UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 15-23412-CIV-MORENO

ADRIENNE WARD and KRAIG F. LYNCH,

Plaintiffs,

vs.

ST. JUDE MEDICAL, INC., ST. JUDE MEDICAL S.C., INC. and DOES 1-100,

Defendants.
_____/

ORDER GRANTING MOTION TO DISMISS

THIS CAUSE came before the Court upon Defendant's Motion to Dismiss Plaintiffs' First Amended Complaint with Prejudice and Supporting Memorandum of Law (D.E. 19). The defendant alleges that the plaintiffs' common law state claims are preempted by federal law. The Court has considered the motion, the response in opposition, and the reply along with the pertinent portions of the record and is otherwise fully advised in the premises.

I. BACKGROUND

This is a product liability case involving a Class III medical device. The Court dismissed the plaintiffs' original complaint on federal preemption grounds. Here, the amended complaint alleges the same three common law claims: negligence (Count 1), strict liability (Count 2), and loss of consortium (Count 3). According to the complaint, plaintiff Adrienne Ward was outfitted with an implantable cardioverter-defibrillator with defective "leads," which are essentially thin, insulated wires that connect the defibrillator to the muscle tissue. Upon taking judicial notice that the device at issue in this case was a Class III medical device, the Court determined that the claims were expressly preempted by the Medical Devices Amendments of 1976 to the Food, Drug, and Cosmetic Act of 1938. Plaintiffs contend that the common law state claims of negligence, strict liability, and loss of consortium are not preempted because they are based on state requirements that are parallel to federal requirements.

II. DISCUSSION

The medical device amendments expressly preempt certain state requirements for Class III medical devices. Courts utilize a two-prong test to determine whether a state requirement on a Class III medical device is preempted. First, courts determine whether the federal government has established device-specific requirements. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008) (citing 21 U.S.C. § 360k(a)). Both parties agree, and the Court has taken judicial notice, that the St. Jude Durata Leads are Class III medical devices. As such, the Food and Drug Administration has established device-specific requirements through a "rigorous" premarketing approval process. *See id.* at 316-17 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)). Accordingly, the Court finds that the first prong has been satisfied.

The Court must next determine whether the second prong has been satisfied. The Eleventh Circuit held in *Wolicki-Gables v. Arrow Int'l Inc.*, that claims may avoid preemption only when they are predicated on state requirements that are "genuinely" equivalent to existing federal device-specific safety and effectiveness requirements. 634 F.3d 1296, 1301 (11th Cir. 2011) (citing *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005). The common law state claims of strict liability, negligent design, and negligent manufacture are not genuinely equivalent because they "impose requirements 'different from, or in addition to' federal requirements." *Riegel*, 552 U.S. 312, 321-22 (2008) (Citing *Lohr*, 518 U.S. at 512), *Llado-Carreno v. Guidant Corp.*, 2011 U.S. Dist. LEXIS 149116, *9 (S.D. Fla. 2011). The plaintiffs argue, however, that their negligence, strict liability, and loss of consortium claims are not preempted because they are parallel to federal requirements.

Parallel requirements are common law claims based on state requirements that are premised on federal regulation violations. *Wolicki-Gables*, 634 F.3d. at 1300. A parallel claim must be expressly stated in the pleading, setting forth how specific failures to comply with device-specific medical device amendment premarketing approval regulations that are linked to the plaintiffs' alleged injury. *Id.* at 1301-02. Although the amended complaint alleges that the defendants violated various federal statues, it does not present device-specific premarket violations linked to the plaintiffs' alleged harm. Rather, the claims put forth in the amended complaint contest the safety and effectiveness of the device—squarely within the scope of express preemption. In light of these facts, and the significant case law on preemption, the Court

finds that the plaintiffs' amended complaint fails to sufficiently allege parallel claims, thus the claims presented are expressly preempted by federal law.[1]

III. CONCLUSION

Accordingly, it is hereby

ORDERED AND ADJUDGED that the motion to dismiss is **GRANTED**.

DONE AND ORDERED in Chambers at Miami, Florida, this 25th of March 2016.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record

[1] Though not specifically raised by the parties, implied preemption prevents plaintiffs from using state claims to essentially enforce MDA violations on behalf of the FDA, which the plaintiffs in this case seem to suggest with the FDA warning letter on which they heavily rely. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (citing 21 U.S.C. § 337(a)), *see also Brady v. Medtronic, Inc.*, 2014 U.S. Dist. LEXIS 52151, *11, (S.D. Fla. 2014). Additionally, Florida does not recognize causes of action pursued for the purpose of enforcing FDA regulation violations. *Jackson v. Neuromodulation Div.*, 2015 U.S. Dist LEXIS 40329, *16, (M.D. Fla. 2015) (citing *Kaiser v. DePuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1192-93 (M.D. Fla. 2013), *Wheeler v. Depuy Spine, Inc.*, 706 F.Supp. 2d 1264, 1268 (S.D. Fla. 2010).