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

SHERYL D. CLINE, Plaintiff, v. ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION, Defendant.	:	CIVIL ACTION NO. 1:11-CV-4064-AT

ORDER

This matter is before the Court on Defendant's Motion to Dismiss Plaintiff's Amended Complaint [Doc. 19]. For the reasons discussed below, the motion to dismiss is **GRANTED IN PART** and **DENIED IN PART**.[1]

I. Procedural Background

Plaintiff Cline filed her Complaint for Damages in the State Court of Fulton County, Georgia, on October 24, 2011. On November 23, 2011, Defendants St. Jude Medical, Inc., and St. Jude Medical S.C., Inc., removed the case to this Court based on diversity jurisdiction.

[1] Plaintiff's Motion for Oral Argument [Doc. 23] is **DENIED** nunc pro tunc.

Defendants[2] moved to dismiss the complaint on November 30, 2011. Plaintiff Cline filed a Motion for Leave to File Amended Complaint on December 7, 2011. As Plaintiff could have filed the Amended Complaint as of right under Rule 15(a)(1), the Court granted Plaintiff's motion and directed the Clerk to enter the Amended Complaint on the docket on January 9, 2012. On January 23, Defendant filed the instant Motion to Dismiss Plaintiff's Amended Complaint under Federal Rule of Civil Procedure 12(b)(6). Defendant contends that both counts of the Amended Complaint fail to allege a well-pleaded claim under Rule 8(a)(2) and that both counts are preempted by federal law under the Medical Device Amendment ("MDA") set forth in 21 U.S.C. §360(c) *et seq*.

II. Motion to Dismiss Standard

In determining whether a complaint states a claim upon which relief can be granted, courts accept the factual allegations in the complaint as true and construe them in the light most favorable to the plaintiff. *Hill v. White*, 321 F.3d 1334, 1335 (11th Cir. 2003). To survive a motion to dismiss, a complaint must allege facts that, if true, "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quotations omitted). A claim is plausible where the plaintiff alleges factual content that "allows the court to draw

[2] On December 8, 2011, the Court entered a Consent Order to Substitute Parties substituting Advanced Neuromodulation Systems, Inc., d/b/a St. Jude Medical Neuromodulation Division for the original named defendants St. Jude Medical, Inc., and St. Jude Medical S.C., Inc. [Doc. 8].

the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The plausibility standard requires that a plaintiff allege sufficient facts "to raise a reasonable expectation that discovery will reveal evidence" that supports the plaintiff's claim. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007).

A court considering a Rule 12(b)(6) motion to dismiss should conduct a three-part analysis. First, the court must identify the elements of the cause of action. *Iqbal*, 129 S. Ct. at 1950-51. Then the Court identifies the "mere conclusory statements" and "[t]hreadbare recitals of the elements of a cause of action" that are not entitled to an "assumption of truth." *Id*. at 1949-51. Finally, the Court must consider the well-pleaded factual allegations to determine if they "plausibly" establish the elements of the claim. *Id*. at 1950.

III. Factual Background[3]

This case arises from the surgical implantation of a medical device and the injuries sustained from its failure and removal. In an attempt to relieve her chronic back and lower body pain, Plaintiff Cline had a medical device surgically inserted in her back on December 24, 2009. (Am. Compl. ¶ 5.) This device, called an implantable pulse generator ("IPG"), is designed to relieve pain through electric stimulation of nerves. (*Id*. at ¶¶ 4, 5.) The IPG implanted in the Plaintiff

[3] Consistent with the standard described above, the facts here are taken from Plaintiff's amended complaint [Doc. 18] and are presumed true for the purpose of reviewing Defendant's motion to dismiss. They do not represent the Court's actual findings of fact. *See Optimum Techs., Inc. v. Henkel Consumer Adhesives, Inc.*, 496 F.2d 1231, 1241 (11th Cir. 2007).

was an Eon Mini Model 3788 Spinal Cord Stimulator ("Model 3788"), which Defendant designed, manufactured, marketed, and sold. (*Id.*)

The Model 3788 relieved Plaintiff's pain initially, but in June 2010, the device stopped working. (*Id.* at ¶ 6.) Plaintiff underwent surgery to extract the Model 3788 on October 20, 2010, and the device was sent to Defendant for analysis. (*Id.* at ¶ 7.) After examination of the device, Defendant wrote Plaintiff's physician on February 15, 2011, explaining that the device failed as "the result of a defective IPG battery." (*Id.* at ¶ 8., Ex. A.)

Defendant made multiple representations and warranties about the battery life of the Model 3788. Immediately prior to the initial surgery on December 2009, Plaintiff Cline received a copy of the "Eon Mini Charging System User's Guide," and spoke with Sean Botha, a Territorial Manager of Defendant involved with the sale of the Model 3788. (*Id.* at ¶¶ 12, 13.) The user guide contains a limited warranty section (the "Limited Warranty") in which Defendant warrants the Model 3788 will be free of defects for one year. (*Id.* at ¶ 12, Ex B.) Plaintiff's discussion with Mr. Botha involved questions about the battery life of the Model 3788, to which Mr. Botha responded that it was "guaranteed to last at least ten years." (*Id.* at ¶ 13.)

Plaintiff filed the instant action seeking damages of $90,000 for the medical expenses from her replacement surgery and subsequent recovery. (*Id.* at

¶ 9.) In addition, Plaintiff seeks compensatory damages, including pain and suffering damages, litigation costs, and attorney's fees. (*Id*. at ¶¶ 33-34.)

IV. Analysis

A. Premarket Approval and Federal Preemption

Much like prescription drugs, medical devices are regulated by the FDA. The Medical Device Amendments ("MDA") of 1976 to the Federal Food Drug and Cosmetic Act grant the FDA regulatory authority over medical devices and define three tiers of regulation. 21 U.S.C §360c. The three regulatory tiers correspond to the inherent risk of using the device, with Class III representing the greatest level of risk. *See Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1003 (2008). Examples of Class III devices include replacement heart valves, implanted cerebella stimulators, and pacemakers. *Id*. Developers of new Class III devices are required to obtain premarket approval, the FDA's highest level of oversight. *Id*. at 1003-1004, 21 U.S.C. §360c(a)(1)(C).

Premarket approval is a "rigorous" process that requires manufacturers of Class III devices to submit an extensive application, including (1) data supporting the safety and effectiveness of the device; (2) detailed descriptions of the device's design, components, and method of manufacture; and (3) a sample of the proposed labeling of the device. *Riegel*, 128 S. Ct. at 1004. The FDA reviews premarket approval applications for a "reasonable assurance of safety and effectiveness." 21 U.S.C. §360e(d). After receiving premarket approval for a

device, manufacturers may not alter the "design, manufacture, label, or other attribute that affects the 'safety or effectiveness' of the device without an additional or supplemental [premarket approval]." *Horn v. Boston Scientific Neuromodulation Corp.*, No. CV409-074, 2011 WL 3893812 at *3 (S.D. Ga. August 26, 2011). The FDA has established guidelines covering the design, production, inspection, testing, labeling, packaging, handling, storage, distribution, and installation of Class III medical devices. *See* 21 C.F.R. §§820.1-820.250.

Along with providing a regulatory framework for medical devices, Congress included a preemption clause in the MDA that states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a).

In *Riegel v. Medtronic*, the Supreme Court applied §360k(a) to preempt a number of common law claims stemming from the failure of a Class III device. *Riegel*, 128 S. Ct. at 1006. The Court established a two-pronged test for claim preemption under §360k(a). *Id.* First, courts must determine if the federal

government has established requirements relating to the device. *Id.* If so, courts then evaluate whether a state claim imposes requirements relating to the safety and effectiveness of the device that are "different from, or additional to," federal requirements. *Id.*

The Court held that the FDA's premarket approval process "imposes requirements under the MDA" for Class III devices. *Id.* at 1007 (internal quotations omitted). Given the comprehensive nature of the premarket approval process, this first prong is almost always satisfied for claims related to Class III devices. Therefore, the issue of preemption commonly turns on the second prong of the *Riegel* test; specifically, whether the claims relate to the safety and effectiveness of the device. *Horn*, 2011 WL 3893812, at *4. In *Riegel*, the Court concluded that common law claims for negligence, strict liability, and breach of implied warranty are examples of state law "requirements" that relate to the safety or effectiveness of a device, and are thus preempted. *Riegel*, 128 S. Ct. at 1007-1008. "State tort law that requires a [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme," and is preempted. *Id.* at 1008.

The Supreme Court has not yet considered whether a claim for breach of express warranty is preempted under the MDA. While the *Riegel* decision spoke to preemption of other common law claims, the express warranty question was not before the Court. *Id.* at 1006 n.2. Similarly, the Eleventh Circuit has not

decided this issue. *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC 2011 WL 3652311 at *10 (N.D. Ga. Aug. 19, 2011). In section B.1 *infra*, the Court deals with this unanswered question by applying the framework outlined in *Riegel*.

The majority's conclusion in *Riegel* also introduced the concept of "parallel claims," which provide a narrow exception to MDA preemption. *Riegel*, 128 S. Ct. at 1011. The Court explained that state claims based on a violation of the FDA regulations are not preempted under the MDA. *Id*. The Court reasoned that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to,' the requirements imposed by federal law." *Id*. (quoting §360k(a)(1)). Thus, purposely pled state claims based on violations of FDA regulations are not preempted by §360k(a), as those claims do not conflict with, but rather parallel, the statutory scheme. *Id*. Plaintiff has alleged such a parallel claim, which the Court discusses *infra* in section B.2.

B. Plaintiff's Claims

1. Is Plaintiff's Claim for Breach of Express Warranty Preempted?

Count I of Plaintiff's Amended Complaint asserts a claim for breach of express warranty. The Model 3788 implanted in Plaintiff worked for approximately six months before the device's battery failed; the IPG was surgically removed shortly thereafter. (Am. Compl. ¶¶ 5-7.) Subsequent analysis by Defendant showed the device failed due to a "defective" battery. (*Id*. at ¶ 8.,

Ex. A.) Attached to the Amended Complaint is the Limited Warranty from the user guide stating the Model 3788 would "be free from defects in material or workmanship within one (1) year from the date of ownership . . . ." (*Id*. Ex B.) Plaintiff asserts the Limited Warranty is an express warranty made by the Defendant and was breached by the failure of the battery.[4] (*Id*. at ¶¶ 12, 18.)

Georgia law provides for the creation of an express warranty in these circumstances:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

O.C.G.A. §11-2-313(1). Taking all facts in the complaint as true and viewing the representations in the light most favorable to the Plaintiff, as required at this stage, Defendant's Limited Warranty for the Model 3788 meets the definition of an express warranty.[5]

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[4] Plaintiff also refers in her Amended Complaint to representations made Mr. Botha, as well as other "oral statements, internet materials, [and] written materials" not attached to the complaint. (Am. Compl., at ¶¶ 13, 14.) As this motion can be decided on the grounds of the Limited Warranty, the Court need not reach the question of whether claims based on these representations are preempted. In any event, an oral statement by a sales representative clearly does not stand on the same footing as Defendant's overt, written contractual warranty. Representations made in internet or written materials similarly command a weaker position.

[5] Defendant notes that the complete user guide contains a General Warning section which discloses the chance of device failure "during or following implantation" and "makes no representations or warranties that failure" will not occur. (Am. Compl. Ex B.) The Limited Warranty section immediately follows this General Warning. The Court interprets this

Defendant argues that claims for breach of an express warranty involving a Class III medical device are preempted under the MDA. Defendant asserts that as part of the rigorous premarket approval process for Class III devices, the FDA reviews the labeling of the device to ensure it is "neither false nor misleading." 21 U.S.C. §360e(d)(1)(A). According to Defendant, the Model 3788's labeling includes its user guide and the Limited Warranty, and any representations made in those documents were approved by the FDA. (Br. Supp. Mot. Dismiss at 21.) Defendant argues that because the FDA regulates the labeling of the Model 3788, any express warranty included in that labeling relates to the "safety and effectiveness" of the device; thus, any claim for breach of express warranty is preempted under §360k(a). (*Id.* at 21, 22.) Defendant contends that "any claim based upon [the Model 3788] labeling necessarily invades an area already regulated by the FDA." (*Id.* at 21.)

Both parties concede that no authority binds the Court on this issue. Accordingly, the Court applies the *Riegel* test for preemption of state law claims under §360k(a). Under the first prong, the Court must determine if the federal government has established requirements relating to the device. *Riegel*, 128 S. Ct. at 1006. The Supreme Court has concluded that "[p]remarket approval . . . imposes 'requirements' under the MDA." *Id.* at 1007. Thus, the labeling of the

inconsistency to mean that Defendant makes no representations or warranties about the device aside from the Limited Warranty in the user guide. *Cf. Rivers v. BMW of North America, Inc.*, 449 S.E.2d 337, 341 (Ga. Ct. App. 1994) (general disclaimer of express or implied warranties does not negate an affirmative express warranty).

Model 3788 reviewed by the FDA as part of the premarket approval process, including the Limited Warranty from the user guide, satisfies the first prong of the test.

The second prong of the *Riegel* test, and the substance of Defendant's argument for dismissal of claims based on the Limited Warranty, focuses on whether a claim for breach of express warranty imposes requirements "different from, or in addition to," those imposed by the FDA relating "to the safety or effectiveness of the device" under §360k(a). While there is a lack of binding authority on the issue, persuasive authority runs in both directions. *Compare Gomez v. St. Jude Medical Diag. Div. Inc.*, 442. F. 3d 919, 932 (5th Cir. 2006) (holding that a claim for breach of express warranty was preempted because it was inconsistent with federal regulations) *and Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 285 (E.D.N.Y. 2009) (holding that an express warranty claim was preempted where "plaintiff broadly alleges that Defendants expressly represented and warranted that Defective Device was safe" (internal quotations omitted)) *with Mitchell v. Collagen Corp.*, 126 F. 3d 902, 915 (7th Cir. 1997) ("A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the [premarket approval], and therefore we cannot say that such a cause of action is preempted") *and Horn*, 2011 WL 3893812 at *10 (discussed below).

Courts have held claims for breach of express warranty to be preempted primarily where the warranty directly relates to the safety or effectiveness of the device. *See Leonard*, 2011 WL 3652311 at *10 (a claim for breach of express warranty that a device was "safe and highly reliable" would conflict with the FDA's conclusion the device was "reasonably safe and effective" and is thus preempted); *In re Medtronic, Inc.*, 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009) (holding that claims for breach of an express warranty of a medical device's safety would require a jury to determine that the device was unsafe); *Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226, 1230 (D. Nev. 2009) (holding that a breach of express warranty claim was preempted where an essential element of the claim includes "proof that a device granted a [premarket approval] is not safe or effective").

This Court is persuaded by the reasoning adopted in *Horn*, a case where the Southern District of Georgia addressed a preemption argument involving remarkably similar facts to this case. In *Horn*, the plaintiff also had an IPG implanted into his back. *Horn*, 2011 WL 3893812 at *1. The device failed within weeks, and plaintiff brought a claim for breach of express warranty. *Id.* The defendant in that case had provided a "Limited Warranty" stating that "the IPG will be free from defects in workmanship for a period of (5) five years from the date of surgical implant of the IPG." *Id.* at *10. The court found that this claim did not involve "a breach of a promise about safety, effectiveness, or any other

requirement imposed by the FDA." *Id.* Rather, the claim was "based on a voluntary contractual promise made by Defendant to Plaintiff." *Id.*

The claims and circumstances presented here are nearly identical. The Limited Warranty provided by Defendant guarantees that the Model 3788 will "be free from defects in material or workmanship within one (1) year from the date of ownership" and use. (Am. Compl. ¶ 12, Ex. B.) The device failed within six months of implantation because of a defective battery. This Court agrees with the analysis in *Horn* and concludes that Plaintiff's claim for breach of express warranty is not preempted for two separate reasons.

First, the Limited Warranty does not implicate the FDA's determination of either safety or effectiveness. Defendant's representation that the Model 3788 will be free from defects for one year does not overlap with the FDA's assessment of whether the Model 3788 is "safe" for implantation or "effective" for the treatment of chronic pain. The Limited Warranty in this case is distinguishable from the persuasive cases discussed above where courts found express warranty claims to be preempted. This express warranty does not guarantee that the Model 3788 relieves back pain, restores natural movement, delivers the best results, or any other claim of safety or effectiveness. Instead, the Limited Warranty simply establishes a brief period of time that Defendant guarantees the craftsmanship of the Model 3788, apart from any FDA standards.

Nor would allowing this claim to proceed require a finder of fact to challenge or usurp the FDA's conclusions of safety and effectiveness. Defendant disputes this, arguing that because the FDA regulates device labeling as part of the premarket approval process, any breach of warranty claim "necessarily invades an area already regulated by the FDA" and is thus preempted. (Br. Supp. Mot. Dismiss at 21). Defendant is correct that the FDA's review of Class III device labeling is extensive, but it does not follow that everything contained in the labeling relates to the safety or effectiveness of the device.

Under §360c(a)(3)(A), device effectiveness is determined by the FDA:

> [O]n the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts *that the device will have the effect it purports or is represented to have* under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(emphasis added). The FDA's review of device labeling "rel[ies] on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness . . . ." §360e(d)(1)(A). In sum, under these two provisions, the FDA executes its statutory responsibility for evaluating the safety and effectiveness of a Class III device through expert investigation of the relevant data and literature. If a device is shown to work, the agency weighs the benefit against any risk associated with the device to determine whether the device can properly be marketed. If so, the

FDA ensures that the label's conditions of use do not detract from the effectiveness of the device by confusing consumers regarding its administration or usage.

Guided by these statutes, it is clear that the Limited Warranty falls outside the scope of the "effectiveness" review performed by the FDA. As such, this express warranty claim does not require a factfinder to reach conclusions on the safety or effectiveness of the Model 3788 or its labeling. Therefore, the claim for breach of the warranty at issue here does not "relate to the safety or effectiveness of the device" under §360k(a).

Moreover, this claim for breach of express warranty is not based on a coercive or regulatory state law "requirement" under the language of §360k(a). Rather, it is based on an obligation that Defendant has freely imposed on itself. The "requirement[s] imposed by an express warranty claim are not imposed under State law, but rather imposed *by the warrantor*." *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2622 (1992) (internal quotations omitted) (emphasis in original). While *Cipollone* interpreted the preemption clause of the federal statute that requires a specific warning on cigarette boxes, the Supreme Court's logic is instructive. "[A] common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a requirement . . . imposed under State law" when considering whether the federal statute preempts a claim. *Id.* (internal quotations omitted).

Here, Defendant made voluntary contractual guarantees to induce consumer reliance and purchase of the Model 3788. The Court is unaware of any FDA regulations governing or requiring such a warranty. Such express warranties tangential to device safety or effectiveness are not state-established "requirements" that trigger preemption under §360k(a). Any additional requirement imposed by an express warranty is one freely and willingly adopted by manufacturers of Class III devices for their commercial benefit, and is thus outside the scope of the MDA.

This Court's decision is consistent with *Riegel*'s discussion of the policy underlying the MDA. The FDA's regulation of Class III devices involves a cost-benefit analysis that measures the total social benefit a device provides. *Riegel*, 128 S. Ct. at 1008. This balance can be extraordinarily difficult: "How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?" *Id.* The potential for state tort jury verdicts disrupts this balance. Faced with common law claims for negligence or strict liability, manufacturers would make Class III devices "safer, but hence less effective, than the model the FDA has approved." *Id.* By preempting many common law claims, the MDA promotes the optimal balance of safety and effectiveness for Class III devices.

Nothing in this decision upsets that balance. Unlike claims for negligence, strict liability, or breach of implied warranty, a claim for breach of an express

warranty unrelated to safety or efficacy does not represent a state's intrusion on the regulatory authority of the FDA. Any requirement or obligation based on the Limited Warranty is not imposed by a state, but voluntarily assumed by the Defendant. Contrary to Defendant's assertion, allowing this claim to proceed does not "backdoor a product liability claim" or otherwise undermine the MDA. Rather, this is a contract claim invited by Defendant's provision of an affirmative express one-year warranty to induce consumer purchases. Since this claim involves neither state-established "requirements" nor FDA determinations of safety or effectiveness, it is not preempted by the MDA.

Defendant's motion to dismiss Count I is therefore **DENIED**.

2. Does Plaintiff's Parallel Claim Satisfy Applicable Pleading Requirements for Violation of FDA Regulations?

Count II of Plaintiff's Amended Complaint alleges Defendant violated FDA regulations related to Class III medical devices. Specifically, Plaintiff directs the Court's attention to "Subparts C, G, H, K and L of Section 820, which govern the design controls, production controls, process controls, inspection, testing, labeling, handling, storage, distribution, and installation of a Class III Medical Device." (Am. Compl. ¶ 22.) Plaintiff identifies 21 C.F.R. §§ 820.30, 820.70, 820.72, 820.75, 820.80, 820.120(b), 820.130, and 820.150, which describe the FDA standards for current good manufacturing practices ("CGMPs") applicable to manufacturers of medical devices. (*Id.* ¶¶ 23-29.) The claim concludes by

asserting Defendant "failed to meet one or more" of the above-cited requirements, and this failure led to the injuries suffered by Plaintiff. (*Id.* ¶¶ 31-32.) By claiming violations of FDA regulations, Plaintiff seeks to allege a parallel claim that is not preempted by §360k(a).

The Eleventh Circuit has specifically addressed the pleading requirements for parallel claims. *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F. 3d 1296, 1301 (11th Cir. 2011). In *Wolicki-Gables*, the court stated that a properly alleged parallel claim must both: (1) claim the violation of a particular federal regulation, and (2) "set forth facts pointing to specific . . . requirements that have been violated." *Id.* (internal quotation omitted). In the Amended Complaint, Plaintiff is essentially asking this Court to infer on its own that the "defective IPG battery" was a result of Defendant's violation of an unspecified FDA regulation. Absent from the complaint are specific factual allegations indicating exactly what FDA regulation was violated and in what manner. The Eleventh Circuit has foreclosed this generic approach to the pleading of parallel claims, holding that it fails to meet the requirements of *Twombly* and *Iqbal*. *Id.* As Plaintiff's Amended Complaint fails to provide a specific factual basis that demonstrates the presence of the elements of a parallel claim, the Court must dismiss Count II under governing Eleventh Circuit precedent. *Id.* at 1302.[6]

[6] At least one other circuit has applied *Twombly*'s pleading requirements differently for a claim involving allegations of a Class III device in violation of FDA requirements. The Seventh Circuit

As a result, Count II of the Amended Complaint is **DISMISSED**.

V. Conclusion

Defendant's motion to dismiss [Doc. 19] is **DENIED** as to Count I and **GRANTED** as to Count II. Plaintiff's motion for oral argument [Doc. 23] is **DENIED** nunc pro tunc.

It is so **ORDERED** this 15th day of June, 2012.

AMY TOTENBERG
UNITED STATES DISTRICT JUDGE

noted the difficult pleading posture of plaintiffs injured by defective medical devices and affirmed the standard of notice pleading for parallel claims. *Bausch v. Stryker Corp*., 630 F. 3d 546, 558 (7th Cir. 2010). The court explained that "much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law." *Id.* Because of this, "formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Id.* The Seventh Circuit therefore reversed the district court's dismissal of the plaintiff's claim for lack of sufficient facts in the Complaint.

In the present case, the Model 3788 was surgically removed from Plaintiff's back and sent directly to Defendant for testing and analysis. Defendant has not made the Model 3788 or the detailed results of Defendant's analysis available to the Plaintiff. It is difficult to see how Plaintiff could satisfy the parallel claim pleading requirements from *Wolicki-Gables* absent extraordinary circumstances, e.g. whistle blowing or FDA disclosure of confidential information. In any event, such relevant information is not alleged here.