UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

JAMIE R. EDWARDS, trustee for the heirs and next of kin of Arvid A. Herrman, decedent,

Plaintiff,

v.

MEMORANDUM OF LAW & ORDER
Civil File No. 20-2451 (MJD/HB)

THORATEC LLC,

Defendant.

Anthony J. Nemo, Sr., and Nathaniel Arthur Dahl, Meshbesher & Spence, Ltd., Counsel for Plaintiff.

Janet H. Kwuon and Lisa Marie Baird, Reed Smith LLP, and Charmaine K. Harris and Deborah Elaine Lewis, Blackwell Burke P.A., Counsel for Defendant.

I. INTRODUCTION

This matter is before the Court on Defendant Thoratec LLC's Motion to Dismiss [Docket No. 17] and Defendant's unopposed Request for Judicial Notice [Docket No. 20]. The Court heard oral argument on March 24, 2021. For the reasons that follow, Defendant's motion to dismiss is denied.

II. BACKGROUND

A. Factual Background

1. The HeartMate 3

Defendant Thoratec LLC ("Thoratec") is a limited liability company with its principal place of business in California. (Compl. ¶ 6.) Thoratec is a subsidiary of Abbott Laboratories, Inc. ("Abbott"). (Id.) Thoratec develops, manufactures, and markets proprietary medical devices used for mechanical circulatory support, including the Heartmate 3™ Left Ventricular Assist System ("HeartMate 3"), an implantable medical device approved by the FDA to treat patients suffering from end-stage heart failure in the form of advanced refractory left ventricular heart failure. (Compl. ¶ 6; Lewis Decl., Ex. 3, Summary of Safety and Effectiveness Data ("SSED") at 1.)

The HeartMate 3 reroutes and pumps blood from the left ventricle into the ascending aorta. (Compl. ¶ 11.) An apical cuff is sewn into the epicardium around a cored opening near the apex of the left ventricle which serves as a securing interface between the HeartMate 3 and the patient's heart. (Compl. ¶¶ 13-14.) The inflow cannula of the pump is then inserted into the apical cuff on the left ventricle and fixed securely into place by a locking mechanism unique to the HeartMate 3 (the "slide-lock mechanism"). (Compl. ¶¶ 15-16.) The slide-lock mechanism affixes the pump to the apical cuff using two symmetrical locking arms which surround the inflow cannula and secure it to the heart by

engaging a metal ring on the apical cuff, creating an airtight seal between the inflow cannula and apical cuff. (Id. ¶ 16.)

2. Implantation of the HeartMate 3 into Arvid Herrman

On June 25, 2019, cardiovascular surgeon John Stulak, M.D., implanted a HeartMate 3 into Arvid Herrman at the Mayo Clinic in Rochester, Minnesota. (Compl. ¶¶ 35, 37.) Herrman was a resident of Wisconsin. (Id. ¶ 4.) Minutes after turning on the HeartMate 3, Hermann's left ventricle and ascending aorta filled with air, and Hermann was placed back on a cardiopulmonary bypass. (Compl. ¶¶ 41-42.) Stulak shut off the HeartMate 3, de-aired the ascending aorta and left ventricle, and then turned on the HeartMate 3 again, weaned Herrman from bypass, and increased the pump speed. (Compl. ¶ 43.) Again, a large bolus of air appeared in the ascending aorta, and Herrman was placed back on bypass. (Id.) The process of de-airing and then restarting the pump was repeated and, a third time, a large amount of air appeared in the left ventricle and ascending aorta, and Herrman was placed back on bypass. (Id. ¶ 44.) While Herrman was still on bypass and the HeartMate 3 pump was running, Stulak observed air entering Herrman's left ventricle from around the inflow cannula. (Id. ¶ 45.)

Stulak noted that the HeartMate 3 could rotate freely on the apical cuff even though it was locked into place by the slide-lock mechanism. (Id. ¶ 46.)

Stulak removed the HeartMate 3 and compared it to the underside of a newly opened replacement HeartMate 3. (Compl. ¶ 47.) He observed that the locking arms of the explanted HeartMate 3 were asymmetrical and that the left locking arm of the explanted HeartMate 3 was bent and distracted away from the inflow cannula. (Id.) Stulak concluded that the bent left locking arm of the slide-lock mechanism rendered the explanted HeartMate 3 device defective and created negative pressure allowing air to leach into the ventricle. (Id. ¶¶ 48-49.)

Stulak implanted a replacement HeartMate 3 with locking arms that were symmetrical and not bent. (Compl. ¶ 50.) He engaged the slide-lock mechanism without difficulty, the pump functioned normally, and the surgery was concluded. (Id.) However, Herrman never regained consciousness and, on July 12, 2019, Hermann passed away. (Compl. ¶¶ 51-53.) His cause of death was determined to be multiple air emboli caused by a leak at the interface between the inflow cannula and apical connector of the explanted HeartMate 3, resulting in severe brain injury and multi-organ failure. (Id. ¶ 53.)

The explanted HeartMate 3 was returned to Thoratec for inspection, and Thoratec confirmed that the locking arms were asymmetrical and one of the arms was bent outward, deviating from the FDA-approved specifications. (Compl. ¶ 54.)

3. Medical Device Amendments

The 1976 Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360C et seq., created a comprehensive "regime of detailed federal oversight" for medical devices. Riegel v. Medtronic, 552 U.S. 312, 316 (2008). The MDA creates three classes of medical devices based on use and level of potential risk. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 343 (2001). The HeartMate 3 is a Class III medical device, i.e., one that "support[s] or sustain[s] human life" or "presents a potential unreasonable risk of illness or injury" and, thus, "incur[s] the FDA's strictest regulation." Id.; 21 U.S.C. § 360c(a)(1)(C)(ii).

> Before a new Class III device may be marketed, the manufacturer must assure the FDA through a rigorous Pre–Market Approval ("PMA") process that the device is safe and effective. Once the product is approved, the manufacturer may not change its design, manufacturing process, labeling, or other attributes that would affect safety or effectiveness without filing a PMA Supplement. The PMA Supplement is reviewed using the same standard as the original PMA.

In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1203 (8th Cir. 2010) (citations omitted) ("Sprint Fidelis II").

4. FDA Approval of the Heartmate 3

On August 23, 2017, the FDA granted premarket approval for the HeartMate 3 for short-term hemodynamic support, as a "bridge to [heart] transplant or bridge to myocardial recovery." (Compl. ¶ 30.) On October 18, 2018, the FDA approved the HeartMate 3 for long-term mechanical circulatory support, or as a "destination therapy." (Id. ¶ 31.) One of the design specifications set forth in the FDA-approved PMA for the HeartMate 3 requires the two locking arms of the slide-lock mechanism to be symmetrical and coapt uniformly around the inflow cannula of the pump, so that the inflow cannula tightly affixes to the apical cuff on the left ventricle and air does not leak at the cannula-cuff interface. (Id. ¶¶ 27-28, 32.)

B. Procedural History

On September 4, 2019, a Minnesota state court appointed Plaintiff Jamie Edwards, a resident of Wisconsin, as trustee for the heirs and next of kin of Herrman. (Compl. ¶ 5.)

On December 3, 2020, Plaintiff filed a Complaint against Abbott and Thoratec in this Court. [Docket No. 1] The Complaint asserts two state law counts against Abbott and Thoratec: Count 1: Negligence; and Count 2: Strict Liability – Manufacturing Defect. On February 19, 2021, Plaintiff voluntarily dismissed Defendant Abbott. [Docket No. 35]

In Count 1: Negligence, Plaintiff alleges that Thoratec had a duty to manufacture the HeartMate 3 so that it was not defective and in accordance with its design specifications, so that the two locking arms were symmetrical and tightly affixed the pump to the left ventricle so that air did not leak at the cannula-cuff interface, that Thoratec breached this duty, and that Herrman died as a result. (Compl. ¶¶ 57-62.) In Count 2: Strict Liability – Manufacturing Defect, Plaintiff further alleges that the explanted HeartMate 3 was in a defective condition and unreasonably dangerous because, when it left Thoratec's control, the left locking arm was bent, not manufactured in accordance with its FDA-approved design specifications, and leaked air at the cannula-cuff interface, which caused Herrman's death. (Id. ¶¶ 66-71.)

Plaintiff has alleged that Thoratec was required under federal law to manufacture the HeartMate 3 according to the following design specifications:

> Manufacturing the HeartMate 3 so that the two locking arms of its slide-lock mechanism are symmetrical;
>
> Manufacturing the HeartMate 3 so that the locking arms of the slide-lock mechanism are not bent out of specification;
>
> Manufacturing the HeartMate 3 so that its slide-lock mechanism tightly affixes the inflow cannula to the apical cuff; and
>
> Manufacturing the HeartMate 3 so that air does not leak at the interface between the inflow cannula and the apical cuff resulting in air embolism.

(Compl. ¶ 32.) Plaintiff alleges that the explanted HeartMate 3 deviated from these federal requirements as found when Stulak inspected the explanted HeartMate 3 and when the explanted HeartMate 3 was returned to Thoratec for inspection.

Thoratec has now moved to dismiss the Complaint on the grounds that Plaintiff's claims are federally preempted.

III. DISCUSSION

A. Motion to Dismiss Standard

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a party may move the Court to dismiss a claim if, on the pleadings, a party has failed to state a claim upon which relief may be granted. In reviewing a motion to dismiss, the

Court takes all facts alleged in the complaint to be true. Zutz v. Nelson, 601 F.3d 842, 848 (8th Cir. 2010).

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. Thus, although a complaint need not include detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.

Id. (citations omitted).

In deciding a motion to dismiss, the Court considers the complaint and "materials that are part of the public record or do not contradict the complaint, as well as materials that are necessarily embraced by the pleadings. For example, courts may consider matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint." Greenman v. Jessen, 787 F.3d 882, 887 (8th Cir. 2015) (citations omitted). Here, the Court grants Defendants' unopposed request that the Court take judicial notice of five documents that are publicly available on the FDA's website. (See Lewis Decl., Exs. 1-5.)

B. Choice of Law

The Complaint does not specify what state law applies. Plaintiff is a Wisconsin resident, and Herrman was a Wisconsin resident at the time of the

surgery. The surgery and injury occurred in Minnesota, and a Minnesota court appointed Plaintiff as trustee. At this stage, Minnesota and Wisconsin law are the same for purposes of the Court's preemption analysis. Thus, at this stage, the Court will apply the law of the forum state, Minnesota.

C. Preemption

"The general law of preemption is grounded in the Constitution's command that federal law 'shall be the supreme Law of the Land.' U.S. Const. art. VI, cl. 2." In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig., 621 F.3d 781, 791 (8th Cir. 2010). "Thus state law that conflicts with federal law has no effect." Id. (citation omitted).

"Express preemption exists where Congress uses explicit pre-emptive language to express its purpose." Id. at 792 (citation omitted).

> Implied preemption exists where a federal statutory or regulatory scheme is so pervasive in scope that it occupies the field, leaving no room for state action—this is termed field preemption. Implied preemption also occurs where state law has not been completely displaced but is superseded to the extent that it conflicts with federal law—this is known as conflict preemption.

Id. (citation omitted).

D. Express Preemption

1. Express Preemption Standard under the MDA

The MDA provides:

> Except as provided in subsection (b), 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). Thus, to determine whether the MDA preempts Plaintiffs' state law claims, first, the Court "must determine whether the Federal Government has established requirements applicable to [Thoratec's HeartMate 3]." Riegel, 552 U.S. at 321. Second, the Court must "determine whether [Plaintiff's] common-law claims are based upon [] requirements with respect to the device that are different from, or in addition to' the federal ones, and that relate to safety and effectiveness." Id. at 321-22 (citation omitted). Thus, the MDA "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." Medtronic, Inc. v. Lohr, 518 U.S. 470, 496–97 (1996) (quoting 21 C.F.R. § 808.1(d)(2) (1995)).

> The Supreme Court thus has made clear that section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law, but it does not extend protection from liability where the claim is based on a violation of federal law. In other words, where state law is parallel to federal law, section 360k does not preempt the claim.

Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010).

2. Whether the Federal Government Has Established Requirements Applicable to Thoratec's HeartMate 3

The first prong of the Riegel test is met because, as a matter of law, the Premarket Approval of a medical device imposes federal requirements applicable to the device. See, e.g., Riegel, 552 U.S. at 322-23.

3. Whether the State Law Claim Would Impose Safety or Effectiveness Requirements with Respect to the Device that Are Different from, or in Addition to, the Federal Requirements

Express preemption does not apply because Plaintiff's state law claims would not impose safety or effectiveness requirements that are different from or in addition to the federal requirements. Rather, Plaintiff asserts a quintessential parallel claim: she alleges that Thoratec is liable for state law manufacturing defect and negligence claims because it produced a device with asymmetrical arms that failed to prevent air from leaking at the cannula-cuff interface, and producing a device with asymmetrical arms that failed to prevent air from

leaking at the cannula-cuff interface also violated the federal PMA requirement for the device. Plaintiff specifically alleges a violation of a particular PMA requirement that also constitutes a violation of state manufacturing defect law. See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) ("Sprint Fidelis I") (noting that "Riegel left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted"). Manufacturing defect claims pled with sufficient specificity regarding how a device deviated from its PMA specifications are not preempted. See, e.g., Sullivan v. Medtronic, Inc., No. 4:20 CV 344 CDP, 2020 WL 6381819, at *6 (E.D. Mo. Oct. 30, 2020) (holding that strict liability and negligence claims were not preempted where plaintiff alleged Medtronic failed to manufacture its infusion pump in accordance with the manufacturing specifications set out in its PMA); Eggerling v. Advanced Bionics, L.L.C., 958 F. Supp. 2d 1029, 1038-39 (N.D. Iowa 2013) (holding manufacturing defect claims not preempted where plaintiff alleged that manufacturer's cochlear implant did not comply with the PMA because it contained an unapproved AstroSeal feed-thru assembly rather than the PA&E feed-thru assembly required by the PMA).

The Court finds no legal support for Defendant's claim that Plaintiff must allege exactly went wrong in Thoratec's proprietary manufacturing process to survive the pleading stage. So long as a plaintiff alleges a violation of a specific PMA requirement (here, the requirement that the device have symmetrical arms) that caused the injury (here, death from multiple air emboli caused by the asymmetrical arm allowing air to leak) and, as required under state law, that defect existed when the device left the defendant's control (Compl. ¶ 68), the claim is sufficient, keeping in mind that the Court "must exercise [care] in applying Riegel's parallel claim principle at the pleading stage, particularly to manufacturing defect claims." Spring Fidelis II, 623 F.3d at 1206-07.

E. Implied Preemption

In addition to express preemption, the MDA provides for implied preemption under 21 U.S.C. § 337(a), which states that "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." "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." Buckman Co., 531 U.S. at 349 n.4.

Because Plaintiff is suing for alleged conduct that both violates federal law and would give rise to recovery under state law in the absence of the FDCA, her claims are not preempted.

F. Conclusion

> Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

Sprint Fidelis II, 623 F.3d at 1204 (citation omitted).

Although Plaintiff is suing for conduct that violates the FDCA (failure to comply with the PMA requirements regarding symmetrical arms), she is not suing because the conduct violates the FDCA, but rather, because the manufacture of the device with asymmetrical arms rendered the HeartMate 3 unreasonably dangerous under state tort law. Therefore, Plaintiff's claims are not preempted, and Defendant's motion to dismiss is denied.

Accordingly, based upon the files, records, and proceedings herein**, IT IS HEREBY ORDERED**:

1. Defendant's unopposed Request for Judicial Notice [Docket No. 20] is **GRANTED**.

2. Defendant Thoratec LLC's Motion to Dismiss [Docket No. 17] is **DENIED**.

Dated: March 31, 2021

s/Michael J. Davis
Michael J. Davis
United States District Court