IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

CLOYS HAYNES and DARLENE HAYNES, Plaintiffs, v. CYBERONICS, INC., Defendant.	CIVIL ACTION NO. 1:09-CV-2700-JEC

ORDER & OPINION

This case is presently before the Court on defendant's Motion for Summary Judgment [23] and defendant's Motion for Leave to File Supplemental Briefing [45]. The Court has reviewed the record and the arguments of the parties and, for the reasons set out below, concludes that both motions should be **GRANTED**.

BACKGROUND

This is a products liability action arising from the implantation of a Vagal Nerve Stimulator into plaintiff Cloys Haynes' neck. Plaintiff[1] began suffering from epileptic type

[1] Although plaintiff Darlene Haynes is joined as a party, the Court will refer to the plaintiff in the singular for simplicity's sake.

seizures after he was involved in a serious automobile accident. (Def.'s Statement of Material Facts ("DSMF") [23] at ¶ 9.) When medication failed to alleviate plaintiff's condition, he was surgically implanted with Cyberonic's VNS Therapy System, pulse model 102, on July 17, 2007. (*Id.* at ¶ 10.) The VNS Therapy System (the "Device" or "Stimulator") is a Class III medical device approved by the United States Food & Drug Administration ("FDA"). (*Id.* at ¶ 2.) The Device received premarket approval from the FDA in 1997 for use as adjunctive therapy for epilepsy that is uncontrolled despite treatment with appropriate anti-epileptic drugs ("refractory epilepsy"). (*Id.* at ¶ 3.)

The Device consists of an electrical generator that sends periodic electronic stimulation via a thin, flexible wire to the left vagus nerve. (*Id.* at ¶¶ 4-5.) This stimulates the brain and helps prevent electrical irregularities that can cause seizures. (DSMF [23] at ¶¶ 4-5.) A surgeon implants the Device under the skin, and a doctor programs the Device by providing an appropriate level of stimulation that comfortably controls the seizures. (*Id.* at ¶ 7.)

After the implantation of the Device in July of 2007, Dr. Phllip Kennedy, plaintiff's treating neurologist, gradually increased the level of stimulation over two months to determine an optimum setting for plaintiff. (*Id.* at ¶ 12.) Around September 18,

2007, the neurologist increased the stimulation level again and plaintiff began complaining of symptoms. (*Id.* at ¶ 13.) Plaintiff began to experience a tingling in his arms and pain in his chest, so he was taken to the hospital. (Cloys Haynes Aff. [36-1] at ¶ 12.) While awaiting treatment in the emergency room, he experienced a sudden and violent shocking sensation radiating through his body originating from where the Device was implanted. (*Id.* at ¶ 13.) Plaintiff's physician disabled the Device. (DSMF [23] at ¶ 14.)

Roughly two months later, plaintiff was admitted to the hospital complaining of tingling and shocking in his left arm. (*Id.* at ¶ 19.) On November 30, 2007, the Device was removed and replaced. (*Id.* at ¶ 20.) During the replacement surgery, one of defendant's clinical engineers performed a diagnostic test on the original Device, both prior to and after its removal. (*Id.* at ¶ 21.) The diagnostic test showed that the Device tested completely normal, operating within its approved parameters and specifications. (*Id.*) No further testing has since been performed. (DSMF [23] at ¶ 22.) Plaintiff now contends that he has suffered permanent left side neurological damage and chronic pain in parts of his body including, but not limited to, his throat and ear. (Am. Compl. [10] at ¶ 12.)

Plaintiff filed a complaint in the State Court of Gwinnett County alleging various causes of action arising from injuries allegedly caused by the Device. (Notice of Removal [1].) The Complaint [1] brings claims for strict liability, negligence, breach of warranty, punitive damages, attorneys' fees, and loss of consortium. Plaintiff has now amended the Complaint to add a negligent manufacturing defect claim. (Am. Compl. [10] at ¶¶ 49-54.)

Four days before the extended discovery period was set to expire,[2] plaintiff moved to dismiss without prejudice or, alternatively, to receive an additional 90 days for discovery [21]. (Order of Dec. 20, 2010 [27].) Defendant opposed the dismissal and also filed the present motion. The Court declined to grant the requested dismissal and ordered plaintiff to respond to defendant's Motion for Summary Judgment. (*Id.*) Plaintiff appealed the Court's decision, but has subsequently dismissed this appeal. (USCA Order of Mar. 16, 2011 [42].)

After briefing on defendant's summary judgment motion was completed, defendant filed a Motion for Leave to File Supplemental Briefing [45]. Defendant's motion focuses on new Eleventh Circuit

[2] On March 3, 2010, the Court granted [7] the parties' joint motion to extend discovery for six months [6]. This extension meant that the parties had received a ten-month discovery period.

authority that speaks directly to the preemption issue in this case. Because this authority was not available to the parties during the briefing period and is helpful to the Court in resolving the present motion, defendant's motion [45] is **GRANTED**.

DISCUSSION

I. SUMMARY JUDGMENT STANDARD

Rule 56 of the Federal Rules of Civil Procedure provides that a motion for summary judgment shall be granted "if 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).[3] The moving party bears the "initial responsibility of informing the...court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *HR Acquisition I Corp. v. Twin*

[3] Federal Rule of Civil Procedure 56 was amended as of December 1, 2010. Pursuant to 28 U.S.C. § 2072 and by the Order of the Supreme Court of the United States, these amendments took "effect on December 1, 2010, and shall govern in all proceedings thereafter commenced and, insofar as just and practicable, all proceedings then pending." Order of the Supreme Court of the United States, April 28, 2010. The Notes of the Advisory Committee on 2010 amendments unequivocally states that "[t]he standard for granting summary judgment remains unchanged." Advisory Committee's Notes on 2010 Amendment on FED. R. CIV. P. 56.

City Fire Ins. Co., 547 F.3d 1309, 1314 (11th Cir. 2008) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). "For issues on which the non-moving party will bear the burden of proof at trial, the non-moving party must either point to evidence in the record or present additional evidence 'sufficient to withstand a directed verdict motion at trial based on the alleged evidentiary deficiency.'" *Hammer v. Slater*, 20 F.3d 1137, 1141 (11th Cir. 1994) (citing *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1116-17 (11th Cir. 1993)).

An issue is material if, "under the applicable substantive law, it might affect the outcome of the case." *LeBlanc v. Unifund CCR Partners*, 601 F.3d 1185, 1189 (11th Cir. 2010). An issue is genuine when the evidence is such that a reasonable jury could return a verdict for the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986).

The court must view all evidence and draw all reasonable inferences in the light most favorable to the non-moving party. *See Patton v. Triad Guar. Ins., Corp.*, 277 F.3d 1294, 1296 (11th Cir. 2002). Nonetheless, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party," there is no genuine issue for trial. *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir. 1997).

Supplementing the general guidance found in the federal rules, this Court's local rules provide a specific procedure by which a party who disagrees with his opponent's statement of a certain fact can communicate that disagreement to the Court. LR 56.1(B)(2)(a)(2), NDGa provides that a movant's facts are deemed to be admitted unless the respondent "(i) directly refutes the movant's fact with concise responses supported by specific citations to evidence (including page and paragraph number); (ii) states a valid objection to the admissibility of the movant's fact; or (iii) points out that the movant's citation does not support the movant's fact or that the movant's fact is not material or otherwise has failed to comply with the provisions set out in LR 56.1(B)(1).").

Plaintiff has wholly failed to respond to defendant's Statement of Material Facts [23], as is required by the local rule. He notes in his Response Brief [36] on page 17 that, consistent with the local rule, "disputed facts are noted in Plaintiff's Responsive Statement of Material Facts Pursuant to local Rule 56.1 In Opposition to Summary Judgment filed separately," but no such document was ever filed.

Plaintiff's Response Brief does set forth his own version of the relevant events by generally citing to evidence. In so doing, he only appears to explicitly contest two of defendant's facts, but even here he fails to offer any citation to the record in support

of his allegation. (Pl.'s Resp. Br. [36] at 4 n.1.) Plaintiff's failure to properly respond to defendant's statement of material facts requires the Court to deem the defendant's facts admitted.

Notwithstanding plaintiff's failure to respond to the defendant's statement of undisputed facts, the Court is not permitted to grant the motion for summary judgment solely as a result of this omission. Rather, the Court is still obliged to review the evidence cited by defendant to insure that it forecloses a genuine issue of material fact. *See Reese v. Herbert*, 527 F.3d 1253, 1267-8 (11th Cir. 2008)(setting forth proper method for evaluating summary judgment where Local Rule 56.1 is not adhered to). Further, for the sake of clarity, the Court has included relevant evidence asserted by plaintiff in his response brief to the extent those assertions do not contradict the facts listed in the movant's statement. *See id.* (requiring court to disregard evidence relied upon by respondent not properly cited in response to movant's statement of undisputed facts "that yields facts contrary to those listed in the movant's statement.").

II. PREEMPTION DOCTRINE

As a result of what plaintiff perceives to have been a malfunctioning of his particular device, he has asserted strict liability, negligence, and breach of warranty claims. Defendant raises the defense of preemption as to all of plaintiff's claims.

Under the doctrine of federal preemption, state laws that conflict with federal law are "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Class III medical devices, like the Stimulator that was implanted in plaintiff, are strictly regulated by federal law under the Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetic Act. 21 U.S.C. § 360c(a)(1)(C); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-17 (2008). Devices subject to these regulations are rigorously tested under the watchful eye of the FDA through a premarket approval process. *Riegel*, 552 U.S. at 317-18. After premarket approval, a manufacturer is prohibited from changing design specifications, manufacturing processes, labeling, or anything else affecting safety or effectiveness, absent FDA approval. *Id.* at 319.

The MDA contains an express preemption clause. 21 U.S.C. § 360k(a).[4] In *Riegel v. Medtronic, Inc.*, the Supreme Court determined that this express preemption clause will bar common law

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[4] (a) General rule. 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.

claims arising from injuries caused by FDA-approved medical devices in many circumstances. Tracking the language of the statute, *Riegel* set forth a two-pronged test for deciding whether state claims are preempted. First the district court must determine whether the federal Government has established requirements applicable to the device. If so, the court must then determine whether the plaintiff's common-law claims are based upon state law requirements (1) that are "different from, or in addition to" the federal ones and (2) "that relate to safety and effectiveness." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300-01 (11th Cir. 2011)(citing *Riegel*, 552 U.S. at 321-22)(emphasis added).

Having undergone and received premarket approval from the FDA as a Class III device, plaintiff's stimulator device is clearly subject to federal "requirements" for the purposes of preemption. *Riegel*, 552 U.S. at 322 ("[p]remarket approval...imposes 'requirements' under the MDA."). Plaintiff does not dispute this point.

Next, one must decide whether the state law imposes requirements that are "different from, or in addition to" the federal regulations, and whether these state law requirements relate to safety and effectiveness. All of plaintiff's state law claims appear to relate to safety and effectiveness, leaving only the

question of whether the state law imposes requirements "different from, or in addition to" the federal regulations.

The Supreme Court in *Riegel* envisioned the possibility of state law claims that did not impose different requirements from those set out in federal law, but that instead actually paralleled these federal regulations. *Id.* at 330. Such "parallel claims" would not be "premised on a violation of FDA regulations" and thus would not be subject to preemption under the MDA.[5] *Id.* To determine whether a claim is indeed parallel, the Eleventh Circuit has endorsed a methodology that compares potential liability under federal and state law. If a manufacturer could be held liable under the state law without having violated the federal law, the claim is not parallel and is thus preempted. *Wolicki-Gables*, 634 F.3d at 1300 (citing *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)).

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[5] There is no federal private cause of action for noncompliance with the medical device provisions, however. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). As a result, the Eighth Circuit has noted that "[t]he plaintiff must be suing for conduct that <u>*violates*</u> the FDCA (or else his claim is expressly preempted by §360k(a)), but the plaintiff must not be suing <u>*because*</u> the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010). Admittedly, the practical distinction between the described two potential bases for a suit appears a bit difficult to discern.

Plaintiff has alleged claims of strict liability (Count I), negligent failure to warn (Count II), negligent design defect (Count III), negligent manufacturing defect (Count IV), breach of warranty (Count V), punitive damages (Count VI), attorneys' fees (Count VII), and loss of consortium (Count VIII). In his response to defendant's motion for summary judgment, plaintiff concedes that the design claim is preempted.[6] (Pl.'s Resp. Br. [36] at 14.) Defendant argues that all claims are preempted and, alternatively, that plaintiff has failed to offer evidence sufficient to withstand summary judgment on the merits.

III. STRICT LIABILITY CLAIMS

In Georgia, strict liability is a creature of statute. *See* O.C.G.A. § 51-1-11. This doctrine holds a manufacturer liable when a product is defective, even if the manufacturer is not at fault for

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[6] Although plaintiff concedes the design defect claims on preemption grounds, the Court notes that summary judgment would be warranted even if this claim were not preempted. Specifically, to defeat summary judgment on the merits, plaintiff would be required to present expert testimony as to a design defect. This is so because expert testimony is almost always needed to apply the risk/utility standard for design defects under Georgia law. *See Mize v. HJC Corp.*, CIVA 103CV2397-JEC, 2006 WL 2639477, at *4 (N.D. Ga. Sept. 13, 2006)(applying factors necessary to find design defect regularly requires expert testimony). Having failed to present expert testimony, plaintiff cannot defeat summary judgment on the merits. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1320 (11th Cir. 1999)(granting summary judgment to defendant after excluding plaintiff's expert).

the defect. O.C.G.A. § 51-1-11(b)(1)[7]. There are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects. *Banks v. ICI Americas, Inc.*, 264 Ga. 732, 733 (1994). As plaintiff has conceded his design claim, the Court addresses only his manufacturing and marketing/packaging defect claims.

A. Manufacturing Defect

To prove a strict liability manufacturing defect claim, "the question is whether the [device] was defective in its manufacture...and whether any such defect existed at the time the [device] was sold." *Collins v. Newman Mach. Co., Inc.*, 190 Ga. App. 879, 881 (1989). Thus, a jury is permitted to find the existence of a manufacturing defect when "the product was defective, the defect existed at the time the product left the manufacturer's control, and the defect in the product was the proximate cause of the plaintiff's injury." GA. JURY INSTRUCTIONS - CIVIL § 62.620. "A manufacturing defect is an unintended flaw or abnormal condition that occurs during the production of the product that makes the

[7] "The manufacturer of any personal property...shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained."

product more dangerous than it would have been had the product been manufactured properly." *Id.*; *Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1239 (N.D. Ga. 2002)("A manufacturing defect is a defect that is 'measurable against a built-in objective standard or norm of proper manufacture.'")

Defendant argues that this claim is preempted by federal law. Clearly, the FDA regulates the manufacturing practices of Class III medical devices. 21 U.S.C. § 360e(c)(1); 21 C.F.R. §§ 814, 820; *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1285 (M.D. Fla. 2009), *aff'd* 634 F.3d 1296 (11th Cir. 2011). Further, a manufacturer could comply with all FDA regulations, but nevertheless produce a product containing an unintended flaw or abnormal condition. That being so, by holding a manufacturer liable under such circumstances, Georgia law would be in the position of imposing requirements "in addition to" federal law. Accordingly, defendant argues, plaintiff's strict liability manufacturing defect claim is therefore preempted. *See, Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301 (E.D. Pa. 2009)(finding state law manufacturing defect claim preempted by MDA); *Banner v. Cyberonics, Inc.*, No. 08-0741 (RBK/KMW), 2010 WL 455286 (D.N.J. Feb. 4, 2010)(same).

The Court agrees. Even were defendant's preemption argument not persuasive, plaintiff could not prevail on his manufacturing defect claim because he has failed to offer any evidence that there

was a defect in his device. Plaintiff has offered no expert testimony to demonstrate the existence of a defect, instead arguing that the fact that he suffered a serious shock with this device suggests that something must have been wrong with it. Yet, as defendant correctly notes, plaintiff's device is a complicated medical device that interacts with the nervous system and the brain. Defendant acknowledges that a severe shock from the device is clearly undesirable, but in deciding whether the device is defective, one must inquire why that shock occurred. Defendant notes that there are multiple potential causes for the emission of an undesired shock, only one of which is a defective device. (Def.'s Reply Br. [39] at 9-10). As plaintiff has offered no proof that a defective device was the cause of the shock, plaintiff has failed to prove the essential element of his manufacturing defect claim.

Plaintiff certainly had an adequate opportunity to find an expert and test the device to determine if there were a defect. Indeed, the Court offered a six month extended discovery period to enable just such testing by an expert to occur. Plaintiff did not seek to have the device tested and, as a result, has no evidence to offer in support of his contention that the stimulator was defective.

Plaintiff has likewise failed to offer any evidence that his claimed injuries were caused by the shock he received from the device. Proof of causation in a products liability case generally requires "reliable expert testimony which is 'based, at the least, on the determination that there was a *reasonable probability* that the negligence caused the injury.'" *Wilson v. Taser Int'l, Inc.*, 303 Fed. App'x 708, 715 (citing *Rodrigues v. Georgia-Pacific Corp.*, 290 Ga. App. 442, 444 (2008); *Silverstein v. Proctor & Gamble Mfg. Co.*, 700 F. Supp. 2d 1312, 1316 (S.D. Ga. 2009)("Under Georgia law, proof of causation in strict products liability cases generally requires reliable expert testimony."). Plaintiff offers no such testimony.[8]

[8] Plaintiff has argued that no expert testimony was required in this case. To the extent plaintiff seeks to rely on the testimony of his treating physician, Dr. Kennedy, the latter was not properly disclosed as an expert. Both the Federal Rules of Civil Procedure and the Local Rules of this Court prohibit admission of such testimony in the absence of some showing of justification, of which there has been none. *See* Fed. R. Civ. P. 26(a)(2)(A), 37(c)(1); LR 26.2(C), NDGa. Furthermore, Dr. Kennedy's opinion regarding what caused plaintiff's injuries would be an opinion, unrelated to treatment, which is "based on scientific, technical, or other specialized knowledge." *Wilson v. Taser Int'l, Inc.*, 303 Fed. App'x 708, 712 (11th Cir. 2008)("Although we agree that a treating physician may testify as a lay witness regarding his observations and decisions during treatment of a patient, once the treating physician expresses an opinion unrelated to treatment which is 'based on scientific, technical, or other specialized knowledge,' that witness is offering expert testimony for which the court must perform its essential gatekeeping function as required by *Daubert*.")(emphasis in original). Based on the proffer offered by plaintiff, it is uncertain that Dr. Kennedy would be deemed qualified to render an opinion as to the causation of injuries arising from Class III medical devices.

Whether the stimulator caused plaintiff's injuries by providing an abnormal amount of stimulation is not a "natural inference that a juror could make through human experience." *Allison*, 184 F.3d at 1320.

Plaintiff having failed to create a genuine issue of material fact as to defect or causation, summary judgment on his strict liability manufacturing defect claim is **GRANTED**.

B. Marketing/Packaging Defect

A packaging defect can be classified as a manufacturing defect or a design defect, depending on the circumstances. For example, when a label is faulty because it deviates from the manufacturer's specifications for such a label, such a flaw would be a manufacturing defect. When the label meets the manufacturer's specifications, but the fact finder decides that the warning was inadequate, a design defect is implicated. *See Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1237-38 (N.D. Ga. 2002)(discussing nature of marketing/packaging defect claims under Georgia law).

Here, plaintiff argues that his device contained an inadequate warning, which is a design defect. Under Georgia law, manufacturers are required to provide "an adequate warning of known or reasonably foreseeable dangers arising from the use of a product." GA. JURY INSTRUCTIONS - CIVIL § 62.680. An inadequate warning may amount to a

design defect and permit the imposition of strict liability. *Id.*

The FDA regulates content and appearance of prescription medical device labels. 21 U.S.C. 360e(c)(1); 21 C.F.R. §§ 801.1, 801.15, 801.109, 814; *Wolicki-Gables*, 641 F. Supp. 2d at 1286. In considering plaintiff's design defect state law claim, a reasonable jury could find that the manufacturer ran afoul of its obligations under Georgia law, even though it complied with all FDA regulations. This means that Georgia law would be imposing "requirements" that are "in addition to" federal regulations. As such, this claim is also preempted.[9] Defendant's Motion for Summary Judgment on this claim is **GRANTED**.

IV. NEGLIGENCE CLAIMS

A. Negligent Failure to Warn

To establish a failure to warn claim, plaintiff must show that defendant had a duty to warn, that defendant breached that duty, and that the breach was the proximate cause of plaintiff's injuries. *Dietz v. Smithkline Beeecham Corp.*, 598 F.3d 812, 815 (11th Cir.

[9] Preemption aside, a plaintiff must typically overcome the obstacle of the learned intermediary doctrine. *See McCombs v. Synthes (U.S.A.)*, 277 Ga. 252, 252 (2003)("Under the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer."). Defendant has not raised this issue in its briefing, and, accordingly, the Court does not consider it.

2010). The duty to warn may be breached by "failing to provide an adequate warning of the product's potential dangers or failing to adequately communicate to the ultimate user the warning provided." GA. JURY INSTRUCTIONS - CIVIL § 62.680. As explained above, the FDA regulates the labeling wherein patients and doctors are given warnings regarding medical devices. Further, plaintiff's failure to warn claim is grounded in defendant's alleged failure to include an *additional* warning regarding the type of injury plaintiff suffered. Thus, state law imposes requirements beyond those set by federal law. As such, they are preempted. *See Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1205 (holding that state law requiring additional warning is preempted). Therefore, defendant's Motion is **GRANTED** as to the negligent failure to warn claim.

B. Negligent Manufacturing Defect

"In order to 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." *Miller v. Ford Motor Co.*, 287 Ga. App. 642, 644 (2007). Proof of negligence requires a showing that the defendant "fail[ed] to observe, for the protection of the interest of another person, that degree of care, precaution, and vigilance which the circumstances justly demand, whereby such

other person suffers an injury." *Ford Motor Co. v. Carter*, 239 Ga. 657, 662 (1977).

In the *Riegel* case, the Second Circuit held that a negligent manufacturing claim would not be preempted to the extent it relied on an allegation that the particular device had not been manufactured in accordance with the FDA's premarket approval process. A jury verdict in favor of a plaintiff on such a claim would not impose different or additional requirements beyond those set out by the PMA approved standards, but "would instead have simply sought recovery for [the manufacturer's] alleged deviation from those standards." *Riegel v. Medtronics, Inc.,* 451 F.3d 104, 123-24 (2nd Cir. 2006). The Supreme Court neither disturbed nor explicitly endorsed that pronouncement as to manufacturing defect claims,[10] so the Court will assume the possibility of a negligent manufacturing claim that tracks the requirements set out by the FDA and alleges a negligent deviation from those requirements.

Nevertheless, for the same reasons that plaintiff could not prevail on his strict liability claim, he cannot prevail on a negligence claim premised on a manufacturing defect. That is,

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[10] The Supreme Court did, however, note that preemption principles would not preclude a state from providing a damages remedy for claims premised on a violation of an FDA regulation because, in such a circumstance, the state duties would parallel, rather than add to, federal requirements. *Riegel,* 552 U.S. 312 at 330.

plaintiff has offered no evidence that his stimulator device had a defect or that this defect caused his injuries. Plaintiff's proffered evidence is, at bottom, a *res ipsa loquitur* argument. The doctrine of *res ipsa loquitur* is a rule of evidence permitting an "inference of negligence to arise from the happening of an event causing an injury to another where it is shown that...the accident was a kind [of] which, in the absence of proof of some external cause, does not ordinarily happen without negligence." *Evans v. Heard*, 264 Ga. 239, 240 (1994). Georgia law rejects the application of the *res ipsa loquitur* theory to a manufacturing defect. *Miller*, 287 Ga. App. at 645 (holding that *res ipsa loquitur* does not apply to manufactured devices, and where the product was not in the exclusive control of the defendant); *ACE Fire Underwriters Ins. Co. v. ALC Controls, Inc.*, No. 1:07-CV-606-TWT, 2008 WL 2229121, at *3 (N.D. Ga. May 28, 2008).

Accordingly, defendant's Motion for Summary Judgment [23] is **GRANTED** on this claim.

V. BREACH OF WARRANTY CLAIMS

Riegel did not address a breach of express warranty claim.[11] Nor has the Eleventh Circuit decided whether a breach of express

[11] Although the district court did not initially dismiss this claim as preempted, the district court subsequently dismissed it on summary judgment, and the plaintiff did not appeal this issue to the Supreme Court. *Riegel*, 552 U.S. at 321 n.2.

warranty claim can be preempted by the MDA. Other federal courts remain divided over the issue. *See Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *7 (D. Colo. 2010)(noting "continuing split amongst the courts" post-*Riegel*); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1302-03 (D. Colo. 2008) (collecting pre-*Riegel* cases on both sides of the issue).

In any event, the express representation claims in this case *would* interfere with the FDA's premarket approval regime. Plaintiffs claim that defendant expressly warranted the stimulator to be "safe, and generally fit for use as an implanted stimulator," when in fact the device was not safe. (Am. Compl. [10] at ¶ 56-57). In order to prove that defendant breached this warranty, plaintiff would need to show that the stimulator was not safe: a finding that would directly conflict with the FDA's premarket approval of the device as reasonably safe and effective. *See* 21 U.S.C. § 360e(d). Moreover, if these warranties were made in materials approved by the FDA in the premarket approval process, then allowing a claim to proceed under Georgia law would subject defendant to state duties above and beyond the federal requirements. *See Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264, 1271 (S.D. Fla. 2010) (finding preempted a breach of express warranty claim based on statements in a FDA-approved brochure). Such a claim would fall within § 360k's preemption clause prohibiting state requirements that are in

addition to, or different from, federal requirements. *See Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic, Inc.*, 623 F.3d 1200, 1208 (8th Cir. 2010)("The district court correctly concluded that this express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted.").

Accordingly, the Court concludes that plaintiff's express warranty claim is also preempted. *See Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1207-08 (8th Cir. 2010)(express warranty claims interfere with the FDA's regulation of Class III medical devices and are conflict preempted); *Timberake v. Synthes Spine, Inc.*, No. V-08-4, 2011 WL 711075, at *6-*7 (S.D. Tex. Feb. 18, 2011)(premarket approval determination that product is safe and effective preempts state law claim based on breach of warranty).[12]

[12] Were plaintiff resting his breach of express warranty claims on statements made by defendant that went beyond those statement allowed under the FDA premarket approval, these claims would not necessarily be preempted. *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777-M, 2010 WL 2679988 (N.D. Tex. June 30, 2010)(finding breach of express warranty claim not preempted where manufacturer represented that product satisfied premarket approval specifications); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 285-86 (E.D.N.Y. 2009)(explaining that there is no preemption where express warranty claim is based on representation that exceeds scope of FDA approved statements); *Yost v. Stryker Corp.*, No. 2:09-cv-28-FtM-29DNF, 2010 WL 1141586 (M.D. Fla. Mar. 23, 2010)("If plaintiff is alleging that defendants breached the express warranty provided by the FDA approved labeling of the [device], then plaintiff may have a 'parallel' claim that is not preempted by the MDA.").

Plaintiff, however, has not identified any express statement made by defendant that went beyond the scope of FDA premarket-

Therefore, the Court grants summary judgment on this claim.

With regard to a breach of the implied warranty of merchantability and fitness for a particular purpose,[13] plaintiff

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approved labeling and therefore cannot seek refuge in this exception to preemption.

[13] O.C.G.A. § 11-2-314 provides that:
(1) Unless excluded or modified (Code Section 11-2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this Code section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.

(2) Goods to be merchantable must be at least such as:
(a) Pass without objection in the trade under the contract description; and
(b) In the case of fungible goods, are of fair average quality within the description; and
(c) Are fit for the ordinary purposes for which such goods are used; and
(d) Run, within the variations permitted by the agreement, of even kind, quality, and quantity within each unit and among all units involved; and
(e) Are adequately contained, packaged, and labeled as the agreement may require; and
(f) Conform to the promises or affirmations of fact made on the container or label if any.

(3) Unless excluded or modified (Code Section 11-2-316) other implied warranties may arise from course of dealing or usage of trade.

O.C.G.A. § 11-2-315 provides that:
Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under Code Section 11-2-316 an implied warranty that the goods shall be fit for such purpose.

appears to lack standing to bring an implied warranty claim under Georgia law. An implied warranty claim requires privity. *Gill v. Blue Bird Body Co.*, 147 Fed. App'x 807, 809-10 (11th Cir. 2005) ("Georgia courts have repeatedly held that where a plaintiff lacks contractual privity with a manufacturer, he cannot bring an implied warranty claim against that manufacturer."); *Baker v. Smith & Nephew Richards, Inc.*, 1999 WL 1129650 (N.D. Ga. Sept. 30, 1999)("Under Georgia law, the recipient of an internally implanted medical device does not have standing to bring a claim for breach of implied warranty."). Although the record is unclear as to how plaintiff came into possession of the Device, the Court suspects that a surgically implanted Class III medical device would first pass to the hospital, and then to plaintiff by a prescription. Certainly, plaintiff has offered no evidence to the contrary.

In any event, the implied warranty of merchantability under Georgia law would require plaintiff to persuade a jury that the Device was not merchantable, safe, and generally fit for its intended use, or, in other words, somehow defective. (Am. Compl. [10] at ¶ 56.) *See also* O.C.G.A. § 11-2-314. The FDA has already set standards for this determination through the premarket approval process. The state law would thus impose requirements beyond what is required by federal regulations. Plaintiff's implied warranty claim is therefore also preempted. *Kinetic Co., Inc. v. Medtronic,*

Inc., No. 08-CV-6062 (PJS/AJB), 2011 WL 1485601, at *4-*5 (D. Minn. Apr. 19, 2011); *Riegel*, 552 U.S. at 328-30. Defendant's motion for summary judgment [23] as to plaintiff's warranty claims is **GRANTED**.

VI. PLAINTIFF'S DERIVATIVE CLAIMS

Plaintiff's claims for loss of consortium, punitive damages, and attorneys' fees are all derivative of a viable cause of action in either tort or contract. *See Miller*, 287 Ga. App. at 645 (holding that loss of consortium claim must be dismissed when substantive tort claims fail); *Benefit Support, Inc. v. Hall Cnty.*, 281 Ga. App. 825, 833 (2006)(failing to recover on underlying tort claims prohibits punitive damages as a matter of law); *Gilmour v. Am. Nat'l Red Cross*, 385 F.3d 1318, 1324 (11th Cir. 2004)(explaining that attorneys' fees under O.C.G.A. § 13-6-11 requires an underlying claim); *Bruce v. Wal-Mart Stores, Inc.*, 699 F. Supp. 905, 906 (N.D. Ga. 1988)(Forrester, J.)(noting that attorneys' fees under O.C.G.A. § 9-15-14 not available in federal court). Because plaintiff's various state law claims are preempted and are otherwise subject to summary disposition, defendant's motion [23] must be **GRANTED** as to these remaining claims.

CONCLUSION

For the foregoing reasons, defendant's Motion for Leave to File Supplemental Briefing [45] is **GRANTED** and defendant's Motion for Summary Judgment [23] is **GRANTED**.

SO ORDERED, this 6th day of September, 2011.

/s/ Julie E. Carnes
JULIE E. CARNES
CHIEF UNITED STATES DISTRICT JUDGE