

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
AIKEN DIVISION**

Carol Ann Tufts, ) Civil Action No: 1:16-cv-00698-JMC  
 )  
 Plaintiff, )  
 )  
 v. ) **ORDER**  
 )  
 Medtronic, Inc. and Medtronic USA, Inc., )  
 )  
 Defendants. )  
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This matter is before the court on Defendants' Rule 12(b)(6) Motion to Dismiss Plaintiff's Complaint, filed March 11, 2016. (ECF No. 5.) Plaintiff did not provide a response.

Plaintiff commenced this civil action by filing her Complaint in the Court of Common Pleas of Aiken County, South Carolina on January 29, 2016. (ECF No. 1-1.) Defendants timely filed a proper Notice of Removal, on March 4, 2016, requesting removal of this case to this court on the basis of diversity jurisdiction, 28 U.S.C. § 1332. (ECF No. 1.) In this action, Plaintiff alleges claims for negligence, strict liability, and breach of implied warranty of merchantability arising out of Defendants' manufacture, design and distribution of a Medtronic SynchroMed II Programmable Pump that delivers medications over time to chronically ill patients. (ECF No. 1-1.) This device was implanted in Plaintiff and allegedly malfunctioned and led to a "toxic overdose of medication" into Plaintiff, causing her severe and permanent injuries. (ECF No. 1-1 at 8 ¶¶ 9-10 & 9 ¶ 14.) On April 14, 2016, the parties filed a Stipulation to Stay Proceedings for one hundred and twenty (120) days for the parties to address certain initial discovery issues. (ECF No. 8.) On December 16, 2016, the court granted Plaintiff's counsel's Motion to Withdraw as Attorney (ECF No. 13), to which Plaintiff consented (ECF No. 13-1), and offered Plaintiff ninety (90) days to secure new counsel.

(ECF No. 14.) Plaintiff failed to secure new counsel and now Defendants' Motion is ripe for ruling.

In their Motion, Defendants argue that Plaintiff's claims are preempted by federal law and therefore should be dismissed. More specifically, Defendants assert that 1) Plaintiff has not "pled facts suggesting that her purported injuries resulted from a violation of any federal requirement applicable to her device"; 2) Plaintiff's claims are not adequately pled; 3) Plaintiff's strict liability design defect claim is barred by comment k to Section 402A of the Restatement (Second of Torts); and 4) Plaintiff's claims that Defendants failed to provide appropriate warnings to her are barred by the learned-intermediary doctrine. (ECF No. 5 at 2-3.)

The Federal Drug Administration strictly regulates the design, manufacture, and sale of Class III medical devices pursuant to the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). The Medical Device Amendments contain an express preemption provision declaring that no state "may establish or continue in effect with respect to a device . . . 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, absent fitting into an exception, state law claims challenging the design, manufacture, or labeling of a premarket approval medical device are expressly preempted. *Riegel v. Medtronic Inc.*, 552 U.S. 312 (2008). Furthermore, in this action, Plaintiff does not allege any claim or defect that is premised on a violation or deviation from federal law. (See ECF No. 1-1.) Thus, this court finds that the FDCA pre-empts Plaintiff's common law claims for negligence, strict liability, and breach of implied warranty of merchantability arising out of Defendants' manufacture, design and distribution of a Medtronic SynchroMed II Programmable Pump, and has held such in a similar case, *see, e.g., Hesik v. Boston Scientific Corp.*, No. 1:12-cv-00014-JMC, 2014 WL

5644699, at \*6-8 (D.S.C. Nov. 4, 2014) (holding that claims based on strict liability, negligence, and breach of implied warranty were expressly preempted). Accordingly, for the reasons stated above, the court **GRANTS** Defendants' Motion to Dismiss (ECF No. 5) with prejudice.<sup>1</sup>

**IT IS SO ORDERED.**

A handwritten signature in black ink, appearing to read "J. Michelle Childs".

United States District Judge

March 21, 2017  
Columbia, South Carolina

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<sup>1</sup>Because the court has determined that Plaintiff's common law claims are preempted, it need not reach a decision on Defendants' other arguments.