UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

KELLY POOLE, ET AL.	CIVIL ACTION NO. 10-314
VERSUS	JUDGE S. MAURICE HICKS, JR.
HOLOGIC, INC.	MAGISTRATE JUDGE HORNSBY

MEMORANDUM RULING

Before this Court is a Motion for Judgment on the Pleadings [Record Document 3] filed on behalf of the Defendant, Hologic, Inc., formerly known as Cytic Corporation ("Hologic"). Pursuant to Rule 12(c) of the Federal Rules of Civil Procedure, Hologic moves the Court to enter judgment in its favor and dismiss Plaintiffs' petition in its entirety on the grounds that: (1) in accordance with Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, preempts all of the state law claims alleged in Plaintiff's petition; and (2) that Plaintiffs' claims are impliedly preempted under Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d (2001). Plaintiff opposes this motion. See Record Document 24.

FACTUAL BACKGROUND

On January 19, 2009, Kerry Tynes, M.D. and Benny Powell, M.D., performed an Endometrial Ablation surgery on the Plaintiff, Kelly Poole. [Petition ¶ 5]. The surgery was performed using a NovaSure™ Impedance Controlled Endometrial Ablation System ("the

NovaSure machine"),[1] which was manufactured by Hologic. During the procedure, Dr. Tynes and Dr. Powell were unable to get a good seal on the NovaSure machine and called a representative/employee of Hologic for assistance. See Record Document 24, p.1. At some point during the procedure, Plaintiff's uterus was perforated and an emergency hysterectomy had to be performed. As a result of the hysterectomy, Plaintiff, age 32, now suffers from premature menopause and has been advised that she will need to take certain medications and hormones on a daily basis until she reaches age 50. [Petition ¶ 8; Record Document 24, p.2].

On January 15, 2010, Plaintiff and her husband commenced this action against Defendant alleging (i) the NovaSure machine was defectively designed [Petition ¶ 6B-C], (ii) the NovaSure machine was defectively manufactured [Petition ¶ 6D-G], (iii) the NovaSure machine did not provide adequate warnings or instructions [Petition ¶ 6H], (iv) the NovaSure machine did not conform to express or implied warranties of fitness [Petition ¶ 6I], (v) that Hologic breached its duties under the Louisiana Products Liability Act ("LPLA") [Petition ¶ 6J], and (vi) that Hologic's employees and/or agents negligently instructed the physicians performing the procedure on the use of the NovaSure machine [Petition ¶ 6K-O]. Shortly thereafter, Hologic filed the instant motion for judgment on the pleadings asserting there "are two fundamental and independent flaws with Plaintiff's claims." [Record Document 3, p.1]. Hologic argues that in Riegel v. Medtronic, Inc., 552

[1]Hologic's NovaSure™ Impedance Controlled Endometrial Ablation System ("the NovaSure machine") is a sophisticated medical device "intended to ablate the endometrial lining of the uterus of pre-menopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete." FDA Approval Order re: P010013, Sept. 28, 2001 <http://www.accessdata.fda.gov/cdrh_docs/pdf/P010013A.pdf>.

U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), the United States Supreme Court held that the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, preempts all state law claims of the type alleged in Plaintiff's petition. Alternatively, Hologic contends Plaintiffs' claims are impliedly preempted under Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d (2001).[2] Hologic's motion for dismissal of Plaintiff's petition is based on the notion that it cannot simultaneously comply with the FDA requirements that its device be designed, manufactured, and labeled in a specific way, and state tort law requiring a different design, manufacture, or label.[3]

RULE 12(c) STANDARD

The standard for dismissal under Rule 12(c) of the Federal Rules of Civil Procedure is the same as that for dismissal for failure to state a claim under Rule 12(b)(6). See Ackerson v. Bean Dredging LLC, 589 F.3d 196, 209 (5th Cir. 2009). Thus, in order to survive dismissal, the plaintiff's complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, – U.S. –, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. at 555, 127 S.Ct. at 1964-65, 167 L.Ed.2d 929 (2007)). "A claim has facial plausibility when the

[2]For the reasons discussed herein, the Court finds Plaintiffs' claims are preempted under the MDA and need not determine whether such claims are impliedly preempted under Buckman.

[3]Interestingly, Plaintiffs' opposition is limited to a defense of its claims for manufacturing defect and inadequate warning under the LPLA and does not address their claims for design defect or breach of warranty. See Record Document 24. Hologic contends that, by their silence, Plaintiffs have conceded their design defect and breach of warranty claims are preempted under the MDA. Nevertheless, in an abundance of caution, the Court will proceed to analyze all of the state law claims asserted by Plaintiff to determine whether such claims are preempted.

plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. In evaluating the defendant's motion, the Court must construe the complaint liberally and accept all of the plaintiff's factual allegations in the complaint as true. See In re Katrina Canal Breaches Litigation, 495 F.3d 191, 205 (5th Cir. 2009).

LAW AND ANALYSIS

A. The Medical Device Amendments

In 1976, Congress passed the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c *et seq.*, to the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.* The MDA classifies medical devices into three different categories depending on the degree of risk the device poses to the public. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 476, 116 S.Ct. 2240, 2246, 135 L.Ed.2d 700 (1996). Medical devices that present no unreasonable risk of illness or injury are designated "Class I" and are subject only to minimal regulation by "general controls," such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Devices that are potentially more harmful are designated "Class II" and must comply with federal performance regulations coined "special controls," such as performance standards and postmarked surveillance measures. 21 U.S.C. § 360c(a)(1)(B). Class I and Class II devices can be marketed without prior approval of the FSA.

Class III is reserved for devices that are "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 which present "a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C). Before a Class III device can be marketed,

the manufacturer must provide the FDA with "reasonable assurance of its safety and effectiveness" through the rigorous premarket approval ("PMA") process. Lohr, 518 U.S. at 477, 116 S.Ct. at 2246. The PMA process requires a manufacturer to submit detailed information regarding the safety and efficacy of the device, including 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 devices "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. Riegel v. Medtronic, Inc., 552 U.S. 312, 318, 128 S.Ct. 999, 1004, 169 L.Ed.2d 892 (2008) (citing 21 U.S.C. § 360e(c)(1)). In determining whether to grant premarket approval, the FDA reviews this information extensively, and may request additional data from the manufacturer and/or refer the application to a panel of outside experts. Id. (citing 21 U.S.C. § 360e(c)(1)(G); 21 C.F.R. § 814.44(a)).

Once a medical device has received premarket approval,[4] the MDA imposes additional obligations on the manufacturer and provides for continued oversight by the FDA. For example, the manufacturer is prohibited from making any changes in design

[4]Not all Class III devices on the market today have received PMA approval because of two important exceptions created by Congress. First, the MDA includes a grandfather clause which permits medical devices marketed prior to 1976 to remain on the market without FDA approval unless and until the FDA implements and completes the PMA process. See Lohr, 518 U.S. at 477-78, 116 S.Ct. at 2247 (citing 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1)). Second, the MDA permits medical devices that are "substantially equivalent" to pre-existing devices to be marketed without the rigorous PMA review. Id. (citing 21 U.S.C. § 360e(b)(1)(B)).

specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness without first receiving permission from the FDA. Id. (citing 21 U.S.C. § 360e(d)(6)(A)(i)). The manufacturer is also subject to ongoing reporting requirements, such as reporting to the FDA new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if the malfunction recurred. Id. (citing 21 C.F.R. §§ 814.84(b)(2), 814.50(a)). The FDA may withdraw premarket approval of any device based on newly reported data, and do so if the new information fails to provide "reasonable assurance that the device is safe or effective under the conditions or uses prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 360e(e)(1). Furthermore, if the FDA finds "there is a reasonable probability that a device intended for human use would cause serious injury, adverse health consequences or death," the FDA can order the device be recalled. 21 U.S.C. § 360h(e)(1).

B. Federal Preemption

To ensure the FDA decision-making and oversight is not controverted by state regulatory measures, Congress included the following pre-emption provision in the MDA:

> 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.

§ 360k(a).[5]

The FDA has promulgated specific regulatory provisions interpreting § 360k which state, in pertinent part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. . .

21 C.F.R. § 808.1(d).

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[5]Subsection (b) of the statute authorizes the FDA to grant certain exemptions to state requirements that would otherwise be pre-empted by subsection (a). Specifically, § 360k(b) provides:

> (b) Exempt requirements
>
> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--
>
> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement--
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

In Riegel v. Medtronic, Inc., supra, the United States Supreme Court set forth a two-prong analysis for determining whether a plaintiff's state law claims are preempted by the MDA. First, the court must determine whether the Federal Government has established requirements applicable to the device at issue. Id., 552 U.S. at 322, 128 S.Ct. at 1006. If there are federal requirements for the device, the court must then determine whether the plaintiff's state law claims are based upon a "requirement" of state law that is "different from, or in addition to" federal requirements and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Id., 552 U.S. at 323, 128 S.Ct. at 1007 (citing 21 U.S.C. § 360k(a)). If a state law claim is based upon a state requirement that is "different from, or in addition to" federal requirements, plaintiff's claim is preempted by the MDA. See id.

In addressing the first prong of the preemption analysis, the Riegel Court reasoned that the PMA process itself imposes "requirements" under the MDA. Id., 552 U.S. at 322-23, 128 S.Ct. at 1007. Devices granted premarket approval by the FDA are required to be made without almost no deviations from the specifications in its approval application since it is the approved form of the device that the FDA has determined "provides a reasonable assurance of safety and effectiveness."[6] Id. Consequently, any device that has received approval from the FDA through the PMA process automatically satisfies the first prong of the preemption analysis. With respect to the second prong, the Riegel Court equated state

[6]Through the PMA process, the FDA "weigh[s] the competing interests relevant to the particular requirement in question" and reaches "an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases," and "implement[s] that conclusion via a specific mandate on manufacturers or producers." Gomez v. St. Jude Med. Daig Div. Inc., 442 F.3d 919, 930 (5th Cir. 2006) (quoting Lohr, 518 U.S. at 501, 116 S.Ct. 2240).

common-law duties with "requirements," noting that a tort judgment "'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'" Id., 522 U.S. at 324, 128 S.Ct. at 1008 (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992)). In reaching this conclusion, the Court determined that the general common-law duties underlying negligence, strict liability, and implied-warranty claims are maintained "with respect to devices," and specifically rejected the proposition that in order to be preempted the "state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general." Id., 552 U.S. at 327-228, 128 S.Ct. at 1009-10 (emphasis in original).

C. Preemption Analysis of Plaintiff's Claims

There is no dispute among the parties that the NovaSure machine, a Class III medical device, was granted premarket approval by the FDA on September 28, 2001 and that specific requirements were established for the device. See FDA Approval Order re: P010013, Sept. 28, 2001 <http://www.accessdata.fda.gov/cdrh_docs/pdf/P010013A.pdf>. These requirements include the specific design and manufacturing process of the NovaSure machine, the specific labels allowed to be placed on individual devices and their packaging, and the precise wording to be included on advertisements or other descriptive printed material to be issued with respect to the device. See id. In approving Hologic's PMA application for the NovaSure machine, the FDA determined the manner in which the device is to be used and specifically indicated that use of the device is contraindicated for certain uses and/or for patients with certain conditions. See FDA Summary of Safety and Effectiveness Data, NovaSure™ Impedance Controlled Endometrial Ablation System <http://www.accessdata.fda.gov/cdrh_docs/pdf/P010013b.pdf>. Accordingly, the Court

need only determine whether the state law claims asserted by Plaintiff in this matter are based upon state requirements that are "different from, or in addition to" federal requirements, and that "relate to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." See Riegel, 552 U.S. at 323, 128 S.Ct. at 1007 (citing 21 U.S.C. § 360k(a)).

In Gomez v. St. Jude Medical Daig Div. Inc., 442 F.2d 919 (5th Cir. 2006), the plaintiff sued the manufacturer of the Angio-Seal, a Class III FDA-approved medical device, under the LPLA for unreasonably dangerous design, failure to warn of the dangers of the Angio-Seal, failure to train medical personnel to use the Angio-Seal properly, lack of informed consent, breach of express warranty, redhibition, and failure to manufacture the device in accordance with FDA specifications. Utilizing the two-part preemption analysis subsequently adopted by the Supreme Court in Riegel, the Fifth Circuit affirmed dismissal of plaintiff's product liability claims on the ground that "this state-law challenge" to the FDA requirements of the device was preempted by the MDA.[7] The Fifth Circuit reasoned that permitting "a jury to second-guess the [FDA's requirements] by applying the Louisiana statutory standard for unreasonably dangerous [products] would risk interference with" the standards and criteria approved by the FDA and "would displace the FDA's exclusive role and expertise in this area." Id. at 930-31. The Fifth Circuit also concluded

[7]After the district court initially granted summary judgment on the manufacturing defect claim, the district court granted the plaintiff's Rule 59 motion based upon previously-unavailable documents demonstrating a genuine issue of material fact as to whether the Angio-Seal was made in accordance with the FDA-approved specifications. Gomez, 442 F.3d at 926. Here, Plaintiffs take issue with the manufacturing process, the specifications, and other manufacturing-related parameters with respect to the NovaSure machine, but there are no allegations within Plaintiffs' Petition that the specific device used in the surgery failed to meet FDA-approved standards.

that plaintiff's breach of warranty claims were preempted because "the warranty is intertwined with the FDA's standards concerning the device's design, testing, intended use, manufacturing methods, performance standards and labeling." Id. at 931. Because the representations made by a manufacturer are approved by the FDA through the PMA process, "the duties arising under the Louisiana breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme." Id.

Plaintiffs herein assert similar causes of action under the LPLA, specifically alleging that the NovaSure machine manufactured by Hologic was unreasonably dangerous "in design" [Petition ¶ 6B], "in construction and/or composition," Id. at ¶ 6F, because it "did not provide or contain an adequate warning," Id. at ¶ 6H, "because it did not conform to both an express warranty of fitness and an implied warranty of fitness," Id. at ¶ 6I, and because Hologic's "employees and/or agents failed to properly and adequately train the physician(s) involved on the use of the NovaSure machine."[8] Id. at ¶ 6L. However, a finding under the LPLA that the NovaSure machine was improperly designed, improperly manufactured, equipped with inadequate warnings and training materials, and/or failed to conform to express and implied warranties of fitness would impose requirements that are "different

[8]To the extent Plaintiffs' petition could be construed to allege additional state law claims against Hologic based on their contention that the NovaSure machine is "unreasonably dangerous," the Court finds that such claims are barred under Louisiana law. It is now well-established that the LPLA "establishes the exclusive theories of liability for manufacturers for damages caused by their products," and a plaintiff "may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth" in this Act. La. R.S. § 9:2800.52. "While the statutory ways of establishing that a product is unreasonably dangerous are predicated on principles of strict liability, negligence or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent theory of recovery against a manufacturer." Jefferson v. Lead Ind. Ass'n, Inc., 106 F.3d 1245, 1251 (5th Cir. 1997).

from, or in addition to" the requirements approved by the FDA. Moreover, a finding that the NovaSure machine is "unreasonably dangerous" as alleged by Plaintiffs would directly controvert the FDA's determination that the device is safe and effective.[9] As the Supreme Court made clear in Riegel, states are not permitted to indirectly regulate the safety and effectiveness of an FDA approved medical device through the tort system. See Riegel, 552 U.S. at 324, 128 S.Ct. at 1008; see also, Demahy v. Actavis, Inc., 593 F.3d 428, 435 (5th Cir. 2010), pet. for cert. filed, 78 USLW 3745 (June 7, 2010) (citing to Riegel, the Fifth Circuit recognized that Congress expressly preempted state failure-to-warn claims for medical devices governed by the FDCA); Lemelle v. Striker Orthopaedics, 2010 WL 996523 (W.D.La. Mar. 15, 2010) (wherein the district court determined that the plaintiff's redhibition claim was preempted under the MDA); McQuiston v. Boston Scientific Corp., 2009 WL 4016120 (W.D.La. Nov. 19, 2009) (wherein the district court found that the plaintiff's state law claims for design defect, inadequate testing, inadequate warnings, breach of express and implied warranties, manufacturing defect, negligence, fraud, and loss of consortium were preempted under the MDA); Rollins v. St. Judge Med., 583 F.Supp.2d 790 (W.D.La. 2008) (wherein the district court determined plaintiff's claims were

[9]Absent any allegations that the specific NovaSure machine used in Mrs. Poole's surgery failed to conform to the FDA-approved standards, see supra, n.6, Plaintiffs' manufacturing defect claims fall within the scope of Riegel and are preempted by the MDA. See also, Carson v. Deputy Spine, Inc., 365 Fed.Appx. 812, *1 (9th Cir. 2010) (where a medical device has received premarket approval from the FDA, the plaintiff must prove the particular device varied from the specifications approved by the FDA); McQuiston v. Boston Scientific Corp., 2009 WL 4016120 (W.D.La. Nov. 19, 2009) (where the plaintiff challenges the manufacturing process approved by the FDA by virtue of the PMA process, a finding under state law that there was a manufacturing defect would impose a requirement "different from, or in addition to" the requirements imposed by federal law).

preempted by the MDA "to the extent they [were] based on actions by defendant which complied with FDA-approved standards and requirements").

CONCLUSION

Based on the foregoing analysis, the Court finds all claims asserted by Plaintiffs in this action are expressly preempted by the MDA or are derivative of such claims. Accordingly, Hologic's Motion for Judgment on the Pleadings [Record Document 3] shall be **GRANTED** and all claims asserted by Plaintiffs in this matter shall be **DISMISSED WITH PREJUDICE.**

A Judgment consistent with this Memorandum Ruling shall issue herewith.

THUS DONE AND SIGNED in Shreveport, Louisiana, this 29th day of July, 2010.

S. MAURICE HICKS, JR.
UNITED STATES DISTRICT JUDGE