IN THE SUPREME COURT OF MISSISSIPPI

NO. 2009-CA-00594-SCT

WILLIAM SANDERS

v.

ADVANCED NEUROMODULATION SYSTEMS, INC.

DATE OF JUDGMENT:	04/03/2009
TRIAL JUDGE:	HON. JAMES LAMAR ROBERTS, JR.
COURT FROM WHICH APPEALED:	LEE COUNTY CIRCUIT COURT
ATTORNEY FOR APPELLANT:	D. L. JONES, JR.
ATTORNEY FOR APPELLEE:	LEAH NICHOLS LEDFORD
NATURE OF THE CASE:	CIVIL - PERSONAL INJURY
DISPOSITION:	AFFIRMED - 09/30/2010
MOTION FOR REHEARING FILED:	
MANDATE ISSUED:	

BEFORE WALLER, C.J., DICKINSON AND CHANDLER, JJ.

CHANDLER, JUSTICE, FOR THE COURT:

¶1. This case involves whether a trial court erred by granting summary judgment in favor of Advanced Neuromodulation Systems, Inc. (ANS) on the basis of federal preemption for a medical device regulated by the United States Food and Drug Administration (FDA). The case turns on whether a genuine issue of material fact exists as to classification of the device. A medical device designated as a class II device is subject to state law, whereas a medical device designated as a class III device is entitled to federal preemption.

¶2. William Sanders (Sanders) filed a complaint against ANS, North Mississippi Medical Center, Inc. (NMMC), Dr. Benjamin Wiseman, and John Does one through five in the Circuit

Court of Lee County, Mississippi. Sanders alleged that he had an operation on September 14, 2005, at NMMC to remove the left lead of a spinal-cord stimulator. A spinal-cord stimulator is for treatment of chronic intractable pain of the trunk or limbs. Dr. Wiseman and NMMC purchased the spinal-cord stimulator from ANS, the manufacturer and distributor of the medical device used in the procedure. During the operation to remove the left lead of the spinal-cord stimulator, the product broke, allegedly causing Sanders's injury and damages. Sanders's causes of action included (1) negligent manufacture of the spinal-cord stimulator by ANS; (2) distribution of a defective and dangerous product in commerce by ANS, NMMC, and Dr. Wiseman; and (3) strict liability for injuries resulting from the manufacture, sale, and distribution of a defective product by ANS.[1] ANS filed its answer and affirmative defenses. Thereafter, ANS filed a motion for summary judgment and memorandum in support of its motion. After conducting a hearing, the trial court granted summary judgment in favor of ANS, finding that Sanders's claims against ANS were barred by the Medical Device Amendments (MDA) preemption clause and that ANS was entitled to judgment as a matter of law.[2] Following this decision, Sanders appealed to this Court.

FACTS

¶3. ANS manufactures a spinal-cord stimulator known as a GenesisXP Implantable Pulse Generator System (GenesisXP). This device uses low-intensity electrical impulses to interfere with pain signals sent to the brain to prevent pain to a patient. While these devices

[1] The trial court docket indicates that the trial court granted a motion to dismiss in favor of NMMC and Dr. Wiseman on May 2, 2008.

[2] Medical Device Amendments of 1976, 21 U.S.C. § 360k (2006).

may be either partially or totally implantable in a patient, the GenesisXP at issue is a totally implantable device. In February 2005, ANS sent NMMC a GenesisXP, a Quattrode lead, and a Patient Programmer for the GenesisXP.

¶4. The FDA regulates drugs and devices pursuant to the Federal Food, Drug, and Cosmetic Act (the FDCA). *See* 21 U.S.C. §§ 301 to 399 (2006). In 1976, the FDCA was amended with the Medical Device Act (MDA). *See* (Pub. Law 94-295); 21 U.S.C. § 360c (2006). The MDA classified medical devices into three categories, class I, II, and III. *See* 21 U.S.C. § 360c (2006). The classes are distinguished as class I general controls, class II special controls, and class III premarket approval. *See* U.S.C. § 360c(a)(1)(A), (B), and, (C) (2006). The MDA automatically classifies a device as a class III device if it has been introduced into the market *after* May 28, 1976. *See* 21 U.S.C. § 360c(f)(1) (2006).[3]

[3] 21 U.S.C. § 360c states, in part:

> (f) Initial classification and reclassification of certain devices
>
> (1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless--
>
> (A) the device--
>
> (i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and
>
> (ii) is substantially equivalent to another device within such type, or

However, a manufacturer may petition the FDA to reclassify a device from class III to class I or II. *See* 21 U.S.C. § 360c(f)(1)(B) (2006).

¶5. The GenesisXP was placed on the market after May 28, 1976. In June 1999, ANS petitioned the FDA to reclassify the totally implanted spinal-cord stimulator for pain relief from a class III device to a class II device. However, the FDA denied ANS' petition to reclassify the device from a class III to a class II device in February 2001. In its letter, the FDA described the history and classification process, as follows:

> In accordance with sections 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking. Those devices remain in class III and require premarket approval, unless and until: (1) the device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA); or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(I) of the act (21 U.S.C. 360c(I)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).
>
> As you know, on June 16, 1999, you submitted a petition requesting

---

> (B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II.
>
> A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

21 U.S.C. § 360c (2006).

> reclassificiation of the Totally Implanted Spinal Cord Stimulator for Pain Relief from a class III into class II. The petition was submitted under section 513(f)(2) of the act, now section 513(f)(3) of the act, as amended by FDAMA, and 21 CFR 860.134 of the agency's regulations**. In accordance with section 513(f)(1) of the act, the Totally Implanted Spinal Cord Stimulator for Pain Relief was automatically classified into class III because the device was not within a type of device introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and had not been found to be substantially equivalent to a device placed in commercial distribution after May 28, 1976, that had been reclassified into class II or class I.**

(Emphasis added.) By way of the February 2001 FDA letter to ANS' director of regulatory affairs, Drew Johnson, the FDA acknowledged that pursuant to the FDCA, ANS' spinal-cord stimulator was categorized as a class III device automatically. This was because the device had not been introduced into interstate commerce for commercial distribution prior to May 28, 1976, and it had not been determined to be substantially equivalent to a similar device placed into commercial distribution after that date which had been designated as a class I or class II device.

¶6. In its later-published notice of ANS' petition to reclassify the totally implanted spinal-cord stimulator, the FDA announced that it had denied the petition. In so doing, the FDA stated that it was "announcing that it has denied a petition submitted by Advanced Neuromodulation Systems, Inc. (ANS), to reclassify the totally implanted spinal-cord stimulator (SCS) for treatment of chronic intractable pain of the trunk or limbs from class III into class II . . . . After considering all the available information, including the public comments of the Panel's recommendation, FDA denied the reclassification petition by order in a letter to the petitioner." Further, the FDA's supplementary information included with the notice described the regulatory history of the device, in part, as follows:

> The totally implanted SCS [spinal cord stimulator] intended for treatment of chronic intractable pain of the trunk or limbs is a postamendments device classified into class III under section 513(f)(2) of the act. Therefore, this device cannot be placed in commercial distribution for treatment of chronic intractable pain of the trunk or limbs unless it is reclassified under section 513(f)(2) of the act, or subject to an approved PMA under section 515 of the act.

Again, the FDA described ANS' spinal-cord stimulator as a class III device.

¶7. ANS then sought premarket approval of the spinal-cord stimulator in accordance with the FDA premarket process. On July 16, 2002, the FDA notified ANS that it had completed its evaluation for the premarket approval application (PMA) for the GenesisXP. The FDA approved the PMA application by order and required ANS to comply with required MDA conditions.

¶8. In February 2005, ANS shipped a GenesisXP, a Quattrode lead, and a Patient Programmer of the GenesisXP to NMMC for Sanders. After surgery, Sanders filed suit against ANS on September 7, 2007. In his complaint, Sanders alleged that, on or about September 14, 2005, he was a patient at NMMC. During the surgery, the left lead of the spinal-cord stimulator broke, allegedly causing Sanders's injury and damages.

¶9. On January 14, 2009, the trial court heard arguments on ANS' motion for summary judgment. Following the arguments, the trial court determined that Sanders's claims were barred by the MDA's preemption clause and issued an order granting summary judgment in favor of ANS. Sanders appealed, raising three issues, which have been condensed into one: Whether the trial court erred by granting summary judgment to ANS. We find that the trial court did not err and affirm the judgment of the Circuit Court of Lee County.

DISCUSSION

¶10. On appellate review, a trial court's grant or denial of summary judgment is reviewed de novo. ***Moss v. Batesville Casket Co., Inc.***, 935 So. 2d 393, 398-399 (Miss. 2006). Mississippi Rule of Civil Procedure 56(c) provides that summary judgment shall be rendered by a court "if the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Miss. R. Civ. P. 56(c).

¶11. The court reviews the record before it, taking "all the evidence in the light most favorable to the non-moving party." ***United States Fid. and Guar. Co. of Miss. v. Martin***, 998 So. 2d 956, 962 (Miss. 2008). Affirmance is required where the record before the trial court demonstrates no genuine issue of material fact, and where the movant is entitled to a judgment as a matter of law. ***Id***. While the movant has the burden of showing that no genuine issues of material fact exist, diligence is required of the party opposing the motion and "may not rest upon the mere allegations or denials of the pleadings, but instead the response must set forth specific facts showing that there is a genuine issue of material fact for trial." ***Harmon v. Regions Bank***, 961 So. 2d 693, 697 (Miss. 2007) (quoting ***Harrison v. Chandler-Sampson Ins., Inc.***, 891 So. 2d 224, 228 (Miss. 2005)). A material fact is one that "tends to resolve any of the issues properly raised by the parties." ***Palmer v. Anderson Infirmary Benevolent Ass'n***, 656 So. 2d 790, 794 (Miss. 1995). "The presence of fact issues in the record does not per se entitle a party to avoid summary judgment." ***Moss***, 935 So. 2d at 398-99. "[T]he existence of a hundred contested issues of fact will not thwart summary judgment where there is no genuine dispute regarding the material issues of fact." ***Id***. (citing ***Simmons v. Thompson Mach. of Miss., Inc.***, 631 So. 2d 798, 801 (Miss. 1994)).

¶12. In ***Harmon***, this Court stated that preemption is proper: "(1) where Congress explicitly preempts state law; (2) where preemption is implied because Congress has occupied the entire field; or (3) where preemption is implied because there is an actual conflict between federal and state law." ***Harmon***, 961 So. 2d at 697-98 (citing ***Cooper v. GMC***, 702 So. 2d 428, 434 (Miss. 1997)); *see also* ***English v. General Elec. Co.***, 496 U.S. 72, 78-9, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990)).

Whether Sanders's claims against ANS are barred by the MDA's preemption clause.

¶13. The trial court granted summary judgment in ANS' favor. In so doing, the trial court distinguished the GenesisXP from the spinal-cord-stimulator definition provided by the regulations on the basis of its characteristics. The trial court stated in part:

> Under the authority granted to it under the Federal Food, Drug, and Cosmetic Act, the FDA has promulgated certain regulations designed to implement the Act. Relevant to the present cause of action, 21 C.F.R. § 882.5880 classifies an "implanted spinal cord stimulator for pain relief" as a class II device. However, this regulation specifically identifies an "implanted spinal cord stimulator for pain relief" as a device consisting of "an implanted receiver . . . and an *external* transmitter . . ." ***Id***. at (a)(emphasis added). No regulation has been issued regarding a fully implantable spinal cord stimulator.

Coupled with the fact that the GenesisXP was introduced after May 28, 1976, and thus, was automatically classified as a class III device, and that the FDA denied ANS' request to reclassify the device, which prompted ANS to start the premarket approval process, the trial court barred Sanders's claims. The trial court barred the claims because (1) the FDA regarded the spinal-cord stimulator as a class III device, and (2) ***Riegel v. Medtronic, Inc.***, 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008), preempted state-law claims challenging the safety and effectiveness of class III devices.

¶14. On appeal, Sanders argues that the trial court erred by granting summary judgment in favor of ANS. Sanders claims that the GenesisXP is a class II device as defined by federal regulations. Further, he claims that the trial court erred by basing its decision on a FDA order which was inconsistent with the FDA's own regulations. That order effectively designated the GenesisXP as a class III device. Consequently, Sanders asserts that the trial court erred by finding that the device had a class III designation, because that classification subjected the state-court causes of action to preemption under federal law. *See* ***Riegel v. Medtronic, Inc.***, 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008).

¶15. On the other hand, ANS argues that the trial court correctly found that the GenesisXP was a class III device. ANS argues that federal regulations have not addressed a totally implantable spinal-cord stimulator. Nevertheless, ANS maintains that, because the device had been introduced into the market after May 28, 1976, pursuant to the FDCA, it automatically received a class III designation. In further support of its position, ANS relies on the FDA's denial of ANS' request to reclassify the GenesisXP from a class III to class II status, the FDA's premarket approval of the device, and the United States Supreme Court holding in ***Riegel***, 552 U.S. 312.

1. Regulations

¶16. Sanders argues that Code of Federal Regulations Section 882.5880 is controlling authority for the classification of the GenesisXP, an implanted spinal-cord stimulator.

¶17. The Code of Federal Regulations defines an implanted spinal-cord stimulator for pain relief. *See* 21 C.F.R. § 882.5880 (2010). The regulation states:

(a) Identification. An implanted spinal cord stimulator for pain relief is a

> device that is used to stimulate electronically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulse across the patient's skin to the implanted receiver.
>
> (b) Classification. Class II (performance standards).

21 C.F.R. § 882.5880 (2010). The federal regulation also defines an implanted spinal-cord stimulator as a class II device. 21 C.F.R. § 882.5880 (2010).

¶18. ANS concedes that no regulation exists for a *totally* implantable spinal-cord stimulator. However, ANS argues that its device is distinguishable from the implanted spinal-cord stimulator defined in Section 882.5880 because the GenesisXP is *totally* implantable, meaning that the receiver and transmitter are both implanted, whereas the spinal-cord stimulator described in the regulation has an implanted receiver and an *external* transmitter for transmitting the stimulating pulse. Thus, the two devices are distinguishable.

2. FDA Order

¶19. Sanders argues that the trial court incorrectly relied on a FDA order to grant summary judgment to ANS. The FDA issued an order to ANS in February 2001, in which it denied ANS' request to reclassify the spinal-cord stimulator from a class III to a class II device. Sanders contends that the FDA order is inconsistent with the FDA regulations, which clearly define the spinal-cord stimulator as a class II device. In support of his position, Sanders cites ***Thomas Jefferson University v. Shalala***, 512 U. S. 504, 520, 114 S. Ct. 2381, 2391, 129 L. Ed. 2d 405 (1994), and ***Wyoming Outdoor Council v. U.S. Forest Service***, 165 F.3d 43, 45 (U.S. App. D.C. 1999), both of which concern an agency's interpretation of its regulations.

¶20. In ***Thomas Jefferson***, the United States Supreme Court considered whether the

Secretary of Health and Human Services' interpretation of medicare regulatory language was reasonable. ***Thomas Jefferson***, 512 U.S. at 506, 114 S. Ct. at 2384. A hospital sought reimbursement for graduate medical-education costs. ***Id***. at 507. The Secretary denied some of the expenses as an impermissible redistribution of costs, and the hospital sought review. ***Id***. at 511.

¶21. The United States Supreme Court held that substantial deference must be given to an agency's interpretation of its own regulations. ***Thomas Jefferson***, 512 U.S. at 512, 114 S. Ct. at 2386. The Court noted that deferral to the Secretary's interpretation was warranted unless an "alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation." ***Id***. (quoting ***Gardebring v. Jenkins***, 485 U.S. 415, 430, 108 S. Ct. 1306, 1314, 99 L. Ed. 2d 515 (1988)). This principle is more justifiable when "the regulation concerns 'a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" ***Id***. (quoting ***Pauley v. Beth Energy Mines, Inc.***, 501 U.S. 680, 697, 111 S. Ct. 2524, 2534, 115 L. Ed. 2d 604 (1991)). The United States Supreme Court upheld the Secretary's interpretation of its own regulations. ***Id***. at 518.

¶22. Likewise, in ***Wyoming Outdoor Council***, the Council appealed a district-court decision which affirmed the United States Forest Service's interpretation of its own regulations. ***Wyoming Outdoor Council***, 165 F.3d at 45. The Council argued that the Forest Service's authorization of oil and gas leasing on land located in the Shoshone National Forest in Wyoming violated its own regulations. ***Id***. The court held that substantial deference is

given to an agency's interpretation of its own regulations. ***Id***. at 52. The interpretation of an agency's regulation is controlling "unless it is plainly erroneous or inconsistent with the regulation." ***Id***. (quoting ***United States v. Larionoff***, 431 U.S. 864, 872, 97 S. Ct. 2150, 53 L. Ed. 2d 48 (1977)). Again, the appellate court upheld the agency's interpretation of its own regulations. ***Id***. at 54.

¶23. ANS contends that the trial court's order is not inconsistent with federal regulations. First, ANS contends that 21 C.F.R. Section 882.5880 defines a stimulator that has both internal and external components. The GenesisXP, however, is totally implantable. ANS argues that, when it initially sought reclassification of the GenesisXP from a class III to a class II medical device, it set forth the specific differences between the stimulator defined by the regulation and its stimulator. Notwithstanding the regulation's classification of a stimulator as a class II device, the FDA's order denied ANS' petition to reclassify the stimulator and stated that, because the stimulator was fully implantable in a human body, the FDA required the device to remain as a class III device.

3. Preemption, premarket approval, and *Riegel*

¶24. Sanders claims that the trial court erred by finding that the spinal-cord stimulator was a class III device. This finding, in turn, provided the trial court with the means to consider ANS' argument that, because it is as a class III device, Sanders's claims are preempted by federal statute and by federal caselaw in ***Riegel v. Medtronic, Inc.***, 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008).

¶25. The federal statute at issue is Section 360k, which provides in part:

(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.

21 U.S.C. § 360k (2006).

¶26. In ***Riegel***, the United States Supreme Court considered whether the preemption clause in the MDA barred common-law claims of safety and effectiveness of a medical device that had premarket approval by the FDA. ***Riegel***, 552 U.S. at 315; *see also* 21 U.S.C. § 360k (2006). Charles Riegel had a coronary angioplasty following a heart attack. ***Id***. at 320. During the procedure, the Evergreen Balloon Catheter, marketed by Medtronic and designated as a class III device, ruptured, causing a heart block. ***Id***. Riegel subsequently had to have emergency coronary bypass surgery. ***Id***. Riegel filed suit in the New York federal district court, alleging that Medtronic's catheter violated New York common law. ***Id***. However, the district court held that Riegel's claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the device were preempted by the MDA. ***Id***. at 320-21.

¶27. The United States Court of Appeals for the Second Circuit affirmed the district court, holding that the Riegels' claims were preempted by federal law. ***Riegel***, 552 U.S. at 321. The basis of the appellate court's decision was that if the Riegels' claims were successful, they would impose state requirements that differ from, or added to the device-specific federal

requirements. ***Id***. at 321. *See* 21 U.S.C. § 360k (2006).

¶28. The United States Supreme Court granted certiorari. ***Riegel***, 552 U.S. at 321. The Court held that the FDA premarket approval process imposes requirements, and it is specific to individual devices. ***Id***. at 323. The premarket approval is considered *the* federal safety review of the device, with safety, as opposed to equivalence, being the key consideration. ***Id***. Once premarket approval is granted, the device has "almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." ***Id***. When analyzing whether the claims relied on a requirement that was "different from, or in addition to, any requirement" pursuant to the federal law for the device and that "relate[d] to the safety or effectiveness" of the device, the United States Supreme Court determined that safety and effectiveness were the essence of the Riegels' claims. ***Id***. Further, the Court determined that "the common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." ***Id***. at 323-24. The United States Supreme Court affirmed the Court of Appeal, which had determined that the MDA preempted the Riegels' claims. ***Id***. at 330.

¶29. We find that the trial court did not err by finding that the GenesisXP was a class III medical device, and as such, Sanders's claims were barred, because the claims were subject to federal preemption. The record shows that the FDA regulates medical devices pursuant to the FDCA. The federal government amended the FDCA in regard to medical devices with the MDA. This act provided that devices introduced after May 28, 1976, automatically received a class III designation. It was undisputed that the GenesisXP was introduced after

May 28, 1976. The GenesisXP, pursuant to the MDA, was classified as a class III device.

¶30. In an attempt to have the GenesisXP reclassified from a class III device to a class II device, ANS petitioned the FDA in 1999. The record contains the FDA's denial of ANS' request at reclassification. In its 2001 denial letter, the FDA unequivocally stated that the stimulator was "automatically classified into class III." The record also has a FDA public notice. The FDA again designated ANS' stimulator as a class III device in its public notice of denial of petition to reclassify the device. The FDA stated that ANS could not place the device into commercial distribution unless it was reclassified or subjected to premarket approval. ANS sought premarket approval. In 2002, the FDA approved ANS' application for premarket approval.

¶31. Sanders does not dispute the FDA documentation; rather he relies on the definition of the stimulator as described in the regulations. *See* 21 C.F.R §882.5880 (2010). The regulation does provide a class II designation for spinal-cord stimulators that have an internal and external component. However, as the evidence shows and as the FDA was aware, the GenesisXP is a fully implantable device. Further, the FDA order, the notice of denial of petition, and the premarket approval correspondence all make clear that the FDA itself considered ANS' GenesisXP stimulator to be a class III device. Consequently, while other stimulators that may have an internal and external component are generally considered class II devices, the FDA did not view the GenesisXP in the same light, so much so that ANS sought the arduous premarket approval process for the device.

¶32. Viewing the evidence in the light most favorable to Sanders, we find that no genuine issue to any material fact as to whether the GeneisXP is a class III device. Further, Sanders's

claims are similar in nature to the claims asserted by the Riegels in ***Riegel***, 552 U.S. at 320. Like the Riegels' claims, Sanders's claims challenge the safety and effectiveness of a class III device that has received premarket approval by the FDA, imposing requirements that are different or in addition to MDA federal requirements. Therefore, the trial court did not err by barring Sanders's claims under the MDA.

CONCLUSION

¶33. For the above-stated reasons, this Court affirms the judgment of the Circuit Court of Lee County.

¶34. **AFFIRMED**.

WALLER, C.J., CARLSON, P.J., DICKINSON, RANDOLPH, LAMAR, KITCHENS AND PIERCE, JJ., CONCUR. GRAVES, P.J., NOT PARTICIPATING.