UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

LINDA MIHOK,	:	
Plaintiff,	:	
	:	
v.	:	**CIVIL ACTION NO.**
	:	**3:14-cv-1169 (VLB)**
MEDTRONIC, INC.,	:	
MEDTRONIC PUERTO RICO	:	
OPERATIONS CO.,	:	
MEDTRONIC NEUROMODULATION,	:	
AND	:	
GREENWICH HOSPITAL,	:	
Defendants.	:	**August 10, 2015**

MEMORANDUM OF DECISION GRANTING PLAINTIFF'S MOTION TO REMAND [Dkt. #23]

Plaintiff Linda Mihok, a citizen of Connecticut, brings claims in both her individual capacity and as Executrix of the Estate of Michael Mihok, against Defendants Medtronic Inc., Medtronic Puerto Rico Operations Co., Medtronic Neuromodulation (collectively the "Medtronic Defendants"), and Greenwich Hospital ("Greenwich"), for violations of the Connecticut Products Liability Act ("CPLA"), Conn. Gen. Stat. §§ 52-572m-q, Connecticut's Unfair Trade Practices Act ("CUTPA"), Conn. Gen. Stat. §§ 42-110a, and loss of consortium. Mihok's claims concern injuries suffered by her spouse, Michael Mihok, when a surgically-inserted catheter fractured, depriving him of necessary medication.[1]

The Complaint was originally filed in the Connecticut Superior Court, Judicial District of Stamford/Norwalk, at Stamford, on July 7, 2014, docket number FST-CV14-6023001-S. On August 13, 2014, the Medtronic Defendants filed a Notice of

[1] **Michael Mihok was originally a plaintiff in this action. *See* [Dkt. #1-1]. On June 15, 2015, the Court granted Linda Mihok's motion to substitute party, upon notice of Mr. Mihok's death. *See* [Dkt. #39]. Accordingly, Plaintiff Linda Mihok proceeds as the sole plaintiff.**

Removal, pursuant to 28 U.S.C. §§ 1441(a), 1331, and 1332, in which they asserted (i) that the allegations in the Complaint are sufficient to establish "arising under" jurisdiction and (ii) that Defendant Greenwich, the only non-diverse defendant, was fraudulently joined. [Dkt. #1]. Currently pending before the Court is Plaintiff's Motion to Remand this action back to the Connecticut Superior Court. For the reasons that follow, the Court GRANTS Plaintiff's Motion to Remand and REMANDS this matter back to the Connecticut Superior Court.

I. Background

Michael Mihok, decedent, was diagnosed with Multiple Sclerosis (MS) in the year 2000. [Dkt. #1-1, Compl. at ¶ 56]. While Mihok lost all function in his legs and some function in his arms and hands, Mihok retained sufficient use of his right arm and hand to successfully operate his motorized wheelchair and maintain his employment. [*Id*.].

On December 11, 2006, in an effort to manage his symptoms, Mihok underwent a procedure at Greenwich Hospital to implant the Medtronic's SynchroMed® II Implantable Infusion System (the "System"), which administered medication to control muscle spasticity. [*Id*. at ¶ 57]. The System consisted of a Medtronic pump and a catheter. [*Id*.]. In addition to implanting the System, the Complaint alleges that Defendant Greenwich sold various medical products to patients, "including the . . . System at issue in this claim." [*Id*. at ¶ 11; *see also id.* at ¶ 14 (stating that Defendant Greenwich "sells the [System], which is a programmable infusion system implanted in the body for drug delivery")]. Following this procedure, and for several years thereafter, the medication delivered by the System effectively managed Mihok's symptoms. [*Id*. at ¶ 58].

On July 5, 2011, Defendant Medtronic Neuromedical issued a notification warning users of the System that, as a result of a malfunctioning battery, the pump component might require replacement sooner than had originally been anticipated. [*Id*. at ¶ 59]. As a result, on July 6, 2012, Mihok underwent a pump replacement procedure at Greenwich. [*Id*. at ¶ 60]. The pump was replaced with no surgical complications, but the doctor did not remove the original catheter. [*Id*.].

Two weeks after the procedure, Mihok began to show signs of withdrawal, and his spasticity returned, resulting in the loss of function in his hands and arms, along with painful and debilitating spasms. [*Id*. at ¶ 62]. Mihok visited several different doctors following the onset of these symptoms. On September 7, 2012, after evaluating Mihok's symptoms and the pump, Dr. Kenneth Vives, a surgeon at Yale Neurosurgery, determined that the catheter had fractured. [*Id*. at ¶ 63]. Thereafter, another doctor, Dr. Kenneth Vines, of the Associated Neurologists of Southern Connecticut, replaced the catheter, and Mihok's symptoms subsided. [*Id*. at ¶ 65].

The System is a Class III medical device, approved by the Food and Drug Administration ("FDA") through the pre-market approval ("PMA") process. [*Id*. at ¶ 15]. At times before and after the System was implanted in Michael Mihok (December 11, 2006), the FDA issued Warning Letters to Medtronic stating that Medtronic violated various provisions of the Current Good Manufacturing Practice ("CGMP") regulations promulgated under the Food, Drug, and Cosmetic

Act ("FDCA"). *See* [*id*. at ¶¶ 33-55, 66].[2] Accordingly, the Complaint asserts that the Defendants manufactured, warranted, prescribed, and sold to Michael Mihok a defective pump system, in violation of the CPLA and CUTPA, which caused injuries to both Michael and Linda Mihok, in the form of loss of consortium. In essence, the Complaint alleges that the Defendant's violated the Connecticut Products Liability Act by (or as evidenced by) manufacturing, marketing, selling or implanting a device placed into the stream of commerce without complying with the applicable FDA regulations.

II. Discussion

A. Motion to Remand

"It is a fundamental precept that federal courts are courts of limited jurisdiction and lack the power to disregard such limits as have been imposed by the Constitution or Congress." *Durant, Nichols, Houston, Hodgson, & Cortese-Costa, P.C. v. Dupont*, 565 F.3d 56, 62 (2d Cir. 2009) (citation and quotations omitted). The party asserting federal jurisdiction bears the burden of proving that the case is properly before the federal court. *See McNutt v. General Motors Acceptance Corp.*, 298 U.S. 189, 189 (1936). Where federal jurisdiction is asserted by a defendant pursuant to the removal statute, 28 U.S.C. § 1441, "the defendant has the burden of establishing that removal is proper." *United Food &*

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[2] **The CGMP "requirements set forth a quality control system and 'govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.'" *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 152 (S.D.N.Y. 2011) (quoting 21 C.F.R. § 820.01(a)(1)). To comply with the CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventative action. *Id*. (citing 21 C.F.R. §§ 820.01-.250).**

***Commercial Workers Union, Local 919 v. Centermark Properties*, 30 F.3d 298, 301 (2d Cir. 1994) (citations omitted). "In light of the congressional intent to restrict federal court jurisdiction, as well as the importance of preserving the independence of state governments, federal courts construe the removal statute narrowly, resolving any doubts against removability." *Purdue Pharma L.P. v. Kentucky*, 704 F.3d 208, 213 (2d Cir. 2012) (citation and quotations omitted). A party may remove "[a]ny civil action of which the district courts have original jurisdiction." 28 U.S.C. § 1441(a). Section 1331, the federal-question statute, provides that "[t]he district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Section 1332, the diversity statute, states that "[t]he 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." 28 U.S.C. § 1332(a)(1).**

Defendants assert that this Court has jurisdiction on both federal-question and diversity grounds. Accordingly, the Court takes up each of these arguments.

B. <u>The Court Lacks Federal-Question Jurisdiction Under *Gunn-Grable*</u>

Federal courts have original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. In the "vast bulk" of cases, a suit arises under federal law where the complaint pleads a federal cause of action. *Gunn v. Minton*, 133 S. Ct. 1059, 1064 (2013). In addition,

> **[t]hree situations exist in which a complaint that does not allege a federal cause of action may nonetheless 'arise under' federal law for purposes of subject matter jurisdiction: first, if Congress expressly provides, by statute, for removal of state law claims . . . second, if the state law claims are completely preempted by federal law . . . and third, in certain cases if the vindication of a state law right**

necessarily turns on a question of federal law

***Fracasse v. People's United Bank*, 747 F.3d 141, 144 (2d Cir. 2014) (citations and quotations omitted).**

Here, the parties appear to acknowledge that only the third situation is potentially applicable, and the Court agrees. The Supreme Court recently opined on this third situation and found that only a "special and small" number of cases fall within it. *Gunn*, 133 S. Ct. at 1064. To aid courts in identifying the "extremely rare exceptions" comprising this group, *id*., the Supreme Court has fastened a four-part test:

> **[F]ederal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.**

***Id*. at 1065 (quoting *Grable & Sons Metal Prods. Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 313-14 (2005)).**

Federal-question jurisdiction lies only "[w]here all four of these requirements are met." *Id*. Applying the four-part *Gunn-Grable* test, the Court concludes that the third prong, substantiality of the federal issue, is lacking, and thus finds that federal-question jurisdiction is absent.

1. <u>The Complaint Necessarily Raises a Disputed Issue of Federal Law</u>

As for the first two elements of *Gunn-Grable*, the Court agrees with Defendants that the Complaint necessarily raises a federal issue which the parties actually dispute. The allegations in the Complaint are plainly grounded in Defendants' alleged violations of the federal CGMP requirements. *See* [Dkt. #1-1 Compl. at ¶¶ 23-55, 81-87, 91-97, 102, 104, 110]. As Defendants point out, if Plaintiff's state law claims "challenging the safety of an FDA-approved medical

device" were *not* "'parallel' claims, such as claims 'premised on a violation of FDA regulations' where state law provides a damages remedy for such violations," they would be preempted under the FDCA. *Otis-Wisher v. Medtronic*, Inc., No. 14-3941, 2015 WL 3557011, at *1 (2d Cir. Jun. 9, 2015) (Summary Order) (citing and quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 220 (2008)); *see also* 21 U.S.C. § 360k(a);[3] *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 104 (D. Conn. 2014) (holding plaintiff's statutory products liability claim not preempted upon determining that the state law claim was parallel to and "not different from or in addition to federal law"). Thus, to the extent Plaintiff's claims are not preempted, they raise an issue of federal law.[4]

Equally clear is the fact that "Medtronic disputes that it violated federal law." [Dkt. #29, Defs.' Opp. at 14]. Accordingly, the Court agrees with Defendants that the first two prongs of the *Gunn-Grable* test are satisfied.

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[3] 21 U.S.C. § 360k(a) states, in full:

> **Except as provided in subsection (b) of this section no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –**
>
> **(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and**
>
> **(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.**

[4] As the Court concludes that it lacks subject matter jurisdiction over this case, it does not reach the issue of whether any or all of Plaintiff's claims are preempted under the FDCA.

2. <u>The Issue of Federal Law is Not "Substantial" Within the Meaning of *Gunn-Grable*</u>

In *Gunn*, the Supreme Court clarified the inquiry to be considered under the substantiality prong by explaining that "it is not enough that the federal issue be significant to the particular parties in the immediate suit . . . . The substantiality inquiry under *Grable* looks instead to the importance of the issue to the federal system as a whole." *Gunn*, 133 S.Ct. at 1066. The Court then identified two prior cases which satisfied prong three, *Grable* and *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921). *Id*. In *Grable*, the IRS had seized property from the plaintiff, sold it to satisfy the plaintiff's federal tax delinquency, and the plaintiff sued the third party purchaser, alleging that the IRS failed to comply with certain statutorily imposed notice requirements. *See Grable*, 545 U.S. at 310-11. The Court found a substantial federal issue since "the meaning of [a] federal statute [wa]s actually in dispute," and the dispute implicated "a strong interest" of the federal government, which, in turn, created for the Government "a direct interest in the availability of a federal forum to vindicate its own administrative action." *Gunn*, 133 S.Ct. at 1066 (quoting *Grable*, 545 U.S. at 315). Similarly, in *Smith*, the plaintiff argued that the Government unconstitutionally issued certain bonds which the defendant bank purchased. *Smith*, 255 U.S. at 198. There, the Supreme Court found a substantial federal issue because the case called into question "'the constitutional validity of an act of Congress'" and whether "the Government 'securities were issued under an unconstitutional law.'" *Gunn*, 133 S.Ct. at 1066 (quoting *Smith*, 255 U.S. at 201). Each of these cases raised questions concerning the construction and validity of federal statutory law, conduct undertaken by the Government under such law, and whether the Government

conduct was permissible. Further, the resolution of the issue in each case had the potential to affect the Government monumentally.

Since *Gunn*, the Second Circuit has had four occasions on which to apply the *Gunn-Grable* test. In only one of those four cases did the Second Circuit (in a split decision) find that there was federal-question jurisdiction. In *NASDAQ OMX Grp., Inc. v. UBS Sec., LLC*, 770 F.3d 1010 (2d Cir. 2014), broker-dealer and investment advisor UBS commenced an arbitration proceeding against NASDAQ, a publicly-traded, self-regulatory organization (SRO) registered as a national securities exchange. *See id*. at 1013. The proceeding concerned the series of technical failures that plagued the much-anticipated IPO of Facebook, "one of the largest IPOs in history." *Id*. at 1014 n. 10. Underlying UBS's four state law claims was NASDAQ's "singular duty" under the Securities Exchange Act "to operate a fair and orderly market." *Id*. at 1021.

In applying the substantiality prong, the majority focused on a statement by the SEC, which described "[n]ational securities exchanges," like NASDAQ, as "critical components of the National Market System, which provide[] the foundation for investor confidence in the integrity and stability of the United States' capital markets." *Id*. at 1024 (quoting SEC Release No. 34-69655, 2013 WL 2326683, at *1). While the majority acknowledged that "the importance of stock exchanges and securities markets to the national economy does not necessarily render every federal question pertaining thereto sufficiently substantial," it found particularly compelling the fact that the SEC made this statement in connection with NASDAQ's handling of the Facebook IPO. *Id*. at 1025. This statement by an agency of the federal government about a federally-registered SRO concerning

the very duty implicated by the state law claims brought by UBS "strongly signal[ed] the substantial importance of the[] federal issues" at stake in the litigation. *Id*. Accordingly, the majority found "that the disputed federal issue . . . whether NASDAQ violated its Exchange Act obligation to provide a fair and orderly market in conducting an IPO . . . is sufficiently significant to the development of a uniform body of securities regulation to satisfy the requirement of importance to the federal system as a whole." *Id*. at 1024 (quotations omitted).

By contrast, in every other instance, the Second Circuit has found the substantiality prong under *Gunn-Grable* unmet. *See Anghel v. Ruskin Moscou Faltischek, P.C.*, No. 14-1127-CV, 598 F. App'x 805, 807 (2d Cir. Apr. 8, 2015) (Summary Order) (affirming district court dismissal for lack of subject matter jurisdiction and finding "plaintiff's argument . . . was not 'substantial' in the sense required by *Grable* and *Gunn*" where plaintiff brought state law malpractice claims based on defendant's representation of plaintiff in a professional disciplinary action in which plaintiff was found to have violated the CLIA); *Fracasse v. People's United Bank*, 747 F.3d 141 (2d Cir. 2014) (vacating district court's order dismissing plaintiffs' complaint and finding district court lacked subject matter jurisdiction over state law wrongful termination and breach of covenant of good faith and fair dealing claims where plaintiffs merely "cite[d] to [federal law] in their causes of action"); *Congregation Machna Shalva Zichron Zvi Dovid v. U.S. Dep't of Agric.*, 557 F. App'x 87, 90 (2d Cir. Feb. 27, 2014) (Summary Order) (affirming district court's refusal to exercise federal jurisdiction over a state law claim because "the determination at issue here is a fact-specific

application of [federal] regulations to [the plaintiff] that does not implicate the validity of the regulations themselves").

Here, Defendants' primary argument under the substantiality prong is that the Complaint "contains numerous allegations of Medtronic's violation of the FDA's [CGMP regulations]" and that these "requirements, in certain cases, are plainly subject to interpretation." [Dkt. #29, Defs.' Opp. at 15]. Thus, according to Defendants, because "Plaintiffs' parallel claims will require this Court to interpret and construe FDA regulations as a matter of law and ultimately decide whether Medtronic violated those regulations" the claims are sufficient to raise a substantial issue of federal law under *Gunn-Grable*. [*Id*. at 17]. Defendants are mistaken for several reasons.

First, the allegations in the Complaint suggest that any state court analysis and application of the FDA regulations will be limited. The Complaint is rooted in FDA Warning Letters which state that Medtronic failed to comply with the CGMP regulations. Thus, the relevant federal regulator has had an opportunity to consider and opine on the precise issue of federal law the parties dispute, and it was the *FDA* who first determined that Medtronic's conduct fell outside federal regulatory requirements. While perhaps not dispositive on the issue, the FDA's conclusions and interpretations of its own regulations are likely to receive a considerable degree of deference. *See, e.g., Conroy v. Dannon Co., Inc.*, No. 12 CV 6901 (VB), 2013 WL 4799164, at *6 (S.D.N.Y. May 9, 2013) (stating that the FDA's interpretations of its own regulations promulgated under title 21 "are 'controlling unless plainly erroneous or inconsistent with the regulations' or there is any other reason to doubt that they reflect the FDA's fair and considered

judgment") (citing and quoting *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2575 (2011)); *Dorsey v. Housing Auth. of Baltimore City*, 984 F. 2d 622, 632 (4th Cir. 1993) (finding district court abused its discretion in refusing to consider regulatory agency's assessment of defendant's compliance with agency regulations and noting that the district "court should welcome [the agency's] appraisal of [the defendant's] compliance with regulations, given its concern for deference to agency interpretations of its own regulations"). Indeed, it is precisely when a court is called upon to interpret the regulations, *i.e.*, when they are ambiguous, and where their application to facts raises complex issues, that the court is most likely to defer to the FDA's prior determinations. *See Wilson v. Frito-Lay N. Am. Inc.*, 961 F. Supp. 2d 1134, 1142 (N.D. Cal. 2013) (noting that "an agency's informal interpretation of its own ambiguous regulation is [typically] controlling" but declining to give "deference to two warning letters that the FDA sent" because neither party to the case "contended that the FDA regulations . . . [w]ere ambiguous, and the Court d[id] not find that they [we]re"); James T. O'Reilly, et al., 1 Food & Drug Admin. § 4:56 (4th Ed. 2015) ("The FDA is allowed great deference in the interpretations of its own regulations . . . . The more complex the issue, the more scope is likely to be given for the FDA to draw the interpretations.").

As to deference, Defendants cite a non-binding case, *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939 (E.D. Wisc. 2008), for the proposition that "a warning letter from the FDA is not considered a final agency action," and contend that, as a result, "Plaintiffs' allegations . . . raise legal questions as to the potential effects of various actions by a federal agency .

. . [which] should be decided in a federal forum." [Dkt. #29, Defs.' Opp. at 16]. The Second Circuit has not taken a position on whether an FDA Warning Letter is considered a final agency action. Even if it is not, such letters may still be entitled to deference. *See Cmty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 138 (2d Cir. 2002) ("[E]ven relatively informal [agency] interpretations, such as letters from regional administrators, warrant respectful consideration" where the statute at issue is complex and the regulatory agency possesses "considerable expertise") (citations and quotations omitted). Regardless, they may serve as evidence of regulatory violations. *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 155-56 (S.D.N.Y. 2011) (finding plaintiffs who provided FDA Warning Letters as evidence of violations of FDA regulations stated claims for manufacturing defects). In addition, contrary to Defendants' contention, Connecticut courts are capable of and experienced in determining and applying the proper degree of deference to federal agency decisions. *See, e.g., Bell Atl. Mobile, Inc. v. Dep't of Public Util. Control*, 754 A.2d 128, 138 (Conn. 2000) (applying *Chevron* analysis to determine degree of deference to afford FCC's interpretation of relevant federal statutes); *Ahern v. Thomas*, 733 A.2d 756, 764-65 (Conn. 1998) (considering *Chevron* deference); *Comm'r of Public Health v. Freedom of Info. Comm'n*, 86 A.3d 1044, 1048 n. 4 (Conn. 2014).

With the issue of whether Medtronic violated the regulations likely in the background, the core remaining issue in this matter appears to be one of causation. *See Giglio v. Conn. Light & Power Co.*, 429 A.2d 486, 488 (Conn. 1980) (noting that to prevail on a products liability claim plaintiff must prove that "the defect caused the injury for which compensation was sought"); *Abrahams v.*

***Young & Rubicam, Inc.*, 692 A.2d 709, 712 (Conn. 1997) ("[I]n order to prevail in a CUTPA action, a plaintiff must establish both that the defendant has engaged in a prohibited act and that, 'as a result' of this act, the plaintiff suffered an injury."). This is an issue squarely within the purview of state courts. *See DeLuca v. Tonawanda Coke Corp.*, No. 10-CV-859S, 2011 WL 3799985, at *5 (W.D.N.Y. Aug. 26, 2011) (finding no federal-question jurisdiction as to plaintiff's state law claims where "all but one of the causes of action . . . turn[ed] entirely on questions of state law, including traditional tort law questions of duty, breach, causation, and damages"). Given the limited review the state court is likely to have to undertake, the appropriate regulator has already considered and taken a position on the federal issue, and the issue that is most likely to take primacy is one in which state courts have at least as much expertise as federal courts, there is not "a serious federal interest in claiming the advantages thought to be inherent in a federal forum." *Grable*, 545 U.S. at 313.**

Second, the court's analysis of the FDA regulations will take the form of a highly "fact-specific application" of the regulations to Medtronic's conduct that is unlikely to substantially impact the federal system. *Dovid*, 557 F. App'x at 90. For instance, Plaintiffs cite a violation of 21 C.F.R. § 820.30(c)[5] where "design input work for [Medtronic's] 8731 Intrathecal Catheter has not resulted in development

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[5] 21 C.F.R. § 820.30(c) states:

> **Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented**

of a complete design specification for the Platinum/Iridium (Pt/Ir) catheter tip bond." [Dkt. #1-1, Compl. at ¶ 33 a.]. It is difficult to see how determinations concerning these and similarly discrete allegations would substantially impact the federal system. *See* [*id*. at ¶¶ 33 b-c; 35 b-c.; 39; 41-47; 51-53; 66]. That the application of the regulations may require a state court to "grapple with federal law" and perform "an individualized assessment of both the scope of the [federal regulation] at issue and the particular conduct alleged to fall within (or without) that [regulation]" is not alone sufficient to "warrant federal jurisdiction." *In re Standard & Poor's Rating Agency Litig.*, 23 F. Supp. 3d 278, 398 (S.D.N.Y. 2014) (granting motion to remand); *see also Eugene Iovine, Inc. v. City of New York*, No. 98 Civ. 2767 (HB), 1999 WL 4899, at *4 (S.D.N.Y. Jan. 5, 1999) (rejecting plaintiff's contention that "federal question jurisdiction must exist" where claim implicates an interpretation of federal regulations). As the district court in *Dovid* noted, "state courts are more than competent to interpret federal regulations," and thus, "[a] state law cause of action that requires the interpretation of a federal regulation, by itself, is not sufficiently 'substantial' to create federal jurisdiction." *Dovid v. U.S. Dep't of Agric.*, No. 11-CV-2746 (PAC), 2013 WL 775408, at *12 (S.D.N.Y. Mar. 1, 2013) *aff'd,* 557 F. App'x 87 (2d Cir. Feb. 27, 2014).

Third, the CGMP regulations, under which Plaintiff brings her claims, do not implicate a duty that comes close to the core duty identified by the Second Circuit in *NASDAQ*. It is significant that "[c]ourts have disagreed as to whether a plaintiff can plead a parallel claim by alleging that a defendant violated a CGMP requirement." *Gelber*, 788 F. Supp. 2d at 158. Numerous courts have found these regulations "too generic and vague to serve as the basis for a parallel claim." *Id*.

(citing *Bausch v. Stryker Corp.*, 630 F.3d 546, 554 (7th Cir. 2010)). Instead, "[d]istrict courts have noted that the CGMP requirements 'are intended to serve only as an umbrella quality system providing general objectives medical device manufacturers must seek to achieve.'" *Id*. (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009)). The vague and general nature of the duties imposed by the CGMP bear little resemblance to NASDAQ's "singular duty" under the Securities Exchange Act "to operate a fair and orderly market." *NASDAQ*, 770 F.3d at 1021.

Fourth, Congress anticipated and approved of limited state court analysis and application of the FDA regulations when it decided not to completely preempt parallel state law claims. *See Riegel*, 552 U.S. at 330. In order to offer a damages remedy for regulatory violations, state courts must reach the issue of whether or not the regulations were violated. In relying on the FDCA preemption provision as evidence of a substantial federal issue, Defendants overlook this point. [Dkt. #29, Defs.' Opp. at 17]. In addition, Defendants' argument appears to confuse ordinary (or defensive) preemption, which is at issue here, with complete preemption, which is not. While the latter "transform[s], for jurisdictional purposes," a plaintiff's state law claims "into federal claims . . . [t]he Supreme Court has left no doubt . . . that a plaintiff's suit does not arise under federal law simply because the defendant may raise the defense of ordinary preemption." *Sullivan v. Am. Airlines, Inc.*, 424 F.3d 267, 272-73 (2d Cir. 2005). That Defendants may assert preemption as "the basis of a federal defense," or even if such a "defense [wa]s anticipated in the plaintiff's complaint," removal jurisdiction is

neither created nor supported. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987).

Finally, each of the cases Defendants cite in support of their position that the Complaint raises substantial federal issues are inapposite. For instance, in *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187 (2d Cir. 2005), the Second Circuit did not find a substantial federal issue merely because the allegations in the complaint "involved federal regulation of cable companies." [Dkt. #29, Defs.' Opp. at 16]. The putative class plaintiff in *Broder* brought "distinct claims" seeking a declaratory judgment "establishing that [the defendant's] actions violated . . . 47 U.S.C. § 543(d)," a federal *statute*. *Broder*, 418 F.3d at 195. In assessing the substantiality prong, the Second Circuit relied heavily on the fact that Broder's claims involved issues concerning the construction, scope, and application of a particular section of federal law. *Id*. (noting the complaint raised questions concerning the applicability of certain "exempt[ions] from the § 543(d) uniformity requirement"). Here, as Defendants acknowledge, the Plaintiff's "claims necessarily depend on whether Medtronic fulfilled its . . . obligations under the federal *regulations*." [Dkt. #29, Defs.' Opp. at 12 (emphasis added)].

While Defendants contend that the Complaint also "assert[s] violations of federal statutes, including 21 U.S.C. §§ 351(h) and 360e(d)(6)(A)(i)," the two cited paragraphs in the Complaint indicate that any claims under these statutes are based entirely on violations of the CGMP regulations. [Dkt. #1, Notice of Removal, at ¶ 19]. Paragraph 23 simply quotes 21 U.S.C. § 351(h), which states that "[i]f a manufacturer fails to insure that the methods used in, or the facilities or controls used for, their manufacture, packing, storage or installation are *not in*

***conformity with the [CGMP] requirements* . . . then such products are adulterated." [Dkt. #1-1, Compl. at ¶ 23 (emphasis added)]. Paragraph 55 cites 21 U.S.C.§ 360e(d)(6)(A)(i) in support of Plaintiff's assertion that "all changes to [a PMA] device that affect its safety or effectiveness have to be approved as well." [*Id*. at ¶ 55]. However, nothing in this paragraph, or in the ones immediately preceding or following it, suggests a cause of action separate from Medtronic's failure to comply with the CGMP. Standing alone, these citations and "passing references to a federal statute" are insufficient to raise a substantial federal issue. *Fracasse*, 747 F.3d at 145.**

In addition, the degree of impact of the plaintiff's claims in *Broder* on "the complex federal regulatory scheme applicable to television rates," dwarfs that of the Complaint. *Broder*, 418 F.3d at 195. As discussed above, the federal issue here is whether the Defendants' discrete acts concerning their manufacturing and sale of the System violated FDA regulations and caused injuries to, at most, two individuals. *See supra* at 14-15. *Broder* concerned the failure of the defendant, Cablevision, to comply with a federal statute which resulted in harm to an entire class of plaintiffs for at least a six-year period. *Broder*, 418 F.3d at 191-92. As the Second Circuit recently clarified, that a claim may concern a federal issue "does not necessarily render every federal question pertaining thereto sufficiently substantial." *NASDAQ*, 770 F.3d at 1025.[6]

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[6] Moreover, as has been pointed out by other courts, *Broder* was decided without the benefit of *Gunn*, which clarified the substantiality prong of the *Gunn-Grable* test. *See Knox v. Mazuma Credit Union*, No. 15-0288-CV-W-ODS, 2015 WL 3407618, at *3 n. 1 (W.D. Mo. May 27, 2015) (distinguishing *Broder*, in part, because it was "decided before the Supreme Court's decision in *Gunn*" and finding defendant's arguments for substantiality insufficient).

Similarly inapposite is *In re Zyprexa Prods. Liab., Litig.*, Nos. 04-MD-1596, 07-CV-1933, 2008 WL 398378 (E.D.N.Y. Feb. 12, 2008). The scope and impact of this multi-district litigation, which "involve[d] thousands of individuals, organizations and governmental entities all over the United States," over Zyprexa, a drug which, at the time of the litigation "ha[d] been prescribed to over twelve million people worldwide," and whose sales were "in the billions of dollars annually," render this case plainly distinguishable from the present matter. *In re Zyprexa*, 2008 WL 398378, at *1. By contrast, the parties here have not identified any related litigation, and the Complaint asserts that as of June 3, 2013, soon after the catheter in Michael Mihok was found to have fractured, "there were 261,109 SyncroMed pumps implanted worldwide." [Dkt. #1-1 Compl. at ¶ 54]. *See also In re Oxycontin Antitrust Litig.*, 821 F. Supp. 2d 591, 596-97 n. 2 (S.D.N.Y. 2011) (rejecting defendant's analogy to *Zyprexa* and concluding case which involved only one state litigant and that state's law "lack[ed] the scope of the Zyprexa MDL and its need for national uniformity").

Finally, Defendants' citation to *Bowdrie v. Sun Pharm. Indus. Ltd.*, 909 F. Supp. 2d 179 (E.D.N.Y. 2012), is unpersuasive. In *Bowdrie*, another pre-*Gunn* case, the court found the plaintiffs' "causes of action implicate[d] the labeling requirements for generic drug manufacturers nationwide," and thus went "far beyond simply incorporating a federal standard into a state law cause of action." *Id*. at 184-85. As explained above, resolution of the allegations in the Complaint does not appear likely to impact medical device manufacturers nationwide. Moreover, the duty that was alleged to have been breached in *Bowdrie*, the "ongoing federal duty of sameness," is much closer to the core duty at issue in

NASDAQ **than the vague and generic duties in play here.** ***See PLIVA, Inc. v. Mensing*****, 131 S. Ct. 2567, 2575-76 (2011) (deferring to FDA's views on labeling regulations and noting the agency's position that the "duty of sameness" concerns a "central premise of federal drug regulation [] that the manufacturer bears responsibility for the content of its label at all times") (citation and quotations omitted).**

C. <u>The Court Lacks Diversity Jurisdiction Because Defendant Greenwich is a Connecticut Citizen and is Not Fraudulently Joined</u>

In addition to federal-question jurisdiction, Defendants assert that this Court has diversity jurisdiction over this case because the only non-diverse defendant, Greenwich, is fraudulently joined.

Under the fraudulent joinder doctrine, "courts overlook the presence of a non-diverse defendant if from the pleadings there is no possibility that the claims against that defendant could be asserted in state court." ***Briarpatch Ltd. v. Phoenix Pictures, Inc.*****, 373 F.3d 296, 302 (2d Cir. 2004). "In order to show that naming a non-diverse defendant is a 'fraudulent joinder' effected to defeat diversity, the defendant must demonstrate, by clear and convincing evidence, either that there has been outright fraud committed in the plaintiff's pleadings, or that there is no possibility, based on the pleadings, that a plaintiff can state a cause of action against the non-diverse defendant in state court."** ***Pampillonia v. RJR Nabisco, Inc.,*** **138 F.3d 459, 461 (2d Cir. 1998). Put another way, "[j]oinder will be considered fraudulent when it is established that there can be no recovery against the defendant under the law of the state on the cause alleged."** ***Whitaker v. Am. Telecasting, Inc.*****, 261 F.3d 196, 207 (2d Cir. 2001). "The defendant seeking removal bears a heavy burden of proving fraudulent joinder, and all factual and**

legal issues must be resolved in favor of the plaintiff." *Pampillonia,* 138 F.3d at 461.[7]

The fraudulent joinder standard is strictly applied by courts in this Circuit. *See In re Fosamax Prods. Liab. Litig.*, No. 09-CV-4061, 2009 WL 3109832, at *2 (S.D.N.Y. Sept. 28, 2009) ("Most courts in this district have applied the 'no possibility' standard rather strictly."); *see also Stan Winston v. Toys "R" Us, Inc.*, 314 F. Supp. 2d, 177, 183 (S.D.N.Y. 2003) (concluding that defendants had not shown that it was "legally impossible" for non-diverse defendant to be liable under state law); *Nemazee v. Premier, Inc.,* 232 F.Supp.2d 172, 178 (S.D.N.Y.2002) (noting that fraudulent joinder "turns on whether recovery is per se precluded"; "[a]ny possibility of recovery, even if slim, militates against a finding of fraudulent joinder"). As courts have explained in the context of fraudulent joinder, "it is not sufficient to argue that the complaint fails to state a claim against [a non-diverse] defendant." *Stan Winston*, 314 F. Supp. 2d at 182; *see also Read v. Nationwide Mut. Ins. Co.*, No. 3:06-cv-00514 (JCH), 2006 WL 2621652, at *1 (D. Conn. Sept. 13, 2006) ("To show that a 'fraudulent joinder has occurred, the defendants must do more than show that the plaintiff has failed to state a claim upon which relief can be granted."). Even allegations that are "general and at times in barebones language" may be sufficient to defeat a claim of fraudulent

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[7] "The language 'no possibility' has been interpreted as meaning no 'reasonable possibility' or 'no reasonable basis.'" *Doe v. Fed. Express Corp.*, No. 3:05-cv-1968 (WWE), 2006 WL 1405641, at *1 (D. Conn. May 22, 2006) (quoting *In re Rezulin Prods. Liability Litig.*, 133 F. Supp. 2d 272, 280 n. 4 (S.D.N.Y. 2001)). While aware of the different formulations, for the reasons discussed below, *see infra* at 22-28, "the court finds that it need not choose among the[m]" because it "finds no fraudulent joinder in the present case, even if it interprets the *Pampillonia* 'no possibility' standard as 'no reasonable basis'" or no reasonable possibility. *Oliva v. Bristol-Meyers Squibb Co.*, No. 3:05-cv-00486 (JCH), 2005 WL 3455121, at *2 (D. Conn. Dec. 16, 2005).

joinder. *Ulysse v. AAR Aircraft Component Servs.*, 841 F. Supp. 2d 659, 684 (E.D.N.Y. 2012) (finding no fraudulent joinder and remanding case).

Applying this standard, the Court turns to Defendants' contention that Plaintiff cannot recover against Defendant Greenwich under the CPLA.

1. <u>Plaintiff's CPLA Claim Against Defendant Greenwich is Legally Possible</u>.

Among the causes of action constituting a "[p]roduct liability claim" under the CPLA are "all actions based on . . . strict liability . . . ." Conn. Gen. Stat. § 52-572m(b). The elements of a strict liability action under Connecticut law are "(1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in condition." *Giglio v. Connecticut Light & Power Co.*, 429 A.2d 486, 488 (Conn. 1980). Products liability claims also include "all claims or actions brought for personal injury . . . caused by the . . . marketing . . . of any product." Conn. Gen. Stat. § 52-572m(b).

While the allegations in the Complaint are generally pled and are at times barebones, the Complaint may be construed to allege that Defendant Greenwich engaged in sales of the System to patients, sold Michael Mihok the System containing a defective catheter, performed a surgical implantation procedure for the sole purpose of delivering the System to Mihok, and the catheter later fractured, causing Mihok's injuries. *See* [Dkt. #1-1, Compl. at ¶¶ 11, 14, 31, 57, 63, 65, 103]. In addition, the Complaint contends that Defendant Greenwich "furthered the marketing of the [System] . . . by serving as the party who made

the final delivery of the product to . . . Michael Mihok." [*Id*. at ¶ 31]. Accordingly, these allegations may be construed to raise two theories of products liability against Defendant Greenwich: (i) a strict liability theory based on Greenwich's initial sale of the System to Michael Mihok and (ii) a theory that Greenwich marketed the System when it implanted it in him.[8]

To maintain a statutory products liability action, "the plaintiff must establish and prove, inter alia, that the defendant was engaged in the business of *selling* the product and the defect existed at the time of the sale." *Zichichi v. Middlesex Memorial Hosp*., 528 A.2d 805, 807 (Conn. 1987) (emphasis in original) (citations and quotations omitted). Once a particular transaction is labeled a 'service,' as opposed to a 'sale' of a 'product,' it is outside the purview of [Connecticut's] product liability statute." *Id*.

Defendants assert that Plaintiff's CPLA claim fails as a matter of law because Defendant Greenwich cannot constitute a "product seller" within the statutory meaning of the term. *See* [Dkt. #29, Defs.' Opp. at 3]. Under the CPLA, a "product seller" is "any person or entity, including a manufacturer, wholesaler, distributor or retailer who is engaged in the business of selling such products whether the sale is for resale or for use or consumption." Conn. Gen. Stat. § 52-572m(a). Defendants claim that "all Connecticut Appellate Court decisions that have addressed this issue have determined that in situations where the hospital is providing medical services—even when it sells the medical product in connection with providing those services—it is not a product seller as a matter of

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[8] The Court considers the allegations against Defendant Greenwich only under the fraudulent joinder standard articulated above. *See supra* at 20-21. It neither considers nor reaches the question of whether the allegations are sufficient to survive a motion to dismiss.

law." [Dkt. #29, Defs.' Opp. at 3-4]. In support of their statement of law, Defendants rely on three cases involving hospital defendants, a Connecticut Supreme Court decision, *Zichichi*, an intermediate appellate decision, *Zbras v. St. Vincent's Med. Ctr.*, 880 A.2d 999 (Conn. App. 2005), and a trial court decision, *O'Dell v. Greenwich Healthcare Servs., Inc.*, No. CV116008364S, 2013 WL 2278752 (Conn. Super. Apr. 25, 2013). While these cases may well preclude Plaintiff's second theory of liability, and even the first at summary judgment, at the present stage, they do not appear to render legally impossible Plaintiff's first theory, *i.e.*, strict liability based on Greenwich's pre-procedure sale of the System to Mr. Mihok.

In *Zichichi*, the Connecticut Supreme Court held that the plaintiff's products liability claim against the defendant hospital, based on the purported sale of blood in the course of a blood transfusion, was precluded as a matter of law because such sales do not constitute the sale of a product. *See Zichichi*, 528 A.2d at 808. The court reached its conclusion after considering Connecticut's "blood shield" statute, which states that "blood, blood plasma, and the components, derivatives or fractions thereof, or tissue or organs *shall not* be considered commodities subject to sale or barter, but *shall* be considered as medical services." *Id*. (quoting Conn. Gen. Stat. § 19a-280) (emphasis in original). In light of this clear statutory language and legislative history, which evinced an intent "to treat blood and blood derivatives differently from other 'products,'" the court found that "the plaintiff ha[d] no basis for asserting a claim under § 52-572m et seq." *Id*. Defendants do not raise—nor is the Court aware of the existence—of any similarly worded statute which could possibly apply to the

System. While *Zichichi* makes clear that the CPLA does not apply to transactions which are "labeled a 'service,'" it does *not* categorically hold that because a device was purchased in connection with a medical procedure, the transaction is necessarily the provision of a service. *Id*. at 807. *Zichichi* is also distinguishable because receipt of a blood transfusion during the course of a medical procedure is fundamentally different from a pre-procedure sale of a medication delivery system followed by a medical procedure undertaken for the sole purpose of installing that system.

For the same reasons, the other appellate decision to which Defendants cite, *Zbras*, does not support their broad categorical rule. In *Zbras*, during the course of a surgical procedure, a doctor employed medical implants which were brought in by the manufacturer's representative for use at the doctor's discretion. *Zbras*, 880 A.2d at 1001. In holding that the hospital was not a seller of a product, the Appellate Court of Connecticut stated that a "defendant can bill for goods provided incidental to surgery without being in the business of selling goods." *Id*. at 1002. Once again, this case is factually distinguishable from the strict liability theory posed here, as the "good" at issue, the System, was not "provided incidental to surgery." *Id*. It was, in fact, the very reason for the surgery, and its sale constituted a separate and distinct transaction. By contrast, the *Zbras* court made clear that "[t]he transaction in this case, [was] a surgery." *Id*.[9]

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[9] Defendants' reliance on *Lambert v. Charlotte Hungerford Hosp.*, No. CV054002013S, 2006 WL 3491275 (Conn. Super. Nov. 2, 2006) is similarly misplaced. *Lambert* involved injuries stemming from defective "pedicel rods" which were "used in the plaintiff's back fusion operation." *Id*. at *1. Like *Zbras*, which the court determined was controlling, the *Lambert* court merely held "that when a hospital provides the surgeon with hardware to perform a surgical procedure, it is performing a service and not selling a product." *Id*. at *2. Such

Defendants also cite an unreported trial court decision, *O'Dell v. Greenwich Healthcare Servs., Inc.*, No. CV116008364S, 2013 WL 2278752 (Conn. Super. Apr. 25, 2013). In *O'Dell*, the trial court granted summary judgment on behalf of two hospital defendants and another healthcare services provider, where the plaintiff sustained injuries from an injection of neuraxial medications pursuant to a pain management therapy the plaintiff was undergoing at one of the defendant hospitals. *Id*. at *1. The court found that the treating hospital was not a product seller because the evidentiary record (at summary judgment) showed that "the delivery of the neuraxion medication . . . was part of . . . pain therapy under the supervision of [the plaintiff's treating physician]" and that "this treatment, as supported by the facilities of [the defendant hospital] was a service." *Id*. at *5. The court reached its conclusion upon determining that the plaintiff's treating physician had prescribed the medication, was treating the plaintiff at the defendant hospital, that the neuraxial medication was part of this treatment, and that the treating hospital was merely providing services in support of this treatment. *Id*. at *2. *O'Dell* is distinguishable because the role of the treating hospital was limited to providing support to treatment performed by a physician, and there is no indication that anyone at the hospital marketed or sold the

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holding does not address the strict liability theory raised in the Complaint here, because there is no indication that the plaintiff was sold (or was even made aware of) the rods prior to the surgical procedure, nor was the plaintiff's receipt of the rods the sole or even the primary purpose of the surgery. Instead, implantation of the rods was incidental to the fusion of the plaintiff's back, which was the ultimate intent of the procedure.

neuraxial medication to the plaintiff or to patients generally.[10] As for the two other defendants, since there was "no evidence that [they] played any role in supplying the neuraxial medicine to [the plaintiff]," the court found no basis for liability under the CPLA. *Id*.

In addition, the *O'Dell* court reached its conclusions after reviewing the evidentiary record on summary judgment.[11] As the court explained, the defendants' motion for summary judgment "relie[d] primarily on an affidavit" which "describe[d], and partially explain[ed] the process of billing [plaintiff O'Dell] and describe[d] the role of the hospital pharmacy department in obtaining the neuraxial medication for [plaintiff O'Dell's] treatment." *Id*. at *2; *see also id*. at *5 (reciting findings of fact). Thus, *O'Dell* is distinguishable on both its facts and procedural posture, and does not preclude Plaintiff's theory as a matter of law.[12]

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[10] At most, the opinion indicates that the treating hospital "may have made a very small profit . . . for pharmacy services" in connection with the medication. *O'Dell*, 2013 WL 2278752, at *5.

[11] While the *O'Dell* plaintiffs asserted that they had not taken discovery prior to the defendants' motion for summary judgment, the court addressed this argument, stating that there "ha[d] been ample opportunity for discovery" and plaintiffs did not file an affidavit stating their belief that more discovery was required. *O'Dell*, 2013 WL 2278752, at *4.

[12] Both the *O'Dell* court and Defendants here cite *Truglio v. Hayes Constr. Co.*, 785 A.2d 1153 (Conn. App. 2001), a case that did not concern the sale of medical devices or hospital defendants. *See* [Dkt. #29, Defs.' Opp. at 3]. In *Truglio*, the Appellate Court of Connecticut "suggested that a party be considered a product seller where a sale of a product is a principal part of the transaction, and where the essence of the relationship between the buyer and the seller is not the furnishing of professional skill or services." *Id*. at 1156. The Connecticut Supreme Court has not yet weighed in on this "suggestion," and this case is also inapposite because it, like *O'Dell,* was decided at summary judgment. Indeed, as the concurring judge stated, "the issue" before the Appellate Court in *Truglio*, was "not whether the plaintiffs alleged a recognized cause of action, *which they did*, but whether they could prevail on the facts alleged as a matter of law." *Id*. at 1161 (emphasis added) (stating that

Finally, Connecticut law does not clearly establish that a hospital cannot be the seller of a medical device implanted in a patient on its premises. The Plaintiff identifies several decisions which post-date the appellate decisions raised by Defendants and suggest that a products liability claim against a hospital defendant based on the sale of a medical device that the hospital subsequently implanted would survive a motion to dismiss. *See Basso v. Boston Scientific Corp.*, No. CV 0760001429S, 2008 WL 5252198, at *3 (Conn. Super. Nov. 21, 2008) (denying motion to strike products liability claim against defendant hospital for use of a "basket" during a kidney stone extraction which broke inside plaintiff during the procedure and noting that "[f]ollowing discovery, it is possible that the plaintiff would be able to bring forth evidence establishing that this particular hospital was engaged in the practice of selling medical products such as the basket"); *Farrell v. Johnson & Johnson*, No. CV 116014102S, at *1 (Conn. Super. Jul. 1, 2014) ("There is no Supreme Court or Appellate Court authority prohibiting a plaintiff from maintaining a product liability claim against a hospital.") (denying defendant hospital's motion for summary judgment); *Herrick v. Middlesex Hosp.*, No. CV 030100932, 2005 WL 1760785, at *2-3 (Conn. Super. Jun. 27, 2005) (citing federal district court and Connecticut trial court decisions which "appear to suggest that a hospital may be deemed a 'product seller' under the [CPLA]").

Given the allegations in the Complaint, the fact that significant discovery remains to be taken in this matter, and the reasonable possibility that a claim against a hospital defendant for the sale of a medical device that is surgically

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the question of whether defendant was a product seller as a matter of law was properly decided on a motion for summary judgment rather than on a motion to strike which "tests the legal sufficiency of a complaint to state a recognized cause of action").

implanted in a patient could survive under Connecticut law, Defendants' fraudulent joinder argument must fail.[13]

III. Conclusion

This case does not raise a substantial federal issue and it has not been clearly and convincingly established that there is no reasonable possibility for Greenwich Hospital to be liable to the Plaintiff under the Connecticut Products Liability Act. Accordingly, the Plaintiff's Motion to Remand is GRANTED. The case is ordered REMANDED back to the Connecticut Superior Court for further proceedings. The clerk is directed to close this case.

IT IS SO ORDERED.
/s/
Vanessa L. Bryant
United States District Judge

Dated at Hartford, Connecticut: August 10, 2015.

[13] **As the Court has determined that Plaintiff's CPLA claim is not legally impossible, and therefore, that non-diverse Defendant Greenwich was not fraudulently joined, the Court lacks subject matter jurisdiction and does not reach the issue of the viability and sufficiency of Plaintiff's CUTPA claim. *See* [Dkt. #29, Defs.' Opp. at 10-11; Dkt. #31, Pl.'s Reply at 2].**