what was required of it during the PMA process.

A. Negligence

In her Amended Complaint, plaintiff alleges that "Defendant Medtronic was negligent in the design, manufacture, assembly, testing, inspection, provision with warnings and instructions, marketing, and distribution of the Medtronic infusion pump . . . ." Amended Complaint ¶ 9. She contends that "hardware and/or software errors could lead to the pump delivering improper dosages of medications." Id. at ¶ 10. However, the "design, manufacture, assembly, testing, inspection, provision with warnings and instructions, marketing, and distribution" of the Pump were approved by the FDA as part of its PMA. Accordingly, to contend that the device should have been designed, manufactured, assembled, tested, inspected, provided with warnings and instructions, marketed, and/or distributed in a manner different than that approved by the FDA imposes requirements "different from, or in addition to," the FDA's premarket approval. Therefore, such a claim is preempted.

B. Strict Liability

According to the Amended Complaint, "Defendant Medtronic designed, manufactured, assembled, tested, inspected, provided with warnings and instructions, marketed, and distributed the infusion pump, . . . such that when the pump was placed into the stream of commerce, it was in an unreasonably dangerous and inherently defective condition . . . thereby rendering Defendant Medtronic strictly liable for the resulting injuries and damages." Id. at ¶ 14. However, as noted earlier, plaintiff has conceded that the Pump's design, manufacture, assembly, testing, inspection, provision with warnings and instructions, marketing, and distribution complied with the terms of its premarket approval. Requiring anything more of Medtronic under these circumstances necessarily imposes requirements "different from, or in addition to," the FDA's premarket approval and, therefore, plaintiff's claim is preempted.

C. Breach of Warranty

Plaintiff's breach of warranty claim is likewise preempted because the success of her claim necessarily depends on a finding that the Pump was unsafe or ineffective despite its compliance with the terms of its premarket approval. She contends that "[b]y designing, manufacturing, assembling, testing, inspecting, providing with warnings and instructions, marketing, distributing, and/or otherwise placing the infusion pump, . . . into the stream of commerce in a condition in which it was

defective and unreasonably dangerous . . . , unmerchantable, unfit for its ordinary and intended purpose, Defendant Medtronic, and contrary to the terms of its Pre-Market Approval, breached these express and implied warranties." Amended Complaint ¶ 20. However, "Riegel is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass on [a breach of warranty claim]. No state common-law claim can survive if it allows a claimant to proceed without showing a departure from federal standards. There simply is no wiggle room to find otherwise." Williams v. Cyberonics, Inc., 654 F.Supp.2d 301, 306 (E.D. Pa 2009).

In order for her breach of warranty claims to survive Riegel preemption, plaintiff must show that the Pump was not manufactured in accordance with FDA standards. This she cannot do. See Rankin v. Boston Scientific Corp., 2010 WL 672135, *4 (E.D. Ky. Feb. 19, 2010) ("The plaintiffs argue that their state tort claims should be allowed to proceed because the Maverick Balloon, which was rated for 12 atm, burst at 6 atm. In other words, the plaintiffs contend that because the device failed during normal use, Boston Scientific has violated some federally imposed requirement or regulation. However, Boston Scientific received premarket approval for the Maverick Balloon at issue in this case. The fact that the Maverick Balloon allegedly failed during normal use does not override the clear language of §

360(a) or the Supreme Court's ruling in Riegel that the plaintiffs' claims are preempted by federal law.").

IV. Conclusion

For the reasons set forth above, the court **GRANTED** defendant's renewed motion for summary judgment.

The Clerk is directed to forward a copy of this Memorandum Opinion to all counsel of record.

It is **SO ORDERED** this 24th day of November, 2010.

ENTER:

David A. Faber
Senior United States District Judge