IN THE SUPREME COURT OF THE STATE OF MISSISSIPPI
IN THE COURT OF APPEALS OF THE STATE OF MISSISSIPPI

SUPREME COURT NO. 2009-CA-00594

WILLIAM SANDERS **APPELLANT**

VERSUS

ADVANCED NEUROMODULATION SYSTEMS, INC. **APPELLEE**

BRIEF OF THE APPELLEE

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CERTIFICATE OF INTERESTED PERSONS

1.	William Sanders	Plaintiff-Appellant
2	Advanced Neuromodulation Systems, Inc.	Defendant-Appellee
3.	D.L. Jones, Jr.	Attorney for Plaintiff-Appellant
4.	James P. Streetman, III Leah N. Ledford	Attorneys for Defendant-Appellee

SO CERTIFIED, this the 19th day of January, 2010.

Leah N. Ledford

Leah N. Ledford
One of the Attorneys for
Defendant-Appellee

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

FEDERAL STATUTES

FEDERAL REGULATIONS

SECONDARY SOURCES

STATEMENT OF THE ISSUE

Did the trial court err in granting summary judgment on the basis of federal preemption where Advanced Neuromodulation Systems, Inc. clearly provided the court with sufficient evidence confirming that the product at issue has always been and continues to be a Class III medical device that properly obtained and maintained its pre-market approval from the United States Food and Drug Administration?

STATEMENT OF THE CASE

By way of introduction, the specific device at issue in this matter is the GenesisXP Implantable Pulse Generator system ("GenesisXP") — a device which is totally implantable in the human body. (R. at 13-14, 23, 30) The GenesisXP uses low-intensity electrical impulses to interfere with pain signals in order to keep the signals from reaching the patient's brain. (R. at 13, 14)

The United States Food and Drug Administration ("FDA") has the authority to regulate drugs and devices under the Federal Food, Drug, and Cosmetic Act ("The Act"). (R. at 24, 48, 70-71). The Act was amended by the Medical Device Amendments of 1976 ("MDA"). (R. at 24, 48, 70-71) Following this amendment, any device introduced into the market after May 28, 1976 was automatically classified as a Class III devices. (R. at 24, 48, 70-71) These post-amendment devices remain in Class III generally unless a manufacturer petitions the FDA for an order reclassifying a Class III device into a Class I or Class II device. (R. at 24, 48, 70-71)

On or about June 11, 1999, Advanced Neuromodulation Systems, Inc. ("ANS") petitioned the FDA to reclassify the device type at issue, a totally implantable spinal cord stimulation system for pain relief, from Class III to Class II. (R. at 41) ANS's petition

for reclassification was denied by the FDA on or about February 23, 2001. (R. at 48-51) In its Order, the FDA made abundantly clear that totally implantable spinal cord stimulation systems, including the GenesisXP, were from their outset Class III medical devices, and would remain so absent a successful reclassification by the FDA. (R. at 48-51)

The GenesisXP was ultimately granted pre-market approval ("PMA") by the FDA on July 16, 2002 as a Class III device. (R. at 33-34) Pursuant to the approval letter, this system was approved as an "aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain." (R. at 33-34) Defendant ANS's application for PMA of the GenesisXP was submitted as a Supplement to the previous PMA that ANS had received for a prior model, the Genesis spinal cord stimulator system ("Genesis"). (R. at 30, 35-36) The original Genesis model received PMA from the FDA on November 21, 2001. (R. at 30, 35-36)

Once a supplement to a PMA is approved, the changes approved through the PMA supplement are subject to all of the terms and conditions contained within the approval of the original PMA. (R. at 30-32) The approved PMA Supplement required ANS to be in compliance with labeling, manufacturing, sterilization, packaging and design specifications as approved by the FDA. (R. at 30-32) ANS has complied with all FDA requirements and Conditions of Approval for both the original PMA and the PMA Supplement through its labeling, manufacturing, design, postmarket surveillance, and general medical device reporting for the Genesis and GenesisXP. (R. at 30-32) As such, it is undisputed the GenesisXP continues to operate as a Class III medical device

pursuant to the PMA afforded it by the FDA on July 16, 2002. (R. at 30-32)

According to the *Complaint*, on or about September 14, 2005, William Sanders ("Appellant") was a patient at North Mississippi Medical Center where he underwent a surgical procedure to remove the left lead of a spinal cord stimulator manufactured and distributed by Defendant ANS. (R. at 4-6) Appellant alleges that during the course of this procedure, the left lead of the spinal cord stimulator broke, thereby causing alleged injury to him. (R. at 4-6) Thereafter, on September 7, 2007, Appellant filed his *Complaint* against several Defendants, including ANS.[1] (R. at 4-6) In his *Complaint*, Appellant alleges that ANS negligently manufactured the spinal cord stimulator, distributed a defective and dangerous product, and that ANS is strictly liable for injuries sustained by Appellant as a result of its manufacture, sale and distribution of a defective product. (R. at 4-6)

ANS filed its Motion for Summary Judgment and Memorandum Brief in Support of same on October 20, 2008. (R. at 7-17) Because the GenesisXP is a Class III medical device that has properly received and maintained PMA, Appellant's claims are preempted by federal law. (R. at 7-17)

Appellant argues that the GenesisXP is instead a Class II device but acknowledges it received PMA from the FDA. (R. at 18-20) Appellant further concedes that if the GenesisXP is a Class III medical device, then it is exempt from litigation pursuant to the doctrine of federal preemption. (R. at 18-20)

1

North Mississippi Medical Center, Inc. and Benjamin Wiseman, M.D. were subsequently dismissed from the claim by the circuit court on or about May 2, 2008. Plaintiff has named these two Defendants in a separate suit in the Circuit Court of Lee County, Cause Number CV07-170(PF)L.

A hearing was held on January 14, 2009. (Hr'g Tr. 1-19) Honorable James L. Roberts, Jr. granted ANS's Motion for Summary Judgment on April 3, 2009, holding that the GenesisXP was a Class III medical device that had received pre-market approval from the FDA. (R. at 70-72) Appellant subsequently appealed the Order, filing his Notice of Appeal on April 6, 2009. (R. at 73-74)

SUMMARY OF THE ARGUMENT

Appellant cites FDA regulation 21 C.F.R. § 882.5800 in support of his argument that the GenesisXP is not a Class III medical device. This regulation classifies an "implanted spinal cord stimulator for pain relief" as a Class II device. However, this regulation specifically identifies such device as consisting of "an implanted receiver with electrodes that are placed on the patient's spinal cord and an *external* transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver."

The device at issue, the GenesisXP, is a *totally implantable* device within the human body. There has not been a regulation issued to date regarding a totally implantable spinal cord stimulator. However, because this device was introduced after May 28, 1976, it was automatically classified as a Class III device pursuant to The Act.

ANS petitioned the FDA to reclassify totally implantable spinal cord stimulation systems from Class III to Class II; however, the FDA issued an order denying ANS's petition on February 23, 2001. The FDA specifically found that Class II controls would not sufficiently ensure the safety and effectiveness of this device type. Accordingly, ANS subsequently sought and obtained PMA from the FDA for the GenesisXP on July 16, 2002 as a Class III device. ANS's application for PMA of the GenesisXP was submitted as a Supplement to the previous PMA that ANS had received for a prior model, the

Genesis. The original Genesis model received PMA from the FDA on November 21, 2001.

Mississippi courts and the United States Supreme Court have ruled that the MDA's preemption clause bars state tort lawsuits challenging the safety or effectiveness of a Class III medical device that received FDA pre-market approval. *See Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008); *see also Rutland v. Mentor Corp.*, 1994 WL 454741 (Miss. Cir. 1994). Despite the classification, it cannot be denied that the GenesisXP underwent the rigorous process and received PMA. However, because the device at issue is indeed a Class III device that has received and maintained PMA, the Appellant's claims against ANS are barred by the MDA's preemption clause.

ARGUMENT

I. The Standard Of Review

In general, the Supreme Court reviews a trial court's grant or denial of a party's motion for summary judgment under a de novo standard. *Burley v. Douglas*, 2009 WL 3645687 (Miss. 2009). If no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law, summary judgment should be entered in that party's favor. *McCullough v. Cook*, 679 So.2d 627, 630 (Miss. 1996). The nonmoving party must "make a showing sufficient to establish the existence of elements essential to his case." *Kerr-McGee Corp. v. Maranatha Faith Ctr., Inc.*, 873 So.2d 103, 107 (Miss. 2004) (citing *Cothern v. Vickers, Inc.*, 759 So.2d 1241, 145 (Miss. 2000)). The nonmoving party must then go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial. *Kerr-McGee Corp.*, 873 So.2d at 107. In other words, a simple denial to a motion for summary judgment is not enough to create

an issue of fact. The opposing party, in order to defeat a motion for summary judgment, must provide more than general allegations; specific facts showing that material issues of fact exist are required. *Brooks v. Roberts*, 882 So.2d 229, 232 (Miss. 2004) (citing *Bowie v. Monfort Jones Mem'l Hosp.*, 861 So.2d 1037, 1040-41 (Miss. 2003)).

II. The GenesisXP Is A Class III Medical Device That Received Pre-Market Approval From The FDA On July 16, 2002

A. The Pre-Market Approval Application Process

The FDA stringently regulates medical devices by means of a comprehensive regulatory system implemented under the authority of the federal Food, Drug, and Cosmetic Act "FDCA"). *See* 21 U.S.C. §§ 321 *et seq.* The regulatory system is designed to ensure the safety and effectiveness of medical devices through both pre-market and post-market controls. *See, e.g.,* Ctr. For Devices and Radiological Health, U.S. Food and Drug Admin., Device Advice, available at http://www.fda.gov/cdrh/devadvice/overview.html.

The Medical Device Amendments to the FDCA, 21 U.S.C. § 360k, classifies medical devices into three categories based on the degree of risk they pose to the public. *See, e.g., Martin v. Medtronic, Inc.*, 254 F.3d 573, 576 (5th Cir. 2001). Class III devices, such as the GenesisXP, are the most strictly regulated and to obtain pre-market approval, must undergo a thorough, rigorous and costly process with some 1,200 FDA man-hours at hundreds of thousands of dollars in cost. *Martin*, 254 F.3d at 576.

Under this rigorous PMA process, the manufacturer must provide the FDA with detailed information regarding the safety and efficacy of the device, including full reports of all information that is known by the applicant, a full statement of the device's components, ingredients, and properties, a full statement of the principle or principles

of operation, samples of the proposed labeling and the device itself (or access thereto), and a full description of the methods and facilities used for designing, manufacturing and testing the device. *See* 21 U.S.C. § 360e(c)(1). A manufacturer is prohibited from producing or labeling any device in any manner inconsistent with the conditions of approval specified by the FDA. *See* 21 C.F.R. § 814.80. Moreover, the manufacturer must submit a supplemental application for certain proposed changes for FDA approval before implementing such changes. *See* 21 C.F.R. § 814.39(d).

B. The GenesisXP Received Pre-Market Approval From The FDA On July 16, 2002 As A Class III Device

ANS maintains that the GenesisXP is a Class III medical device. See *Product Classification Database Search Results,* database maintained by the U.S. Food and Drug Administration, available at http://www.fda.gov. To date, no regulation has been assigned to a *totally implantable* spinal cord stimulator, as with the external spinal cord stimulator governed by 21 C. F. R. § 882.5880. However, there are numerous other documents which support the ANS's position that the GenesisXP is indeed a Class III medical device.

As stated *supra*, ANS petitioned the FDA on June 11, 1999 to reclassify totally implantable spinal cord stimulation systems from Class III to Class II. (R. at 41) This request was made because this device type was developed post-amendment and therefore, governed by The Act. *See* 21 U.S.C. § 301, *et. seq.* Post-amendment devices are simply devices that were not in commercial distribution prior to May 28, 1976, when The Act was amended by the Medical Device Amendments of 1976. These post-amendment devices are classified automatically by statute into Class III without any FDA rulemaking process. These devices remain in Class III, unless the device is

reclassified into Class I or II status pursuant to petition by the manufacturer of the device, or found to be substantially equivalent to a predicate device that does not require pre-market approval. (R. at 42-48) The GenesisXP is a post-amendment device classified automatically as a Class III because it was not in commercial distribution prior to May 28, 1976.

Appellant relies solely upon 21 C.F.R. § 882.5800 in support of his argument that the GenesisXP is a Class III medical device, and conveniently ignores the overwhelming evidence presented by ANS. To begin with, the statute cited by Appellant, 21 C.F.R. § 882.5800, specifically identifies "an implanted spinal cord stimulator for pain relief" as a device which consists of "an implanted receiver... and an *external* transmitter..." *Id.* (emphasis added). The difference in the GenesisXP is that it is *totally implantable* in the human body. No regulation has been issued regarding a totally implantable spinal cord stimulator to date.

When ANS petitioned the FDA for reclassification, it specifically referenced 21 C.F.R. § 882.5800 in stating that prior to that time, implanted spinal cord stimulators for pain relief had been classified as Class II. (R. at 41). It further explained that the direct current generator power source for the stimulator identified in 21 C.F.R. § 882.5800 was external. However, subsequently, implantable generators were developed. *Id.* The only difference between the "implanted" and "totally implanted" spinal cord stimulator devices is the location of the generator power source. *Id.*

ANS's petition for reclassification was denied by the FDA on or about February 23, 2001. (R. at 48-53) In its Order, the FDA made abundantly clear that totally implantable spinal cord stimulation systems were from their outset Class III medical

devices because they were not within a type of device introduced into interstate commerce for 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 already been reclassified into Class II or I. (R. at 48, 49) The FDA's Order was further very clear that the pre-market approval process would be necessary to ensure the safety and effectiveness of this device type. (R. at 50-51) Accordingly, there is no doubt that the GenesisXP is a totally implantable spinal cord stimulation device that is subject to the 21 C.F.R § 814 criteria governing PMA of a Class III medical device. *See* 21 C.F.R. § 814. The provisions of 21 C.F.R. § 882.5800 are simply outdated and have effectively been superceded as they apply to this device.

The PMA Supplement application for the GenesisXP was submitted pursuant to the 180-day PMA supplement review program. (R. at 30-32) As part of the process, ANS was required to fully describe the design, intended uses and any potential adverse effects of the GenesisXP. *Id.* ANS was also required to submit a complete description of the methods used in, and the facilities and controls used for, the manufacturing, processing, and packaging of the components of the GenesisXP. *Id.* The FDA also required ANS to demonstrate its quality control and manufacturing control measures relating to the GenesisXP, including its testing and inspection processes. *Id.* The FDA performed a pre-approval inspection and conducted periodic inspections of ANS's quality control and manufacturing control processes to ensure compliance with federal regulations and the PMA Conditions of Approval. *Id.*

The GenesisXP was ultimately granted PMA by the FDA on July 16, 2002 as a Class III device. (R. at 33-34) Pursuant to the approval letter, this system was approved

as an "aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain." *Id.* ANS's application for PMA of the GenesisXP was submitted as a Supplement to the previous PMA that ANS had received for a prior model, the Genesis. The original Genesis model received PMA from the FDA on November 21, 2001. (R. at 35-36)

Once a supplement to a PMA is approved, the changes approved through the PMA supplement are subject to all of the terms and conditions contained within the approval of the original PMA. (R. at 31-32) The approved PMA Supplement required ANS to be in compliance with labeling, manufacturing, sterilization, packaging and design specifications as approved by the FDA. *Id.* ANS has complied with all FDA requirements and Conditions of Approval for both the original PMA and the PMA Supplement through its labeling, manufacturing, design, postmarket surveillance, and general medical device reporting for the Genesis and Genesis XP. *Id.* As such, the Genesis XP continues to operate as a Class III medical device pursuant to PMA afforded it by the FDA on July 16, 2002.

C. Despite Its Classification, The GenesisXP Received Pre-Market Approval

ANS maintains that the GenesisXP is indeed a Class III medical device. However, even if the device was a Class II device as claimed by Appellant, it cannot be denied that GenesisXP underwent the rigorous process and obtained pre-market approval. *See* Brief of the Appellant, p. 7.

Courts have consistently held that the concentration is "not on the product's classification, but rather on the process the product underwent in order to obtain FDA

approval." *Rousseau v. Depuy Orthopaedics, Inc.*, 2006 WL 3716061 (W.D.La.); *see also Martin*, 254 F.3d at 575; and *Gomez v. St. Jude Medical Daig Division, Inc.*, 442 F.3d 919, 930 (5th Cir. 2006). In *Rousseau*, the product at issue was Simplex bone cement ("Simplex"). *Id.* at 1. In that case, Simplex was approved as a Class III medical device that underwent the rigorous PMA process. *Id.* However, in 2002, it was reclassified to Class II. *Id.* at 2. Despite the reclassification, the court held that the approval process is the key to the preemption analysis. *Id.* at 8. Because Simplex had received PMA from the FDA, plaintiff's claims were dismissed under the doctrine of preemption. *Id.* at 9-11.

ANS does not concede that the GenesisXP is a Class II device; however, despite its classification, it is undisputed that it underwent the rigorous pre-market approval process which is the primary focus of the preemption analysis. Accordingly, because the GenesisXP properly obtained and has maintained its PMA from the FDA, Appellant's claims are still preempted.

III. The Order of the FDA is not Inconsistent with its Regulations

Appellant also argues that the FDA's order is "plainly erroneous and inconsistent with the regulation at 21 CFR Part 882.5800." *See* Brief of the Appellant, p. 7. Appellant cites two (2) cases in support of this argument. In *Thomas Jefferson University v. Shalala*, 512 U.S. 504 (1994), the plaintiff, a qualified Medicare provider, sued Donna Shalala, the Secretary of Health and Human Services, regarding a decision of the agency that reimbursement of certain educational expenses would constitute an impermissible redistribution of costs. *Id.* The Supreme Court, in affirming the lower courts' rulings, held that the Secretary's interpretation of the anti-redistribution principle was

reasonable. *Id.* The Court stated the Secretary's interpretation of her own regulation must be given controlling effect unless it is plainly erroneous or inconsistent with the regulation. *Id.* The Court further stated that broad deference is warranted when the regulation concerns a complex and highly technical program in which the identification and classification of relevant criteria require significant expertise and entail the exercise of judgment grounded in policy concerns. *Id.* at 505.

Appellant also cites *Wyoming Outdoor Council v. United States Forest Service*, 165 F.3d 43 (U.S.App.D.C. 1999), in support of this argument. First and foremost, this matter is not binding or controlling authority over this Court. In *Wyoming Outdoor Council*, Wyoming Outdoor Council ("WOC") and various other environmental groups brought an action challenging the United States Forest Service's authorization of oil and gas leasing of land in the Shoshone National Forest in north-western Wyoming. The United States Court of Appeals, District of Columbia Circuit, affirmed the lower courts decisions and held the Forest Service did not violate its own regulations.

Similarly, this Court should also find that the FDA's order is not erroneous or inconsistent with its regulation. Just as in *Thomas Jefferson University*, broad deference is warranted in this matter due the complexity of the regulation requiring significant expertise of the FDA. *Id.* at 505. The language of 21 C.F.R. § 882.5880 could not be any clearer regarding the fact that the implanted spinal cord stimulator for pain relief consists of an implanted receiver and an *external* transmitter. The subject device, the GenesisXP, instead is fully implantable in the human body. ANS very specifically laid out the differences in the spinal cord stimulator identified in 21 C.F.R. § 882.5880 and the GenesisXP in its petition for reclassification. Moreover, the FDA's order

denying that petition was very clear that because the GenesisXP was fully implantable within the human body, it would need to remain a Class III device to ensure its safety and effectiveness. (R. at 48-51) Therefore, the FDA's order was not erroneous or inconsistent with 21 C.F.R. § 882.5880.

VI. Appellant's Claims Are Preempted By Federal Statute

In his *Complaint*, Appellant alleges that ANS negligently manufactured the spinal cord stimulator, distributed a defective and dangerous product, and that ANS is strictly liable for injuries sustained by Appellant as a result of its manufacture, sale and distribution of a defective product. (R. at 4-6)

The United States Supreme Court has unequivocally stated that the preemption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, bars state tort lawsuits challenging the safety or effectiveness of a Class III medical device given pre-market approval by the FDA. *Riegel*, 128 S.Ct. at 1003. Because the GenesisXP is (1) a Class III medical device and (2) has received pre-market approval by the FDA, Appellant's claims against ANS are preempted by federal law.

In *Riegel*, the plaintiff sued Medtronic, Inc. after a Medtronic catheter (also a Class III medical device that received pre-market approval from the FDA) ruptured in the plaintiff's coronary artery during the surgery. *Id.* at 1005. The plaintiff brought claims against Medtronic under New York common law based on strict liability, breach of implied warranty and negligence in the design, inspection, distribution, labeling, marketing and sale of the catheter. *Id.* at 1005-06. Medtronic defended on the ground that § 360k(a) of the MDA preempted plaintiff's common law claims. The Court sided with Medtronic, finding that private actions based on state law have the same - if not

greater - potential to interfere with the FDA's regulatory regime than state legislative or agency action:

> State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Id. at 1008.

The Supreme Court held in *Riegel* that state law claims are expressly preempted whenever the following two conditions exist: (1) specific federal requirements apply to the particular medical device that is the subject of the state-law claim; and (2) the state-law tort claim imposes a standard of care or behavior that is "different from, or in addition to" the specific federal requirements. *Id.* at 1006-08. The Supreme Court noted that the PMA process is a "rigorous" one which certainly imposes "specific federal requirements" applicable to a particular device. *Id.* at 1004, 1007. As to the second prong, *Riegel* held that state law tort claims indeed impose requirements upon medical device manufacturers that "are different from, or in addition to" those imposed under the PMA process. *Id.* at 1011 (citing 21 U.S.C. § 360k(a)(1)). Accordingly, the *Riegel* Court affirmed the dismissal of plaintiff's claims. *Id.*

The instant Appellant asserts essentially the same theories of liability as claimed in *Riegel*. Appellant's claims against ANS can be distilled down to the following: strict

liability, negligence, and distribution of a defective product. These claims clearly relate to and revolve around the safety and effectiveness of the subject device. *Id.* at 1007. Moreover, they impose requirements that are different from or in addition to federal MDA requirements. *Id.* at 99, 1004-07.

Decisions of Mississippi courts, as well as those of the Fifth Circuit, are in accord with the *Riegel* opinion. Even before the Supreme Court's decision in *Riegel*, Mississippi law recognized federal preemption in medical device cases. In *Rutland v. Mentor Corp.*, 1994 WL 454741 (Miss. Cir. 1994), the plaintiff had a procedure to install a penile prosthesis and subsequently experienced an infection which resulted in the removal of the prosthesis. *Id.* at 1. Plaintiff subsequently filed a complaint against Mentor as the manufacturer of the prosthesis alleging strict liability, negligence, and breach of warranty. *Id.* However, the Circuit Court of the First Judicial District of Harrison County, Mississippi found that because the prosthetic device was a Class III device with PMA, then plaintiff's claims were preempted by 21 U.S.C. Section 360k. *Id.* at 2. As a result, the court granted summary judgment in favor of Mentor. *Id.* at 4; *Hearn v. Advanced Bionics Corp.*, 2008 WL 3896431 (S.D. Miss.) (acknowledging *Riegel); Hughes v. Boston Scientific Corporation*, 2009 WL 3817586 (S.D. Miss.) (acknowledging *Riegel*); *Martin*, 254 F.3d at 573 (holding that state common law products liability claims, for manufacturer's breach of duty in connection with its design, labeling and manufacture of pacemaker which had already been subject to rigorous premarket approval were preempted by MDA). For all of these reasons, Appellant's claims are preempted by federal statute and ANS is entitled to judgment as a matter of law.

CONCLUSION

It is undisputed that the doctrine of federal preemption is applicable to this matter. ANS has presented this Honorable Court with ample evidence proving indeed that the GenesisXP is a Class III medical device. Further, despite the product's classification, it is further undisputed that the GenesisXP has received and properly maintained pre-market approval from the FDA. Courts have continuously held that the focus is not on the classification, but the process undertaken to obtain approval from the FDA. As such, even though ANS maintains the GenesisXP is a Class III medical device, the main focus is that it has received and properly maintained pre-market approval from the FDA.

Because the GenesisXP is a Class III device that has received pre-market approval from the FDA, Appellant's claims are preempted by federal statute.

Appellant's whole argument centers around a baseless premises that the GenesisXP is a Class II medical device. It is readily apparent that Appellant continues to advocate holding the GenesisXP to a less rigorous review and approval process, simply to allow him the ability to recover against ANS in the instant suit. To allow such a recovery contorts the law and policy behind the classification system. Accordingly, for all of these reasons, the ruling of the lower court should stand.

Respectfully submitted,

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I, Leah N. Ledford, do hereby certify that I have mailed via U.S. Mail a copy of the foregoing Brief of the Appellee to:

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SO CERTIFIED, this the 19th day of January, 2010

Leah N. Ledford

Leah N. Ledford.