UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

KIRK J. BLEDSOE,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.

CAUSE NO.: 2:18-CV-133-TLS

OPINION AND ORDER

This matter is before the Court on Defendant Medtronic, Inc.'s Motion for Summary Judgment [ECF No. 61], which is fully briefed and ripe for ruling. For the reasons set forth below, the Court grants the Defendant's motion.

PROCEDURAL BACKGROUND

On November 3, 2017, Plaintiff Kirk J. Bledsoe, through counsel, filed a Complaint [ECF No. 5] against Defendant Medtronic, Inc. The Plaintiff alleged two counts of negligence and one count of strict liability, all under the Indiana Product Liability Act (IPLA), Ind. Code § 34-20-1-1 et seq. Compl. at 4–9, ECF No. 5. The Plaintiff claimed he suffered injuries as the direct and proximate result of a defective, implantable SynchroMed® II infusion pump, model 8637-40, which was manufactured, sold, and monitored by the Defendant. *Id.* at 1, 4.

The Defendant moved to dismiss the Plaintiff's claims for failure to state claim. ECF No. 8. On January 3, 2020, the Court ruled on the motion to dismiss, beginning its analysis by explaining that the IPLA permits three types of actions—failure to warn, design defect, and manufacturing defect. ECF No. 24, p. 11. The Court dismissed the Plaintiff's failure to warn and design defect claims as preempted by the Medical Device Amendments (MDA) to the Food,

Drug and Cosmetic Act, 21 U.S.C. § 360k(a),[1] but permitted the Plaintiff's manufacturing defect claim to move forward. ECF No. 24, p. 11–15. The Court held that, "to the extent the Plaintiff's Complaint alleges that his injuries were caused by a manufacturing defect in the production of his medical device *and* that the defect was caused by a violation of the federal requirements, his claim is properly pled and not preempted." *Id.* at 15. The Court explicitly noted that, "[t]o prevail on his claim, the Plaintiff will ultimately have to specify a violation of a particular federal requirement and will have to prove that his injury was the direct and proximate cause of that violation." *Id.*

On April 28, 2021, the Defendant filed the instant Motion for Summary Judgment [ECF No. 61] on the Plaintiff's manufacturing defect claim. On May 27, 2021, the Plaintiff, who is now proceeding pro se, filed a Response [ECF No. 69], and on June 9, 2021, the Defendant filed a Reply [ECF No. 72]. On June 15, 2021, the Plaintiff filed a "Reply" [ECF No. 73] to the Motion for Summary Judgment.

SUMMARY JUDGMENT STANDARD

Summary judgment is warranted when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The movant may discharge this burden by "either: (1) showing that there is an absence of evidence supporting an essential element of the non-moving party's claim; or (2) presenting affirmative evidence that negates an essential element of the non-moving party's

[1] The MDA preemption provision states:

> [N]o 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).

claim." *Hummel v. St. Joseph Cnty. Bd. of Comm'rs*, 817 F.3d 1010, 1016 (7th Cir. 2016) (citation omitted). In response, the non-movant "must make a sufficient showing on every element of his case on which he bears the burden of proof; if he fails to do so, there is no issue for trial." *Yeatts v. Zimmer Biomet Holdings, Inc.*, 940 F.3d 354, 358 (7th Cir. 2019) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)).

In ruling on a motion for summary judgment, a court must construe all facts and draw all reasonable inferences in the light most favorable to the nonmoving party. *Id.* (citation omitted). A court's role "is not to sift through the evidence, pondering the nuances and inconsistencies, and decide whom to believe. The court has one task and one task only: to decide, based on the evidence of record, whether there is any material dispute of fact that requires a trial." *Waldridge v. Am. Hoechst Corp.*, 24 F.3d 918, 920 (7th Cir. 1994) (citations omitted). Facts that are outcome determinative under the applicable law are material for summary judgment purposes. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

FACTUAL BACKGROUND

The SynchroMed® II Infusion System is a Class III[2] medical device that treats certain medical conditions by delivering medication (e.g., baclofen or morphine sulfate) via an implanted pump and catheter directly to the "intrathecal" area where fluid flows around the

[2] The United States Congress has established a regulatory regime for medical devices that classifies devices by the level of risk they present. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); *see also* 21 U.S.C. § 360c. Class III devices require the most oversight. *Riegel*, 552 U.S. at 317. These devices include "replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators." *Id.* In *Riegel*, the United States Supreme Court described Class III devices as follows:

> 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)).

spinal cord. Glen Smythe Decl. ¶ 4, ECF No. 63-1. The U.S. Food and Drug Administration (FDA) approved the SynchroMed® II Infusion System and its component parts for commercial release via its Premarket Approval (PMA), PMA Supplement, and Annual Report processes. *Id.* at ¶ 5. The FDA approves products for market release via a PMA or PMA Supplement only after it is satisfied there is a reasonable assurance that the devices are safe and effective for their intended uses and comply with the FDA-mandated requirements for approval. *Id.*

On November 5, 2004, the Plaintiff had implanted a Model 8637-40 SynchroMed® II pump (serial number NGV004193N) and a Model 8731 intrathecal catheter (serial number N001532131). Wade Linnertz Decl. ¶ 4, ECF No. 64. On June 14, 2011, the Plaintiff had implanted a different Model 8637-40 SynchroMed® II pump (serial number NGV450625H). *Id.* at ¶ 5. And on December 3, 2014, the Plaintiff had implanted a Model 8780 Ascenda® catheter (serial number N505359002). *Id.* at ¶ 6.

The FDA granted PMA to the original SynchroMed® Infusion System via PMA 860004 on March 14, 1988. Smythe Decl. at ¶ 6. The FDA granted PMA to the Model 8637 SynchroMed® II pump via PMA 860004, Supplement 56, on September 12, 2003. *Id.* at ¶ 7. The FDA granted PMA to the Model 8731 intrathecal catheter on October 11, 2002, via PMA 860004, Supplement 54, *id.* at ¶ 8, and to the Model 8780 Ascenda® catheter on May 2, 2012, via PMA 860004, Supplement 125, *id.* at ¶ 9.

Since the FDA's original approval of the SynchroMed® Infusion System in 1988 through the present date, the FDA has maintained oversight of the design, manufacture, composition, labeling, warnings, marketing, sale, device tracking, and performance reporting for the device, including the above-mentioned pumps, catheters, and their accompanying manuals and documents. *Id.* at ¶ 10. The FDA has approved hundreds of supplements concerning the

SynchroMed® II Infusion System, and it retains the authority to initiate proceedings to withdraw approval should it deem any medical device unsafe or ineffective or determine that the medical device's potential risks outweigh its benefits. *Id.* The PMA for the SynchroMed® II Infusion System, including all of the above-mentioned pumps and catheters, remains valid and has never been withdrawn, revoked, or suspended. *Id.* at ¶ 11.

As a Class III, prescription-only medical device, the SynchroMed® II Infusion System is subject to the FDA's enhanced regulatory controls: the Quality Systems Regulations (QSRs) and Current Good Manufacturing Practices (CGMPs) set forth in 21 C.F.R. Part 820 et seq. Linnertz Decl. at ¶ 9. In compliance with the FDA's QSR and CGMP regulations, Medtronic's manufacturing facilities created and follow a quality assurance program, written manufacturing specifications and procedures, written procedures for acceptance, storage, and handling, and written procedures for finished device inspection. *Id.* at ¶ 10.

During the assembly process, every SynchroMed® II Infusion System pump and catheter undergoes testing and inspection to assure that it conforms to the FDA-approved design requirements and specifications, including visual, mechanical, electrical, and dimensional inspections and tests. *Id.* at ¶ 13. Medtronic only provides a SynchroMed® II pump or catheter for sale if it has passed the tests and inspections compiled within the design specifications established for the specific device. *Id.* If a device does not pass each test and inspection, the device is not provided for sale. *Id.*

Medtronic produces a "traceability card" for each device it manufactures. *Id.* at ¶ 11. A traceability card details information such as the device identification number or lot control number, each manufacturing or inspection operation the device goes through, the specification or policy controlling each operation, the identity of the technicians who performed each operation,

the date of each step of the process, and the product labels and literature packaged with the device. *Id.* at ¶ 12. The traceability card for the Plaintiff's second pump demonstrates that his SynchroMed® II Model 8637-40 (Serial number NGV450625H) was manufactured in Medtronic's Juncos, Puerto Rico manufacturing facility from May 3, 2011, through May 31, 2011; met all of Medtronic's FDA-approved specifications; passed each quality assurance inspection and test; and was packaged with the warnings and labeling approved by the FDA. *Id.* at ¶ 18. The traceability cards for the Plaintiff's second catheter demonstrate that his Ascenda® Model 8780 (Serial number N505359002) was manufactured in Medtronic's Sullivan Lake, Minnesota manufacturing facility from October 9, 2014, through October 28, 2014; met all of Medtronic's FDA-approved specifications; passed each quality assurance inspection and test; and was packaged with the warnings and labeling approved by the FDA. *Id.* at ¶ 19.

DISCUSSION

In support of its Motion for Summary Judgment, the Defendant argues three grounds upon which the Plaintiff's manufacturing defect claim fails. First, the Defendant argues the Plaintiff failed to specify a violation of a particular federal requirement and prove that his injury was the direct and proximate cause of that violation. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010) (explaining that the plaintiff may succeed on her state law manufacturing defect claim "so long as she can show that she was harmed by a violation of applicable federal law"). Second, the Defendant argues the Plaintiff has failed to show that the product deviates from its intended design. *See Piltch v. Ford Motor Co.*, 778 F.3d 628, 632–33 (7th Cir. 2015) ("To demonstrate a manufacturing defect, the plaintiff must show that 'the product deviates from its intended design.'" (quoting *Hathaway v. Cintas Corp. Serv., Inc.*, 903 F. Supp. 2d 669, 673 (N.D. Ind. 2012))). Third, the Defendant argues the Plaintiff has failed to disclose an expert

witness to establish causation, which may be required when causation issues are complex. *See Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 642 (7th Cir. 2010) ("[W]hen there is no obvious origin to an injury and it has multiple potential etiologies, expert testimony is necessary to establish causation." (internal quotation marks omitted)). The Court finds that the Plaintiff has failed to present an issue of material fact as to whether the Defendant violated a particular federal requirement. The Court, therefore, does not reach the Defendant's subsequent arguments.

In evaluating the Plaintiff's products liability claim, the Court must apply Indiana law. *See Officer v. Chase Ins. Life & Annuity Co.*, 541 F.3d 713, 715 (7th Cir. 2008) ("When sitting in diversity, we must apply the substantive law of the state as we believe the highest court of that state would apply it . . . ."). In Indiana, the IPLA governs all actions for products liability. *See Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (Ind. 1981) ("The Product Liability Act expressly applies to all product liability actions sounding in tort, including those based on the theory of negligence . . . ."); *see also* Ind. Code. § 34-20-1-1 ("This article governs all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought."). The IPLA provides, in relevant part, that

> a person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user's or consumer's property is subject to liability for physical harm caused by that product to the user or consumer or to the user's or consumer's property if:
>
> (1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;
> (2) the seller is engaged in the business of selling the product; and
> (3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under this article.

Ind. Code § 34-20-2-1.

Notwithstanding the IPLA's governance over Indiana product liability claims, the MDA preempts state product liability requirements that are different from federal requirements. 21 U.S.C. § 360k(a). Specifically, the MDA preemption provision states:

> [N]o 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.

Id.

The United States Supreme Court has outlined a two-part test to determine whether the MDA preempts a state claim related to a particular medical device. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320–21 (2008). First, a court must determine whether the federal government has established requirements particular to the device in question. *Id.* at 321. To satisfy this part of the preemption test, the federal requirement must be specific to the device in question and not simply reflect "'generic concerns about device regulation generally.'" *Id.* at 322 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996)). Second, if the court finds that a federal requirement exists, it must then determine whether the plaintiff's claims rely upon a state law that imposes requirements "different from, or in addition to" the applicable federal requirements and whether the state law "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Id.* at 323 (quoting 21 U.S.C. § 360k(a)).

A claim for defective manufacture in violation of federal law is not expressly preempted by the MDA. *Bausch*, 630 F.3d at 553. Since state requirements are preempted only to the extent they are "different from, or in addition to" the relevant federal requirements, a claim premised on a violation of FDA regulations would not be preempted. *Riegel*, 552 U.S. at 330 ("[Section] 360k(a) 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." (quoting *Lohr*, 518 U.S. at 495)).

Accordingly, at the pleading stage, this Court held that the Plaintiff's manufacturing defect claim was not preempted by the MDA. ECF No. 24 at 14. The Court found that "the complaint certainly alleges that his injuries were the direct and proximate result of the Defendant's negligence and that the Defendant's negligence included, among other things, failing to comply with the federal requirements." *Id.* The Court continued, however, explaining that, "[t]o prevail on his claim" beyond the pleading stage, the Plaintiff must "specify a violation of a particular federal requirement and will have to prove that his injury was the direct and proximate cause of that violation." *Id.* at 15; *see also Bausch*, 630 F.3d at 558 (explaining that the plaintiff may succeed on her state law manufacturing defect claim "so long as she can show that she was harmed by a violation of applicable federal law").

In the Plaintiff's response to the instant motion for summary judgment, he has not argued that the Defendant violated a particular federal requirement, nor has he produced evidence to that effect. The Plaintiff argues that "[n]o company . . . makes perfect assemblies," Pl. Resp. 11, ECF No. 69; that Medtronic could not have total quality control, *id.*; and that Medtronic had several issues with manufacturing at one of its plants, *id.* Additionally, the Plaintiff casts doubt on the reliability of Medtronic's quality control logbooks. *Id.* However, the Plaintiff has not supported these arguments with any facts, documents, depositions, or declarations.

Meanwhile, the Defendant has offered documentation that the FDA approved its devices through the pre-market approval process, and it provided evidence that the devices in question passed each test designed to align them with FDA requirements. The Plaintiff, not having established any facts in the record to support an inference that the Defendant violated a federal

requirement applicable to its devices—a necessary element of the Plaintiff's manufacturing defect claim—has failed to present an issue of material fact that would require a trial.

CONCLUSION

For the reasons set forth above, the Court hereby GRANTS Defendant Medtronic, Inc.'s Motion for Summary Judgment [ECF No. 61]. The Court DIRECTS the Clerk of Court to enter judgment in favor of the Defendant Medtronic, Inc. and against the Plaintiff Kirk J. Bledsoe.

SO ORDERED on October 13, 2022.

s/ Theresa L. Springmann
JUDGE THERESA L. SPRINGMANN
UNITED STATES DISTRICT COURT