IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

CHARLES MARGETTA, Plaintiff, v. MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK USA, INC., Defendants.	)	Case No 2:13-cv-02645-JTF-cgc

ORDER DENYING MOTION TO REMAND

Before the Court comes Plaintiff Charles Margetta's Motion to Remand, filed on September 18, 2013. (D.E. #3). Defendant Medtronic, Inc. filed its Response in Opposition to Plaintiff's Motion on October 7, 2013. (D.E. #12). After reviewing the Motion and Response, the Court DENIES Plaintiff's Motion to Remand.

I. BACKGROUND

On August 15, 2013, Plaintiff Charles Margetta filed his Complaint against Defendants Medtronic, Inc. ("Medtronic") and Medtronic Sofamor Danek USA, Inc. ("MSD") in the Circuit Court of Tennessee for the Thirtieth Judicial District at Memphis, Shelby County. The causes of action are based upon Plaintiff's allegations that Defendants improperly and illegally promoted and sold a bio-engineered bone graft device, the Infuse™ Bone Graft/LT-Cage Lumbar Fusion Device ("Infuse™"), for unapproved and unreasonably dangerous surgical applications. Specifically, Plaintiff contends that, because the use of the Infuse™ was allegedly used in a manner inconsistent with the Food and Drug Administration's ("FDA") approval of the device,

Defendants should be found liable for, *inter alia*, fraudulent use and promotion of the Infuse™ through an off-label manner.

Plaintiff alleges nine state law causes of action: (1) fraudulent misrepresentation and fraud in the inducement; (2) strict products liability—failure to warn; (3) strict products liability—design defect; (4) strict product liability—misrepresentation; (5) product liability—negligence; (6) breach of implied warranty; (7) breach of express warranty; (8) violation of Florida Deceptive and Unfair Trade Practices Act; and (9) punitive damages. Plaintiff requests compensatory damages in the amount of $10,000,000 and various other damages from the court.

Defendant Medtronic removed the case to the Western District of Tennessee, Western Division, on August 19, 2013. (D.E. #1). Subsequently, on September 18, 2013, Plaintiff filed his Motion to Remand the case. Plaintiff argues this case was improperly removed from state court based on both diversity and federal question jurisdiction. Specifically, Plaintiff avers that his claims should be remanded for the foregoing reasons: (1) Medtronic's notice for removal is untimely; (2) federal diversity does not exist; (3) no federal question exists; (4) a petition for removal is procedurally improper unless all defendants join.

Conversely, Defendant asserts that, because the Infuse™ is classified as a Class III, FDA, premarket approved device under the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 360k(a), the case properly belongs under federal jurisdiction. Additionally, Defendant argues that the removal of the case from state court to federal district court was proper. Specifically, Defendant contends: (1) Medtronic's removal notice was not premature; (2) removal based on diversity jurisdiction was proper; (3) Plaintiff's complaint is removal pursuant to federal question jurisdiction; and (4) MSD

was not required to consent to removal because it had not been served at the time.

II. ANALYSIS

A. Procedural Framework Governing Removal

28 U.S.C. § 1446 governs the procedural framework for removing civil actions from state court to federal court. Section 1446(a) states that, "[a] defendant or defendants desiring to remove any civil action from a State court . . . shall file in the district court . . . a notice of removal."

1. Defendant's Notice of Removal was Filed Prematurely

28 U.S.C. § 1446(b)(1) further details the requirements necessary for a defendant to file its notice of removal:

> The notice of removal of a civil action or proceeding shall be filed within 30 days after the receipt by the defendant, through service or otherwise, of a copy of the initial pleading setting forth the claim for relief upon which such action or proceeding is based . . . .

The Supreme Court in *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 347-348 clarified the language of § 1446(b)(1) by holding that "a named defendant's time to remove is triggered by simultaneous service of the summons and complaint, or receipt of the complaint, 'through service or otherwise,' after and apart from service of the summons, but not by mere receipt of the complaint unattended by any formal service." *See also Travelers Property Casualty Co. of America v. Rapid Power*, No. 5:12-cv-00038-R, 2012 WL 1252574, at 2 (W.D. Ky. Apr. 13, 2012) and *Whelan v. Dollar General Corp.*, No. 3:11-cv-495-CRS, 2012 WL 1947179, at 2 (W.D. Ky. May 30, 2012).

In this case, Plaintiff argues that Defendant Medtronic's Notice of Removal was filed untimely and "prematurely." (D.E. # 3, at 3). Plaintiff argues that because Defendant had not been served at the time of its Notice of Removal, it should not be allowed to participate in

gamesmanship by attempting "to circumvent a lack of diversity between the parties." (Id.) Plaintiff is correct. Defendant was not served before removing this case from state court to federal court. There is nothing in the record that indicates the method for which Defendant received notice of the filing of the Complaint. The only indication of notification that Defendant provides is that, "Plaintiff commenced this action by filing a complaint . . . on or about August 15, 2013 . . . and the case was docketed at CT-003525-13." (D.E. #1). Defendant contends that its Notice of Removal was timely and that "the law is clear that a defendant may remove a case prior to service of process." (D.E. #12, at 2). However, Defendant is incorrect; the law is anything but clear.

There is a split within this Circuit as to the issue of a defendant's removal prior to service. *Compare Linder v. Medtronic et al*, No. 13-2346, 2013 WL 5486770, at *2 (W.D. Tenn. Sept. 30, 2013)(stating that "there is nothing in the removal statute that precludes Medtronic from filing a notice of removal prior to Plaintiff effecting service of process upon it. Service of process is not a prerequisite to a defendant exercising its right of removal"), *with Vivas v. Boeing Co.*, 486 F.Supp.2d. 726, 734 (N.D. Ill. 2007)(stating that "[allowing] defendants to file a notice of removal before being served . . . would provide a vehicle for defendants to manipulate the operation of the removal statutes.") However, regardless of the parties' arguments, the Court finds Plaintiff's argument, that Defendant's Notice for Removal is untimely, moot. Defendant was served and summons was executed on October 8, 2013. (D.E. #13). As the *McKeen v. Continental Casualty Co.*, No. 10-10624, 2010 WL 3325200, *2 (E.D. Mich. Aug. 19, 2010) correctly stated, "[i]t would be a colossal waste of time and resources to remand this case only to have [defendant] file a second notice of removal now that is has been served."[1]

[1]The facts of the removal in this case are identical to those in *McKeen*: "[Defendant] possessed a copy of the complaint at removal, which it apparently procured once the complaint had been filed on the docket, and it attached its copy of

2. Defendant's Notice of Removal is Procedurally Proper

Section 1446(b)(2)(A) states that, "[w]hen a civil action is removed solely under section 1441(a), all defendants who have been properly joined and served must join in or consent to the removal of the action." From the language set forth in both §1446(a) and § 1446(b)(2)(A), the courts have derived the rule of unanimity, which "demands that all defendants must join in a petition to remove a state case to federal court." *Loftis v. United Parcel Service, Inc*. 342 F.3d 509, 516 (6th Cir. 2003). See also *Brierly v. Alusuisse Flexible Packaging, Inc.,* 184 F.3d 527, 533 n. 3 (6th Cir. 1999) ("The rule of unanimity requires that in order for a notice of removal to be properly before the court, all defendants who have been served or otherwise properly joined in the action must either join in the removal, or file a written consent to the removal.") However, the *Loftis* Court further explains that, "Although in *Brierly* we mentioned [the unanimity rule] in the context of determining the time within which an earlier-served defendant must consent to a later served defendant's removal effort . . . no case decided in [the Sixth Circuit] has made explicit the rule requiring unanimous consent to removal." 342 F.3d at 516.

Plaintiff argues that, based upon the rule of unanimity, a petition for removal is procedurally improper unless all defendants join. Defendant MSD did not join Defendant Medtronic in the Notice of Removal. Defendant argues that "MSD's consent is not required because this action was not 'removed solely under section 1441(a)'" and "MSD's consent is not required because . . . MSD has not been 'properly joined *and* served.'" (D.E. #12, at 17)(original emphasis).

The *Vivas* Court raises a compelling concern by stating that, "[c[ombining the permission

---

the complaint to its notice of removal. [Defendant] therefore had at its disposal all of the information regarding Plaintiffs' claims at the time it filed its notice of removal. Moreover, the complaint as filed included all of the information pertinent to [defendant's] removal decision." 2010 WL 3325200, at *2.

granted in 28 U.S.C. § 1446(b) for defendants to file a notice of removal before being served with the joined and served requirement of 28 U.S.C. § 1441(b) to allow a [defendant] to remove a case before a plaintiff even has a chance to serve him would provide a vehicle for defendants to manipulate the operation of the removal statutes." 486 F.Supp.2d at 734. However, because this case is not based solely on a federal question jurisdiction question, Defendant MSD was not required to join in the Defendant's Notice of Removal. Additionally, since Defendant MSD was not properly joined and served until October 8, 2013 (D.E. #14), Defendant did not have to join MSD in its Notice of Removal. Therefore, the Court believes that Defendant Medtronic's Notice of Removal is procedurally proper.

B. Jurisdictional Framework Governing Removal

On a motion to remand, a defendant bears the burden of showing that federal court has original jurisdiction through either diversity of citizenship, *see* 28 U.S.C. §§ 1332(a) and 1441(b), or federal question jurisdiction, *see* 28 U.S.C. §§ 1331 and 1441(a). *See Warthman v. Genoa Township Bd. of Trustees*, 549 F.3dd 1055, 1061 (6th Cir. 2008) and *Kramer v. Regions Bank*, No. 09-2408, 2010 WL 797792, at *2 (W.D. Tenn. Mar. 2, 2010). However, it is a well-settled premise in this Circuit that "removal statutes are to be narrowly construed to limit federal court jurisdiction" and "[a]ll doubts should be resolved in favor of remand." *Ethington v. General Electric Co*., 575 F.Supp.2d 855, 860 (N.D. Ohio 2008).

In this case, both diversity of citizenship and federal question jurisdiction issues are raised. Thus, this Court must examine whether these jurisdictional issues exist in this case.

1. Diversity of Citizenship Does not Exist

Both 28 U.S.C. §§ 1332(a) and 1441(b)(2) govern the court's analysis of removal based on

diversity of citizenship. *See* 28 U.S.C. §1332(a)("The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000 . . . and is between citizens of different States. . . ."); *See also* 28 U.S.C. § 1441(b)(2)("A civil action otherwise removable solely on the basis of the jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.") Specifically, the court must look to the forum defendant rule to determine whether diversity of citizenship exists.

Under the forum defendant rule, a defendant is prohibited "from removing a case to federal district court when the concerns that underpin diversity jurisdiction (i.e. prejudice to out-of-state defendants) are not present because the plaintiff chose to file suit in defendant's own home state courts." *Ethington*, 575 F.Supp.2d at 858. In other words, a defendant may remove a case to federal court only when there is complete diversity of citizenship "between all named plaintiffs and all named defendants, and no defendant is a citizen of the forum State." *Lincoln Property Co. v. Roche*, 546 U.S. 81, 84 (2005).

The Supreme Court has expressly stated that, "[i]t is not incumbent on the named defendants to negate the existence of a potential defendant whose presence in the action would destroy diversity." *Id*. Defendant Medtronic correctly identifies the leading Sixth Circuit case, *McCall v. Scott*, 230 F.3d 808, n. 2, which states, in dicta, that "[w]here there is complete diversity of citizenship. . . the inclusion of an *unserved* resident defendant in the action does not defeat removal under 28 U.S.C. § 1441(b)." However, there have been several district courts, within this circuit, that have distinguished the Sixth Circuit's dicta in *McCall*. In *Ethington*, the Court states that,

> Congress intended the "joined and served" part of the forum defendant rule to prevent gamesmanship by plaintiffs, who might name an in-state defendant against whom he or she does not have a valid claim in a complaint filed in state court to defeat otherwise permissible removal by the non-forum defendant(s). . . . The tactics employed by defendants [i.e. the removal of a state court case by a forum defendant, before serve on the forum defendant and/or a non-forum defendant] turn Congressional intent on its head by allowing defendants to employ gamesmanship, specifically by rushing to remove a newly filed state court case before the plaintiff can perfect service on anyone.[2]

575 Supp.2d at 861-862. *See also In re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, No. 2:12-97-DCR, 2012 WL 2919219, at *3 (E.D. Ky. July 17, 2012) ("This Court . . . holds that an in-state defendant cannot avoid the statutory prohibition against removal by removing the case before service.") The same Court further clarified the *Ethington* ruling in *NFC Acquisition, LLC v. Comerica Bank*, 640 F.Supp.2d 964 (N.D. Ohio 2009). In *NFC Acquisition*, the defendant attempted to distinguish the facts of the case with that of *Ethington* "on the basis that a forum defendant filed for removal [in *Ethington*], whereas [in the *NFC Acquisition* case], a non-forum defendant filed for removal." 640 F.Supp.2d at 969. However, the Court ruled that "nothing in the text of § 1441(b) . . . makes the forum defendant rule dependent on which defendant filed for removal." *Id*. Defendant argues that this Court should look to the *Darvocet* Court's dicta for guidance, because the Court states that, "[s]ome district courts in this circuit have rejected [the *McCall* Court's] reading of the statute . . . The majority, however, have adopted the literal reading of the statutory language." 2012 WL 2919219, at *2.

In the case presently before the Court, Plaintiff's Complaint was filed on August 15, 2013

2 The *Ethington* Court goes on further to state that, "Given that Congress intended the 'properly joined and served' language to *prevent* litigant gamesmanship, 'it would be especially absurd to interpret the same 'joined and served' requirement to actually condone a similar kind of gamesmanship from defendants' in instances such as the case at bar."575 F.Supp.2d at 862 (quoting *Allen v. GlaxoSmithKline PLC*, 2008 WL 2247067, at *4).

in state court against Defendants Medtronic, a Minnesota corporation with its principal place of business in Minnesota, and MSD, a Tennessee corporation with its principal place of business in Tennessee. Plaintiff is a resident of Florida. Although there is complete diversity of citizenship among Plaintiff and Defendant Medtronic, MSD, a named Defendant in Plaintiff's Complaint, is a defendant of the forum state. Additionally, neither Defendant Medtronic nor Defendant MSD was served before Defendant Medtronic filed its Notice of Removal on August 19, 2013.

The Court finds the numerous district court opinions on this issue persuasive. Defendant's actions are precisely the type of tactics and gamesmanship the district courts have addressed and warned against. Based upon the facts of this case and the law in this circuit, the Court believes that Defendant's removal of this case from state court to federal court is improper based upon diversity of citizenship. However, even without diversity of citizenship, this Court may still have jurisdiction over the claims if federal question jurisdiction exists. *See Joseph v. Baxter Int'l, Inc*., 614 F.Supp.2d 868, 871 (quoting *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 ("Absent diversity of citizenship, federal-question jurisdiction is required.") Therefore, the Court must now turn to examine whether federal question jurisdiction exists.

2. Federal Question Jurisdiction Exists

In order to analyze whether federal question jurisdiction exists, the Court looks to 28 U.S.C. §§ 1331 and 1441(a). Under 28 U.S.C. § 1331, "[t]he district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." Under 28 U.S.C. § 1441(a), "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant . . . to the district court of the United States for the district and division embracing the place where such action is pending.

The threshold inquiry in determining whether a claim "'arises under' federal law must. . . be determined by reference to the 'well-pleaded complaint.'" *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 808 (1986)(quoting *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 9-10 (1983); *See Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 561 (6th Cir. 2007)(quoting *Franchise Tax Bd.*, 463 U.S. at 10)("For better or worse, under the present statutory scheme as it has existed since 1887, a defendant may not remove a case to federal court unless the plaintiff's complaint establishes that the case arises under federal law.")

It is well settled that neither a federal defense nor the mere presence of a federal issue will establish the necessary jurisdictional elements to remove a state cause of action to federal court. *See Merrell Dow*, 478 U.S. at 813. Although the majority of cases removed to federal court set forth causes of action that plainly raise federal issues, there are three exceptions to the "well-pleaded complaint" that confer federal question jurisdiction, when a federal cause of action is not evident on the face of the complaint: (1) artful-pleading doctrine, (2) complete preemption doctrine, and (3) substantial-federal-question doctrine. *Mikulski*, 501 F.3d at 560. Under the artful pleading doctrine, federal question jurisdiction exists when a plaintiff shrouds its complaint with state law claims in order to avoid federal jurisdiction when its claim are truly federal cause of actions. *See Her Majesty the Queen in Right of the Province of Ontario v. City of Detroit*, 874 F.2d 332, 339 (6th Cir. 1989); *See also Mikulski*, 501 F.3d at 561. However, rarely will the federal court "'seek to determine whether the real nature of the claims is federal, regardless of plaintiff's characterization, [instead] most [removal courts] correctly confine this practice to areas of the law pre-empted by federal substantive law.'" *Mikulski*, 501 F.3d at 561 (internal citation omitted).

Under the complete-preemption doctrine, federal question jurisdiction exists when

Congress has "intend[ed] the preemptive force of a federal statute to be so extraordinary that 'any claim purportedly based on that pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law.'" *Id*. at 563 (internal citation omitted). The Supreme Court has only applied the complete-preemption doctrine in three areas: (1) Section 301 of the Labor Management Relations Act of 1947, 29 U.S.C. § 185; (2) the Employee Retirement Income Security Act of 1975, 29 U.S.C. §§ 1001-1461; and (3) the National Bank Act, 12 U.S.C. § 39.

Lastly, under the substantial-federal-question doctrine, federal question jurisdiction exists when "the state-law claim necessarily state[s] a federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing a congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005). Or more plainly stated, a state law cause of action may arise under federal law where "the vindication of a right under state law depends on the validity, construction, or effect of federal law." *Mikulski*, 501 F.3d at 565; *See also Merrell Dow*, 478 U.S. at 808 (quoting *Franchise Tax Bd*., 463 U.S. at 9).

In the present case, Plaintiff has raised nine state law causes of action regarding Defendants Medtronic's and MSD's alleged improper and illegal use, sale, and promotion of the Infuse™ for unapproved and unreasonably dangerous surgical applications. Defendant Medtronic avers that Plaintiff's claims fall under the substantial-federal-question doctrine because Plaintiff cannot prevail without proving that the Infuse™ did not comply with federal requirements, imposed by the FDA and its premarket approval process. Because Plaintiff's Complaint does not appear to be a blatant avoidance of federal jurisdiction or trigger an analysis under the three statutory areas wholly preempted by federal law, the Court finds it proper to examine this case under the

substantial-federal-question doctrine.

a. Plaintiff's Claims Fall Under the Substantial-Federal-Question Doctrine

The court will confer federal question jurisdiction under the substantial-federal-question doctrine when: (1) the state law has necessarily raised a disputed federal issue; (2) the federal interest in the issue is substantial; and (3) the exercise of jurisdiction does not threaten the state-federal law jurisdictional balance. *See Mikulski*, 501 F.3d at 568. Because the Infuse™ is a Class III, premarket approved device under the MDA, the Court finds that Plaintiff's claims against Defendants Medtronic's and MSD's alleged misuse and improper promotion of the Infuse™ appropriately elicits an analysis under the substantial-federal-question doctrine. Plaintiff's claims undoubtedly require this Court to examine federal law, and, even more specifically, examine federal requirements imposed by the FDA through the premarket approval process. Therefore, this Court finds Plaintiff's claims would be more suitably decided by federal question jurisdiction under the substantial-federal-question doctrine.

i. Plaintiff's State Law Claims Necessarily Raise a Disputed Federal Issue

First, the Court must examine whether the state law claims have raised a disputed federal issue in this case. Since the Infuse™ is a Class III, premarket approved device under the MDA, the Court looks specifically to the MDA to examine this first element of the substantial-federal-question doctrine. The MDA expressly preempts any state requirement on devices intended for human issue that is "different from, or in addition to, any requirement applicable under [the MDA]" or that "relates to the safety or effectiveness of the device . . ." 21 U.S.C. § 360k(a). The only way a state requirement can be exempted from this express preemption is if "the [state] requirement is more stringent than a requirement under [the MDA]

which would be applicable to the device if an exemption were not in effect;" or if the state requirement is "required by compelling local conditions;" and if "compliance with the requirement would not cause the device to be in violation of any applicable requirement [under the MDA]." 21 U.S.C. § 360k(b).

The MDA classifies medical devices in three distinct categories: (1) Class I devices, which are subject to the lowest oversight, *See* 21 U.S.C. § 360c(1)(A); (2) Class II devices, which are subject to special controls, *See* 21 U.S.C. § 360c(1)(B); and (3) Class III devices, which are subject to premarket approval and the highest federal oversight, *See* 21 U.S.C. § 360c(1)(C). Class III devices are classified as such because it

> (i) (I) cannot be classified as a class I device [or class II device] because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurances of the safety and effectiveness of the device . . . , and
>
> * * *
>
> (ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or
> (II) presents a potential unreasonable risk of illness or injury . . .

21 U.S.C. § 360c(a)(1)(C).

The premarket approval process for Class III devices requires multivolume applications to be submitted by the manufacturer and approximately 1,200 hours of review for each application by the FDA. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008). A device will be granted premarket approval only if "there is a reasonable assurance of safety and effectiveness," and if "the proposed labeling is neither false nor misleading." 21 U.S.C. § 360e(a)(1)(A). The FDA determines the safety and effectiveness of the device,

> (A) with respect to the persons for whose use the device is represented or intended,
> (B) with respect to the conditions of the use prescribed, recommended, or suggested in the labeling of the device, and
> (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21 U.S.C. § 360c(a)(2). As the Supreme Court has previously recognized, the FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318.

Once a device receives premarket approval, the FDA requires the device "to be made with almost no deviations from the specifications in its approval application." *Id*. at 323. The only manner for which a device can be modified is for the manufacturer to submit a supplemental application that details the affects the modifications would have on the safety or effectiveness of the device. *See* 21 U.S.C. § 360e(d)(6)(A)(i). After premarket approval, manufacturers are required to submit detail reports for the FDA's continuous oversight of the device. *See* 21 U.S.C. § 360i.

In the present case, Plaintiff argues that Defendants Medtronic and MSD violated, *inter alia*, state law claims of fraudulent misrepresentation when Defendants allegedly improperly and illegally sold and used the Infuse™. Defendant Medtronic argues that Plaintiff's claims necessarily turn on disputed issues of federal law because Plaintiff cannot prevail on his claims, unless he proves that Defendants violated federal requirements imposed by the FDA on the Infuse™. As Defendant Medtronic properly argues, Plaintiff does not address whether his claims necessarily turn on disputed issues of federal law. Plaintiff's only argument to this point is that "if defendant Medtronic wishes to raise the issue of federal pre-emption of state law claims, [it] should do so in a motion to dismiss or motion for summary judgment." (D.E. #3, at 5).

The Court finds Plaintiff's statement ineffective. In Plaintiff's Complaint, Plaintiff states that "[t]his case involves a spinal fusion surgery in which INFUSE™ was used in an *off-label* (i.e. not approved by the FDA) manner…." (D.E. #1-2, at ¶ 3)(original emphasis). Although he argues that the Infuse™ was improperly used, Plaintiff does acknowledge that the Infuse™ was approved by the FDA and granted a Class III, premarket approval. Plaintiff has set the landscape and scope of the issues that will be addressed in this case, and Defendant Medtronic has properly asserted an applicable preemption defense to Plaintiff's claims. This Court believes Plaintiff's claims necessarily raise disputed federal issues. Defendant has carried its burden of the first element of the substantial-federal-question doctrine.

ii. A Substantial Federal Interest Exists in this Case

Next, the Court turns to the second element of the substantial-federal-question doctrine: the substantiality of the federal interest at issue. The courts have identified four factors that must be considered in determining the substantiality of the federal interest in an issue:

> (1) whether the case includes a federal agency, and particularly, whether that agency's compliance with the federal statute is in dispute;
> (2) whether the federal question is important (i.e., not trivial);
> (3) whether a decision on the federal question will resolve the case (i.e., the federal question is not merely incidental to the outcome);
> (4) whether a decision as to the federal question will control numerous other cases (i.e., the issue is not anomalous or isolated.)

Mikulski, 501 F.3d at 570. These factors are to be examined collectively and in light of the issues presented in each case—meaning that "no single factor is dispositive." *Id*.

This case does not involve a federal agency or the agency's disputed compliance with a federal statute. However, because of the nature of the medical device in this case, the FDA is invoked, but the FDA is not the focus of the issue. Instead, the focus of this case and, in turn, the

substantial federal interest in this case is whether the express preemption in the MDA bars Plaintiff's state law claims that challenge Defendants Medtronic's and MSD's use, sale, and promotion of a Class III device. The courts have previously stated that "general federal requirements could never pre-empt, or general state duties [could] never be pre-empted." *Riegel*, 552 U.S. at 322. However, because the Infuse™ is a Class III, premarket approved device, the Court must address an important federal question that deals specifically, and not generally, with federal regulations and requirements regarding a highly regulated medical device. As the Supreme Court stated in *Riegel*, "[u]nlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it *is* federal safety review." 552 U.S. at 322-323 (original emphasis).

Plaintiff argues that Defendant Medtronic's removal is "unsubstantiated." (D.E. #3, at 7). Conversely, Defendant argues that Plaintiff's argument does not effectively address the substantiality of the federal interest in regulating Class III medical devices.

This Court finds that the federal interest at issue is substantial in this case. The federal interest in this issue satisfies three of the four factors identified by the courts: the federal interest (1) presents an important and non-trivial federal question that will (2) dispose of the case when decided upon and will (3) control numerous other cases. Moreover, the thirty-three other cases pending before this Court, involving Defendants Medtronic and MSD in this case and the Infuse™ medical device, alone prove that the Court's ruling of the federal question in this case will not have an inconsequential effect. Consequently, the Court finds the second element of the substantial-federal-question doctrine has been satisfied, because a substantial federal interest exists.

iii. The State-Federal Jurisdictional Balance is Not Damaged by the Conferral of Federal Question Jurisdiction over Plaintiff's Claims

Third, the Court must examine whether a conferral of federal question jurisdiction over Plaintiff's claims would upset the state-federal jurisdictional balance. As the Supreme Court has stated,

> [E]ven when the state action discloses a contested and substantial federal question, the exercise of federal jurisdiction is subject to a possible veto. For the federal issue will ultimately qualify for a federal forum only if federal jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331.

Grable, 545 U.S. at 313-314. As the courts have reiterated time and again, there is no bright-line rule in determining the presence of a federal issue because "determinations about federal jurisdiction require sensitive judgments about congressional intent, judicial power, and the federal system." *Merrell Dow*, 478 U.S. at 810. Therefore, it is imperative for the courts to carefully analyze these factors so that the state-federal jurisdictional balance is not threatened.

Defendant Medtronic contends that the nature of the issues presently before the Court is the type that can only be determined by federal law. *See* D.E. #12, at 17 ("[J]ust as Congress took regulation of innovative medical devices out of the hands of state legislatures and agencies and entrusted it instead to an expert federal agency, so too Congress presumably wanted the litigation of claims involving those devices to be removable to federal court so that it can proceed under the eye of the federal judiciary.") Plaintiff neither refutes nor addresses Defendant's argument.

Here, the issue at hand invokes the MDA because of the categorization of the Infuse™ as a Class III device that has undergone an arduous premarket approval process. As it has been explained above, Congress expressly prescribed the regulation of Class III devices to federal law

through the MDA. The MDA unambiguously states that any state requirement that seeks to impose a requirement "different from, or in addition to, any [federal] requirement applicable … to the device" will be preempted. 21 U.S.C. § 360k(a)(1). The effect of conferring federal question jurisdiction to an issue so closely bound by federal law would have a "microscope effect" on the state-federal jurisdictional balance. *Grable,* 545 U.S. at 315.

When his claims are stripped down to their essential elements, the bases of Plaintiff's Complaint are a challenge to the safety and effectiveness of the Infuse™. The regulations and requirements of the safety and effectiveness of a Class III, premarket approved device belong under the scope of federal question jurisdiction. Therefore, the Court believes that the state-federal jurisdictional balance remains untouched by the conferral of federal jurisdiction over Plaintiff's claims. Consequently, Defendant has established the third, and final, element of the substantial-federal-question doctrine.

III. CONCLUSION

For the foregoing reasons, this Court finds that Defendant Medtronic has met its burden for removal. Consequently, Plaintiff's Motion to Remand is DENIED. This Court has jurisdiction to rule on all claims brought before it regarding this case.

IT IS SO ORDERED this 21st day of November, 2013.

BY THIS COURT:

s/John T. Fowlkes, Jr.
JOHN T. FOWLKES, JR.
United States District Judge