IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

KIMBERLY FREY, *

Plaintiff, *

vs. * CASE NO. 3:20-CV-41 (CDL)

BAYER CORPORATION, *et al.*, *

Defendants. *

O R D E R

Kimberly Frey alleges that she suffered injuries caused by Defendants' Essure product, an implantable birth control device. Defendants assert that all of Frey's claims are preempted by federal law because Essure is a Class III medical device and was approved for sale by the U.S. Food and Drug Administration through its premarket approval process. As discussed below, the Court denies Defendants' motion to dismiss Frey's negligent manufacturing claim and grants in part and denies in part their motion to dismiss Frey's breach of express warranty claim (ECF No. 14).

MOTION TO DISMISS STANDARD

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S.

662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The complaint must include sufficient factual allegations "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. In other words, the factual allegations must "raise a reasonable expectation that discovery will reveal evidence of" the plaintiff's claims. *Id.* at 556. But "Rule 12(b)(6) does not permit dismissal of a well-pleaded complaint simply because 'it strikes a savvy judge that actual proof of those facts is improbable.'" *Watts v. Fla. Int'l Univ.*, 495 F.3d 1289, 1295 (11th Cir. 2007) (quoting *Twombly*, 550 U.S. at 556).

FACTUAL ALLEGATIONS

Frey was implanted with the Essure device, "a form of permanent female birth control." Am. Compl. ¶ 22, ECF No. 12. Following the implantation, Frey suffered "migraine headaches, backaches and pain during intercourse, fatigue, hair loss, weight gain, metal taste in mouth, and receding gums" that she attributes to the Essure device. *Id.* ¶¶ 133, 135. She underwent a hysterectomy and salpingectomy (removal of fallopian tubes) to remove the Essure device. Frey asserts causes of action for negligent manufacturing, *id.* ¶¶ 139-157, and breach of express warranty, *id.* ¶¶ 158-172. Defendants argue that both of Frey's claims are preempted by the Medical Device Amendments to the federal Food Drug and Cosmetic Act.

DISCUSSION

The Medical Device Amendments to the federal Food Drug and Cosmetic Act ("MDA") "imposed a regime of detailed federal oversight" for medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). "The devices receiving the most federal oversight" by the U.S. Food and Drug Administration are Class III medical devices. *Id.* at 317. The MDA "established a rigorous regime of premarket approval for new Class III devices." *Id.* The process involves a multivolume application, and the "FDA spends an average of 1,200 hours reviewing each application." *Id.* at 318. The FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (quoting 21 U.S.C. § 360e(d)). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i), redesignated as 21 U.S.C. § 360e(d)(5)(A)(i)). Frey does not dispute that Essure is a Class III medical device that was approved via the FDA's premarket approval process.

The MDA contains an express preemption clause:

> [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). Thus, state requirements are expressly preempted under the MDA if "they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). But, "duties imposed by state law are preempted only to the narrow extent that they add different or extra requirements to the safety and effectiveness of the medical device beyond those required by the federal scheme." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1326 (11th Cir. 2017) (citing *Riegel*, 552 U.S. at 330)). "'Parallel' state duties survive so long as they claim a violation of state tort law that aligns with a federal requirement." *Id.* "In contrast, a claim that a device 'violated state tort law notwithstanding compliance with the relevant federal requirements' would clearly be preempted." *Id.* (quoting *Riegel*, 552 U.S. at 330).

The Eleventh Circuit has also recognized that the Food Drug and Cosmetic Act impliedly preempts fraud-on-the-FDA claims,

even if they are labeled as something else, like a negligence claim based on a manufacturer's failure to investigate adverse events and report them to the FDA. *Id.* at 1327, 1330 (discussing 21 U.S.C. § 337(a) and *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341 (2001)). But, "traditional state-law tort claims survive implied preemption so long as they don't seek to enforce a duty owed to the FDA." *Id.* at 1327.

In light of these two types of preemption, "a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption)," but to avoid implied preemption she "cannot sue only because the conduct violated that federal requirement." *Id.* The duty allegedly breached cannot be one owed only to the FDA; it must be owed to the product user. "[A] plaintiff may proceed on her claim so long as she claims the 'breach of a well-recognized duty owed to her under state law' and so 'long as she can show that she was harmed by a violation of applicable federal law.'" *Id.* (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)).

Defendants argue that both of Frey's claims are preempted by federal law. Frey contends that her claims are grounded in traditional state tort duties that predated the MDA and are parallel to and not different from or in addition to federal requirements. The Court will examine each claim in turn.

I. Negligent Manufacturing Claim

Frey claims that there were "multiple manufacturing defects in" her Essure device that caused the device "to migrate and/or break/fracture and/or caused" her "to experience heavy menstrual cycle bleeding and long-term chronic pain amongst other side effects." Am. Compl. ¶ 143 (listing manufacturing defects). Frey further asserts that her Essure device "deviated materially from [the FDA-approved] design and manufacturing specifications in such a manner as to pose unreasonable increased risks of serious bodily harm to Plaintiff." *Id.* ¶ 144. She also alleges that although Defendants had a duty to manufacture the Essure device "consistent with the specifications, requirements, federal regulations, [premarket approval], and/or conditions of approval," the Essure device that was implanted in Frey was "unreasonably dangerous due to non-compliance with the [Food Drug and Cosmetic Act] and the regulations promulgated pursuant to it," including the "current good manufacturing practices . . . expressed in 21 C.F.R. part 820." *Id.* ¶¶ 147-149. And, Frey alleges that FDA inspections discovered specific violations of the current good manufacturing practices at Defendants' manufacturing facilities that contributed to manufacturing defects. *E.g., id.* ¶¶ 94-97 (alleging that Defendants' conduct violated 21 C.F.R. § 820.100, which requires manufacturers to maintain procedures for implementing corrective and preventative

action to address product quality issues; 21 C.F.R. § 820.30, which requires design controls to ensure that specified design requirements are met; 21 C.F.R. § 820.70, which requires production controls to ensure conformance to specifications; 21 C.F.R. § 820.90, which requires control of nonconforming product; and 21 C.F.R. part 814, which provides in part that a device may not be manufactured in a manner that is inconsistent with the FDA's conditions of approval).

Georgia law recognizes a common law negligence claim based on a manufacturing defect theory of liability. *See, e.g., Miller v. Ford Motor Co.*, 653 S.E.2d 82, 84 (Ga. Ct. App. 2007) ("[T]o establish a negligent manufacturing claim, the plaintiff must come forward with evidence that, among other things, there was a defect in the product when it left the manufacturer that was caused by the manufacturer's negligence."); *see also Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994) (noting that "a manufacturer has a duty to exercise reasonable care in manufacturing its products so as to make products that are reasonably safe for intended or foreseeable uses"). The Court is satisfied that Frey adequately alleges that a negligent manufacturing defect caused her injuries. *See* Am. Compl. ¶¶ 143-144, 147-149 (alleging that Frey's Essure device had a manufacturing defect that was caused by Defendants' failure to follow FDA manufacturing rules and that Frey suffered injuries

as a result); *see also Mink*, 860 F.3d at 1329 (concluding that a plaintiff adequately alleged a manufacturing defect in the joint replacement system that was implanted in him because he alleged that "a properly manufactured . . . system would not cause immediate and toxic levels of chromium and cobalt in [his] blood from the date of surgery") (second alteration in original). Defendants argue that several district courts have found allegations similar to Frey's to be implausible under *Iqbal* and *Twombly*. With all due respect to those courts, this Court cannot divine that Frey will be unable to prove her allegations. If the manufacturing defect allegations in her Amended Complaint are taken as true, as they must be at this stage in the litigation, then they plausibly give rise to an entitlement to relief.

Defendants argue that even if Frey adequately alleges a negligent manufacturing claim, that claim is preempted by federal law. Again, Frey alleges that Defendants violated the Georgia common law duty to use reasonable care in manufacturing a medical device. "This duty is parallel to the federal requirement that the [Essure device] be manufactured according to the approved specifications for the medical device. Said another way, [Frey] alleges that [Defendants'] violation of a federal requirement also caused the violation of a state-law duty." *Mink*, 860 F.3d at 1330. The Eleventh Circuit has

recognized that "as long as the state tort law claim is premised on a violation of federal law, it survives if it does not impose new requirements on the medical device." *Id.* As discussed above, Frey alleges that Defendants negligently failed to manufacture her Essure device in a manner consistent with federal requirements and that this failure resulted in a manufacturing defect that caused her injuries. *See, e.g.,* Am. Compl. ¶¶ 147-49; *see also Godelia v. Doe 1*, 881 F.3d 1309, 1320 (11th Cir. 2018) (concluding that the plaintiff's negligent manufacturing claim was not preempted because he alleged violations of specific federal regulations, including provisions of the current good manufacturing practices regulations expressed in 21 C.F.R. § 820.1, *et seq.*, and noting that an injured patient likely would not have an opportunity to access documents regarding product-specific regulatory requirements without discovery). Accordingly, Frey's negligent manufacturing claim "is not [expressly] preempted by federal law to the extent that it is premised on a manufacturing defect theory in violation of federal requirements." *Mink*, 860 F.3d at 1331. Nor is Frey's negligent manufacturing claim impliedly preempted because the "duty of a manufacturer to use due care in manufacturing a medical device predates the Medical Device Amendments, and is a duty that [Defendants owe Frey] (as opposed to the FDA)." *Id.* at 1330. "It remains to be seen if [Frey]

can prove [her] allegations, but they are properly pled and not preempted." *Id.* at 1334. Thus, the Court denies Defendants' motion to dismiss Frey's negligent manufacturing claim.

II. Breach of Express Warranty Claim

Frey alleges that Defendants made various misrepresentations in a patient brochure, a physician manual, a product fact sheet, advertising, and news releases—including express warranties to patients like her. Am. Compl. ¶¶ 72, 74, 159-160. She further alleges that Essure "did not conform to the representations" and thus "was not safe and effective." *Id.* ¶¶ 162. And, Frey alleges that both she and her physicians relied on Defendants' representations and marketing in deciding to use Essure for Frey. *Id.* ¶¶ 167-170.

Defendants argue that all the alleged misrepresentations track language that was approved by the FDA during the premarket approval process and that Frey's warranty claim is preempted for this reason. In support of their motion to dismiss, Defendants submitted copies of the Essure instructions for use and patient information booklet. Frey, who alleges that both documents contain misrepresentations, does not dispute that these documents are central to her claims, and she does not challenge the authenticity of the documents.[1] She also does not dispute

[1] Frey does not object to Defendants' reliance on these documents. Even if she had objected, "the court may consider a document attached to a motion to dismiss without converting the motion into one for

that the FDA reviewed and approved the Essure labeling, including the instructions for use (for doctors) and patient information booklet (for patients), as part of the premarket approval process.[2] Defendants assert that the alleged misrepresentations listed in Frey's complaint are all consistent with FDA-approved statements in the instructions for use or the patient information booklet. The Court reviewed the alleged misrepresentations and Defendants' citations to the FDA-approved statements.

1. Alleged misrepresentation: The patient brochure states that Essure is the only FDA-approved female sterilization procedure to have zero pregnancies in the clinical trials Am. Compl. ¶¶ 72(a).
   FDA-approved statement: "In the Essure clinical studies, zero (0) pregnancies were reported in women who had the Essure inserts for up to 5 years." Defs.' Request for Judicial Notice Ex. L, Essure Patient Guide at 12, ECF No. 15-12 (hereinafter "Patient Guide").

2. Alleged misrepresentation: The patient brochure and advertising state that Essure is "surgery-free." Am. Compl. ¶ 72(b).
   FDA-approved statement: The Patient Guide states that Essure is a "Non-Surgical" procedure. Patient Guide at 5.

3. Alleged misrepresentation: The patient brochure and advertising describe Essure as "worry free" and a "simple

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summary judgment if the attached document is (1) central to the plaintiff's claim" and (2) its authenticity is not challenged. *Day v. Taylor*, 400 F.3d 1272, 1276 (11th Cir. 2005).

[2] "The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, [21 U.S.C.] § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, [21 U.S.C.] § 360e(d)(1)(A)." *Riegel*, 552 U.S. at 318. Any requirements for the training of practitioners that use a Class III medical device must appear in the FDA-approved labeling. 21 U.S.C. § 360j(e).

procedure performed in your doctor's office" that takes "less than 10 minutes" and "requires no downtime for recovery." Am. Compl. ¶ 72(c). The Essure website states that correct placement of the device "is performed easily because of the design of the micro insert." Am. Compl. ¶ 72(h).
FDA-approved statement: "Essure may be right for you if . . . [y]ou would like to stop worrying about getting pregnant." Patient Guide at 4. "Essure is a simple procedure that can be done in 10 minutes in your doctor's office." *Id.* at 5. There is "No Downtime to Recover" and "You can go home 45 minutes after the procedure, and return to normal activity within one to two days." *Id.*

4. Alleged misrepresentation: The patient brochure and advertising state that the Essure inserts "stay secure" and that they remain visible outside the fallopian tubes so that a doctor can confirm that they are properly in place. Am. Compl. ¶ 72(d).
   FDA-approved statement: The Essure Instructions for Use state that "3 to 8 expanded outer coils should be trailing into the uterus" and that a physician should visually assess the device's "position immediately after deployment;" the Instructions further explain what to do if "no trailing coils are visible." Defs.' Request for Judicial Notice Ex. K, Essure Instructions for Use at 8, ECF No. 15-11 (hereinafter "Essure Instructions"). The Essure Instructions further state that the device "expands upon release to conform to and acutely anchor in the tubal lumen." *Id.* at 1.

5. Alleged misrepresentation: The patient brochure and advertising state that Essure inserts are made from the "same trusted, silicone free material used in heart stents." Am. Compl. ¶ 72(e).
   FDA-approved statement: "The inserts are made from polyester fibers, nickel-titanium and stainless steel. These same materials have been used for many years in cardiac stents and other medical devices placed in other parts of the body." Patient Guide at 11.

6. Alleged misrepresentation: The patient brochure and advertising state that Essure "is the most effective permanent birth control available-even more effective than tying your tubes or vasectomy," and a news release stated that Essure is "most effective permanent birth control method available." Am. Compl. ¶¶ 72(g), 160.
   FDA-approved statement: The Patient Guide states that Essure "is 99.83% effective based on five-year clinical study data." Patient Guide at 5. The Patient Guide also compares permanent

birth control methods and states that Essure has a lower failure rate than tubal ligation and vasectomy. *Id.* at 15-16.

7. Alleged misrepresentation: The physician training manual states that PET fibers cause tissue growth and that Essure works with the body "to create a natural barrier against pregnancy." Am. Compl. ¶ 72(i).
   FDA-approved statement: The Essure Instructions state, "PET fiber causes tissue in-growth into and around the insert, facilitating insert retention and pregnancy prevention." Essure Instructions 1. The Essure Instructions further state that the device "expands upon release to conform to and acutely anchor in the tubal lumen." *Id.* And, the Patient Guide states that the patient's "body will form tissue around the Essure inserts. This will develop a natural barrier within the fallopian tubes." Patient Guide 6.

8. Alleged misrepresentation: The advertising materials state that a doctor must be "signed-off to perform" the Essure procedure. Am. Compl. ¶ 74(a). They further state that the Essure training program "is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of" the device, and other materials state that to be trained in Essure, a physician must be a "skilled operative hysteroscopist." *Id.* ¶ 74(b).
   FDA-approved statement: The Essure Instructions state, "Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competency is established." Essure Instructions 1.

In summary, the above alleged misrepresentations in Frey's Amended Complaint track the language approved by the FDA during the premarket approval process. Frey did not respond to this argument, and she cannot seriously dispute that any claim for breach of express warranty based on these alleged misrepresentations would require a finding that the FDA's approved labeling was false. Such a finding would impose state

requirements that "are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). Again, "a claim that a device 'violated state tort law notwithstanding compliance with the relevant federal requirements' would clearly be preempted." *Mink*, 860 F.3d at1326 (quoting *Riegel*, 552 U.S. at 330). Thus, to the extent Frey is attempting to assert a defective label claim based on misrepresentations that track language that the FDA approved, such a claim is preempted and therefore dismissed.

In addition to the alleged misrepresentations discussed above, Frey contends that the Defendants warranted Essure as a low-risk, safe procedure. *See, e.g.,* Am. Compl. ¶ 72(f) (alleging that the Essure patient brochure and advertising falsely state that Essure "eliminates the risks, discomfort, and recovery time associated with surgical procedures"); *id.* ¶ 159 (alleging that Defendants made an express warranty that Essure would conform to the representations Defendants made). She further alleges that due to a manufacturing defect, her Essure device did not conform to Defendants' representations, that it was not safe and effective, and that it had "hidden increased risks" and "unreasonable dangers." *Id.* ¶¶ 162, 164. So, Frey contends that Defendants promised her a low-risk procedure, that she relied on that promise, that the device that was implanted in her body had a manufacturing defect caused by Defendants'

failure to comply with FDA manufacturing rules, and that as a result of the manufacturing defect the device that was implanted in her body was unreasonably dangerous and did not fit the description on the label warranting a low-risk procedure. Unlike the other warranty claims discussed above, this is not a "defective labeling" claim. Rather, it is a claim that Defendants, by failing to follow FDA manufacturing rules, produced a device that had manufacturing defects that made it unsafe and thus did not conform to Defendants' promise of a low-risk procedure. Permitting such a breach of warranty claim would not have the effect of imposing state requirements with respect to the device that are different from or in addition to federal ones and relate to safety and effectiveness.[3] Accordingly, to the extent that Frey's breach of express warranty claim is based on her contention that the warranties were breached because her device was not manufactured in accordance with FDA requirements, then that claim is not preempted and therefore not dismissed.

Defendants contend that even if Frey's express warranty claim is not preempted, it fails for several reasons. First, Defendants argue that Frey cannot assert a breach of express warranty claim because her doctor, not Frey, purchased the

[3] The Court notes that if Frey cannot prove a manufacturing defect, her breach of warranty claim will also fail because the FDA concluded that the product as designed and manufactured according to the FDA rules is low risk, safe, and effective.

device from Defendants and Frey thus was not in privity with Defendants. Defendants are correct that in Georgia, the ultimate consumer generally cannot recover on an express warranty claim if the manufacturer does not sell the product directly to that consumer. There is an exception to this rule: if a manufacturer extends an express warranty to the ultimate consumer, the privity requirement is met even if the ultimate consumer received the product through an intermediate seller. *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1326 (M.D. Ga. 2011) (Treadwell, J.); *accord Evershine Prods., Inc. v. Schmitt*, 202 S.E.2d 228, 231 (Ga. Ct. App. 1973). Here, Frey alleges that Defendants made express warranties directly to patients like her, that she relied on those representations, and that Essure did not conform to those representations. Am. Compl. ¶¶ 72, 74, 159-160, 162, 167-170. The Court thus declines to dismiss Frey's breach of warranty claim for lack of privity.

Second, Defendants argue that Frey was obligated to provide pre-suit notice to Defendants and a reasonable opportunity to cure any defect in the Essure device. In support of this argument, Defendants rely on cases that cite the Georgia Commercial Code on the effect of a buyer's acceptance of nonconforming goods. Under Georgia law, a buyer must "provide a seller with a 'reasonable amount of time' to repair prior to bringing a claim for breach of warranty." *Car Transp. Brokerage*

Co. v. Blue Bird Body Co., 322 F. App'x 891, 898 n.3 (per curiam) (11th Cir. 2009); *see* O.C.G.A. § 11-2-607(3)(a) (stating that if tender of goods is accepted, the "buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy"); O.C.G.A. § 11-2-605(a) (stating that a buyer may not rely on an unstated defect to establish breach if "the seller could have cured it if stated seasonably"). The purpose of this notice requirement is to give the seller an opportunity to inspect the problem and repair a defect in accepted goods.[4] Accordingly, courts have required a pre-suit request to repair products like motor coaches, cars, and HVAC components. *See id.* (motor coach); *Knight v. Am. Suzuki Motor Corp.*, 612 S.E.2d 546, 549 (Ga. Ct. App. 2005) (car); *Paws Holdings, LLC v. Daikin Applied Americas Inc.*, No. CV 116-058, 2018 WL 475013, at *5 (S.D. Ga. Jan. 18, 2018) (HVAC components). But here, Frey alleges that she did not discover any defect in her Essure device until after it was implanted in her body, that neither she nor her doctors could have discovered the defect sooner, that the only way to remove Essure was invasive surgery, and that Frey's doctor advised her to undergo a hysterectomy and salpingectomy to relieve the adverse symptoms she alleges were

[4] O.C.G.A. § 11-2-606(1) states that acceptance of goods occurs when the buyer, after "a reasonable opportunity to inspect the goods signifies to the seller that the goods are conforming or that he will take them or retain them in spite of their nonconformity."

caused by the device. Taking these allegations as true and drawing all reasonable inferences in Frey's favor, Frey adequately alleges that Defendants could not have repaired the Essure device that was implanted in her body even if she had given pre-suit notice. Thus, the Court declines to dismiss Frey's warranty claim for failure to provide pre-suit notice.

Finally, Defendants assert that Frey's express warranty claim should be dismissed as an impermissible shotgun pleading that does not adequately differentiate between the four Defendants. The Court disagrees. Frey alleges that all four Defendants made express warranties that she relied on in electing to undergo the Essure procedure. Am. Compl. ¶¶ 159, 161-162, 167-170 (alleging that "Bayer" made representations that Frey relied on); *accord id.* ¶ 6 (stating that all four Defendants are referred to as "Bayer" or "Defendant" in the Amended Complaint). These allegations give Defendants adequate notice of the grounds upon which Frey's express warranty claim rest. Whether Frey will be able to prove that each of the Defendants made representations upon which she relied remains to be seen.

In summary, to the extent that Frey attempts to assert a defective label claim based on misrepresentations that track language that the FDA approved, that claim is preempted and dismissed. But Frey's breach of express warranty claim that her

Essure device did not conform to Defendants' representations due to a manufacturing defect caused by Defendants' failures to comply with FDA manufacturing requirements is not preempted and therefore not dismissed.

CONCLUSION

As discussed above, Frey's "defective labeling" breach of express warranty claim is preempted by federal law and is therefore dismissed. Frey's negligent manufacturing claim and her breach of warranty claim based on a nonconforming device/manufacturing defect, however, are not preempted, and Defendants' motion to dismiss those claims (ECF No. 14) is denied. The stay of discovery is lifted. The Court will issue a separate order requiring the parties to confer and develop a proposed discovery plan.

IT IS SO ORDERED, this 9th day of October, 2020.

S/Clay D. Land
CLAY D. LAND
U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA