IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BRENDA SMITH, Individually and as Administratix of the Estate of RICKY SMITH	:	
Plaintiffs,	:	
v.	:	**3:16-CV-1264**
	:	**(JUDGE MARIANI)**
SAMIR B. PANCHOLY, M.D., et al.,	:	
Defendants.	:	

MEMORANDUM OPINION

Presently before the Court is Plaintiff's Motion to Remand. (Doc. 21). For the reasons that follow, Plaintiff's Motion will be granted.[1]

I. FACTUAL BACKGROUND

On May 24, 2016, Plaintiff commenced this action by filing a Complaint in the Court of Common Pleas of Lackawanna County, asserting various state law causes of action against the Defendants.[2] (Doc. 1, at 2). Defendant Biotronik, Inc. removed the action to this Court on June 24, 2016. (*Id.*). According to Biotronik, "this case is removable to federal court based on the federal question jurisdiction pursuant to 28 U.S.C. § 1331." (*Id.* at 3). "In the alternative, Biotronik requests that this Court exercise its power pursuant to Rule 21 of the

[1] Because the Court is granting Plaintiff's Motion to Remand, (Doc. 21), the Court expresses no opinion on the merit of Defendant Biotronik's pending Motions to Dismiss. (Docs. 13, 15).

[2] "The initial version of the Complaint also included numerous standard product liability claims against Defendant Biotronik. However, Plaintiff has filed an Amended Complaint in which the product liability claims have been removed. The only remaining cause of action against Biotronik is for vicarious liability based upon the negligent statements of its representative." (Doc. 25, at 6-7).

Federal Rules of Civil Procedure to sever Defendants Samir B. Pancholy, M.D., Samir B. Pancholy, LLC, Haitham Abughnia, M.D., and North Penn Cardiovascular Specialists . . . in order to perfect diversity jurisdiction over Biotronik." (*Id.*).

Defendant Biotronik thereafter filed a Motion to Dismiss on July 11, 2016, (Docs. 13, 15), and Plaintiff filed the instant Motion to Remand on July 22, 2016. (Doc. 21). On August 25, 2016, the Court held a Case Management Conference and thereafter issued an order declining to adopt a discovery schedule until consideration of Plaintiff's Motion to Remand.

II. ANALYSIS

A. Plaintiff's Claims Do Not Arise Under Federal Law

Federal district courts have original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Whether an action "arises under" federal law is governed by the well-pleaded complaint rule. *See Caterpillar Inc. v. Williams*, 482 U.S. 386, 392, 107 S.Ct. 2425, 96 L.Ed.2d 318 (1987) ("The presence or absence of federal-question jurisdiction is governed by the 'well-pleaded complaint rule,' which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint.") (citing *Gully v. First Nat'l Bank*, 299 U.S. 109, 112-13, 57 S.Ct. 96, 81 L.Ed. 70 (1936)). If a federal question is presented on the face of the plaintiff's complaint, 28 U.S.C. § 1441(a) generally permits a defendant to remove the action to federal court. It is Defendants' burden to show that removal was

proper and that the "'action is properly before the federal court.'" *Shupp v. Reading Blue Mountain*, 850 F. Supp. 2d 490, 494 (M.D. Pa. 2012) (quoting *Sikirica v. Nationwide Ins. Co.*, 416 F.3d 214, 219 (3d Cir. 2005)).

According to Defendant Biotronik, "[w]hile plaintiffs' claims against Biotronik appear to be pleaded under state law, each claim is predicated on alleged breaches of duties imposed by federal law and challenges the safety and effectiveness of a device subject to pervasive federal regulation and stringent administrative oversight. Notably, plaintiffs cannot state a claim, nor can they prevail in this matter, against Biotronik without setting forth a causally-linked violation of relevant FDA requirements." (Doc. 1, at 6). The Court rejects Biotronik's argument. Simply because a state law claim "involves" a federal statute, such as the Medical Device Amendments, or would require a state court to apply federal law, does not in and of itself provide a basis for removal. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986) (holding that a state court action alleging negligence on the theory that defendant's violation of a federal statute constituted negligence *per se* did not present a federal question and therefore removal was improper). Applying the well-pleaded complaint rule, the Court concludes that nothing on the face of Plaintiff's complaint raises a question of federal law. Nor is there anything in Plaintiff's filings suggesting the "artful pleading" of its claims in an attempt to avoid federal jurisdiction. *Caterpillar*, 482 U.S. at 397. Instead, Biotronik merely raises federal law as a defense to Plaintiff's state law claims. (Doc. 11, at 5). As the Supreme Court has long recognized, a

"case may *not* be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue." *Caterpillar*, 482 U.S. at 393 (emphasis in original). Therefore, Defendants cannot, "merely by injecting a federal question into an action that asserts what is plainly a state-law claim, transform the action into one arising under federal law, thereby selecting the forum in which the claim shall be litigated." *Id.* at 399.

B. The Medical Device Amendments Do Not Completely Preempt State Law

The "complete pre-emption doctrine," a corollary to the well-pleaded complaint rule, provides that in certain limited circumstances "the pre-emptive force of a statute is so 'extraordinary' that it 'converts an ordinary state common-law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule." *Caterpillar*, 482 U.S. at 393 (quoting *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63, 107 S.Ct. 1542, 95 L.Ed.2d 55 (1987)). "Once an area of state law has been completely pre-empted, 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 394 (citing *Franchise Tax. Bd. of California v. Constr. Laborers Vacation Trust for Southern California*, 463 U.S. 1, 22, 103 S.Ct. 2841, 77 L.Ed.2d 420 (1983)).

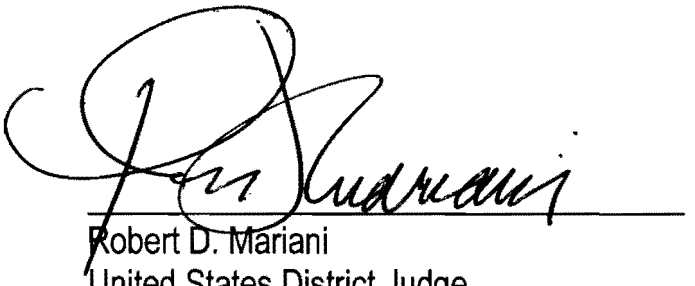
A review of the applicable case law shows that Courts in this Circuit have routinely held that the Medical Device Amendments do not completely preempt state law causes of action

so as to confer federal question jurisdiction. *See, e.g.*, *Guckin v. Nagle*, 259 F. Supp. 2d 406, 408 (E.D. Pa. 2003) (holding that the Medical Device Amendments "do not create an area of complete preemption, such that the state court is barred from hearing [plaintiff's] claims, because the FDCA and MDA do not provide civil remedies for claims that fall within their scope, and there is no clear manifestation of congressional intent to permit removal on the basis that state courts will be forced to interpret federal law."); *Headen v. Mentor Corp.*, No. Civ. A. 96-1459, 1997 WL 27104 (E.D. Pa. Jan. 23, 1997) (holding that the Medical Device Amendments did not completely preempt state law causes of action so as to confer federal question jurisdiction despite absence in complaint of claim based on federal law); *Collins v. Baxter Healthcare Corp.*, 949 F. Supp. 1143 (D.N.J. 1996) (same); *In re Orthopedic Bone Screw Prods. Liab. Litig*, 939 F. Supp. 398 (E.D. Pa. 1996) (same); *Falcone v. Baxter Healthcare Corp.*, No. Civ. A. 96-2943, 1996 WL 482981 (E.D. Pa. Aug. 23, 1996) (same); *Gonoude v. Baxter Healthcare Corps.*, No. Civ. A. 96-3042, 1996 WL 417260 (E.D. Pa. July 17, 1996) (same). In fact, both the Supreme Court and the Third Circuit have explicitly held that the Medical Device Amendments do not completely pre-empt state law causes of action. *See Medtronic, Inc. v. Lohr,* 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (state law causes of action are not completely preempted by Medical Device Amendments); *see also In re Orthopedic Bone Screw Prods. Liab. Litig.*, 132 F.3d 152 (3d Cir. 1997) (holding that the district court lacked subject matter jurisdiction over products liability cases which had been removed to federal court solely on the basis of

federal question because it arose under Medical Device Amendments). Accordingly, because the Court lacks subject matter jurisdiction over Plaintiff's claims, the Court will grant Plaintiff's Motion to Remand. [3]

III. CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Remand, (Doc. 21), will be granted. A separate order follows.



Robert D. Mariani
United States District Judge

[3] The Court finds Biotronik's reliance on *Riegel v. Medtronic Inc.*, 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), to be misplaced. In *Riegel*, the Supreme Court held that because the catheter at issue in the case was a Class III medical device that received premarket approval from the Food and Drug Administration, the plaintiff's state law negligence, strict liability, and implied warranty claims challenging the effectiveness of the catheter were preempted by Section 360(k) of the Medical Device Amendments. Here, in contrast, Plaintiff's state law claims do not challenge the efficacy of a Class III medical device. Rather, they "concern the negligence of an employee for whom Defendant Biotronik is vicariously liable, in negligently misinforming decedent's doctors that the specific device/leads had not malfunctioned in this patient and that it should not be removed." (Doc. 21, at 11-12).

The Court further declines Biotronik's request that it "exercise its power pursuant to Rule 21 of the Federal Rules of Civil Procedure to sever Defendants Samir B. Pancholy, M.D., Samir B. Pancholy, LLC, Haitham Abughnia, M.D., and North Penn Cardiovascular Specialists . . . in order to perfect diversity jurisdiction over Biotronik." (Doc. 1, at 3).