UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

JEFFREY ALAN STANIFER, SR.; and
NANCY STANIFER,

Plaintiffs,

v. Case No. 6:14-cv-1192-Orl-37DAB

CORIN USA LIMITED, INC.; and
STRYKER CORPORATION OF
MICHIGAN,

Defendants.

ORDER

This cause is before the Court on the following:

1. Corin USA Limited's Motion to Dismiss Plaintiffs' Complaint (Doc. 9), filed July 30, 2014;
2. Notice of Joinder of Stryker Corporation to Defendant Corin USA Limited's Motion to Dismiss Plaintiffs' Complaint (Doc. 12), filed July 30, 2014;
3. Jeffrey Alan Stanifer's Response to Defendant, Corin USA Limited, Inc.'s Motion to Dismiss Plaintiff's Complaint (Doc. 24), filed August 11, 2014;
4. Corin USA Limited's Reply Memorandum in Support of Motion to Dismiss (Doc. 32), filed August 22, 2014; and
5. Notice of Joinder of Stryker Corporation to Defendant Corin USA Limited's Reply in Support of Its Motion to Dismiss Plaintiffs' Complaint (Doc. 33), filed August 25, 2014.

Upon consideration, the Court finds that the Motion is due to be granted.

BACKGROUND

This product liability action concerns the Cormet Advanced Hip Resurfacing System ("Cormet System"), which is a medical device designed, manufactured, and distributed by Defendants Corin USA Limited ("Corin")[1] and Stryker Corporation of Michigan ("Stryker"). (Doc. 2, ¶¶ 2–5, 17.) On January 14, 2008, Hany F. Helmy, M.D. implanted the Cormet System into the body of Plaintiff Jeffrey Alan Stanifer, Sr. during a right hip arthroplasty procedure at Wuestoff Memorial Hospital in Brevard County, Florida. (*Id.* ¶¶ 6–7.) Subsequent failure of the Cormet System allegedly caused Mr. Stanifer to suffer a revision left total hip arthroplasty and surgical removal of the Cormet System. (*Id.* ¶¶ 11–13.)

On May 20, 2014, the Mr. Stanifer and his spouse initiated this action in state court seeking to recover "damages and losses" from Defendants based on state law "strict liability" claims for: (1) breach of express warranty (*id.* ¶¶ 16–26, 69–79 (Counts I & VI)); (2) breach of implied warranty of merchantability (*id.* ¶¶27–36, 80–89 (Counts II & VII)); (3) breach of implied warranty of fitness for a particular purpose (*id.* ¶¶37–47, 90–100 (Counts III & VIII)); (4) manufacturing defect (*id.* ¶¶48–57, 101–110 (Counts IV & IX)); and (5) design defect (*id.* ¶¶58–68 & 111–21 (Counts V & X)).[2] (*Id.* ¶¶25–26, 35–36.) After removal of this action from state court (Doc. 1),[3] Corin moved to dismiss

[1] The parties agree that the Complaint incorrectly names "Corin USA Limited, Inc." instead of "Corin USA Limited" (Doc. 1; Doc. 9, p. 1 n.1; Doc. 24, p. 1 n.1.) Plaintiffs should not delay in correcting this error (*see* Doc. 24, p. 1, n.1 (asserting that Plaintiffs will "attempt to rectify" the error)).

[2] Plaintiffs assert Counts I through V against Corin and Counts VI through X against Stryker. (Doc. 2.)

[3] Corin is a foreign entity (Doc. 1, ¶ 8; *see also* Doc. 9, p. 1 n.1), Stryker is a Michigan corporation (Doc. 1, ¶ 9), and Plaintiffs are Florida citizens (Doc. 1, ¶¶ 4–5; Doc. 2, ¶¶ 17, 26, 28, 36, 38, 46). Further, there is no dispute that the amount in controversy is satisfied. Accordingly, removal of this action was properly based on the

Plaintiffs' claims based on federal preemption. (Doc. 9.) Plaintiffs responded (Doc. 24), and Corin replied (Doc. 32). Stryker joined in Corin's Motion and Reply (Docs. 12, 33), and the Motion is now ripe for adjudication.

STANDARDS

I. Preemption[4]

In 1976, the U.S. Congress amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360c, et seq., by enacting The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k, et seq. The MDA includes an express preemption provision (§ 360k) for medical devices as follows:

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

21 U.S.C. § 360k(a). The MDA also includes an implicit preemption provision requiring that any action "for enforcement or to restrain violations" of the FDCA be brought "by and in the name of the United States." *See* 21 U.S.C. § 337(a); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001).

In 2008, the U.S. Supreme Court held that § 360k preemption applies when two conditions are met: (1) first, the Federal Government must establish "requirements applicable" to the device; and (2) second, state law claims concerning the device must

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Court's diversity jurisdiction. 28 U.S.C. § 1332.

[4] The Supremacy Clause of the United States Constitution establishes that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2.

include requirements that are "different from, or in addition to" federal requirements. *See Riegel v. Medtronic*, 552 U.S. 312, 315 & 321–23 (2008). The first *Riegel* condition is satisfied when the U.S. Food and Drug Administration ("FDA") authorizes commercial distribution of a Class III medical device after the "rigorous" pre-market approval process provided for under the FDCA, 21 U.S.C. § 360c, et seq. ("PMA").[5] *Id*. The second *Riegel* condition is satisfied if a plaintiff asserts claims based on state common law duties, including causes of action for "negligence and strict liability." *Id.* at 324–26. Finally, the *Riegel* Court concluded in dicta that § 360k preemption is not absolute—it "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because such a claim would "'parallel,' rather than add to, federal requirements." *Id.* at 330.

After *Reigel*, a plaintiff injured due to use of a Class III device approved through a PMA can escape preemption only if he asserts a "parallel" state law claim. *See Brady v. Medtronic, Inc.*, No. 13-cv-62199-RNS, 2014 WL 1377830, at *4 (S.D. Fla. April 8, 2014) (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). Further, the U.S. Court of Appeals for the Eleventh Circuit has held that plaintiffs cannot effectively state a "parallel claim" absent allegations that the defendant violated a "particular federal specification." *See Wolicki-*

[5] Class III devices are subjected to the highest level of federal oversight. *See Riegel*, 552 U.S. at 315–16. The FDA assigns a device to Class III:

> if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is purported or represented to be for use in in supporting or sustaining human life or for use which is of substantial importance in preventing impairment of human health.

Id. at 316 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300–01 (11th Cir. 2011) (noting that recitation of "magic words" is insufficient).

II. Federal Rule of Civil Procedure 12

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must provide factual allegations sufficient to state a claim that is plausible on its face. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 561–62 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). In assessing the sufficiency of the pleading, the Court must accept as true a plaintiff's well-pled facts and must construe such facts in the light most favorable to the plaintiff. *Twombly*, 550 U.S. at 561–62. Nonetheless, "conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal." *Davila v. Delta Airlines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003).

Rule 12(d) requires that courts treat a motion to dismiss as a motion for summary judgment if "matters outside the pleadings are presented to and not excluded by the court." Notwithstanding Rule 12(d), courts may "take judicial notice of matters of public record without converting a Rule 12(b)(6) motion to a Rule 56 motion." *Halmos v. Bomardier Aerospace Corp.*, 404 F. App'x 376, 377 (11th Cir. 2010) (per curiam); *see also Telltabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322–23 (2007) (requiring courts to consider "matters of which a court may take judicial notice" when resolving a Rule 12(b)(6) motion in a § 10(b) action); *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002) (holding that district court properly took judicial notice a "FDA public file" at the pleading stage).

III. Judicial Notice

Federal Rule of Evidence 201 provides that a court may, "on its own" or when requested by a party who supplies "the necessary information," take judicial notice of an adjudicative fact "at any stage of the proceeding" if it "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Courts in this District and elsewhere regularly take judicial notice of public records available on the FDA's website because such document satisfy the requirements of Rule 201.[6] *See Kaiser v. Depuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1189 n.2 (M.D. Fla. 2013) (taking judicial notice of "public records of the FDA relating to the medical device involved in the case"); *Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013) (taking judicial notice of drug label that was "available on the FDA's website"); *McClelland v. Medtronic, Inc.*, No. 6:11-cv-1444-Orl-36KRS, 2012 WL 5077401, at *2 (M.D. Fla. Sept. 27, 2012) (taking judicial notice of "public records of the FDA" attached to briefing concerning a motion to dismiss based on preemption); *Rounds v. Genzyme Corp.*, No. 8:10-cv-2479-T-23TBM, 2010 WL 5297180, at *1 (M.D. Fla. Dec. 20, 2010) (holding that "the FDA's public records and statements about [a medical device] merit judicial notice"); *see also Oxford Asset Mgmt., Ltd.*, 297 F.3d at 1188.

[6] *See In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1023 (C.D. Cal. 2008) (taking judicial notice of labels "taken from the FDA website, as documents" that comply with the requirements of Rule 201); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003) (taking judicial notice of "the FDA's Center for Drug Evaluation and Research Listing of New & Generic Drug Approvals 1998–2000 and its listing of bupropion hydrochloride which is available at http://www.fda.gov/cder/approval/b.htm").

DISCUSSION

Defendants argue that Plaintiffs' claims are barred by the explicit and implicit preemption provided under the MDA because the FDA classified the Cormet System as a Class III device pursuant to a PMA. (*See* Doc. 9, pp. 6–13.) To establish that the Cormet System is a Class III device approved through a PMA, Defendants have submitted a number of documents, including correspondence addressed to Corin USA from the FDA, which provides notice that the PMA for the "Cormet Hip Resurfacing System" "is approved." (Docs. 9-1, 9-4, 17-1, 17-2 ("PMA Documents".) Defendants urge the Court to take judicial notice that these documents are accessible on the FDA website—http://www.accessdata.fda.gov/MedicalDevices/default.htm—which allows the public to access public documents concerning regulated medical devices. (Doc. 9, p. 6 n.5; Doc. 32, pp. 2–3.) Finally, Defendants argue that Plaintiffs have not alleged a "parallel claim" under the *Wolicki-Gables* standard, and the strict liability warranty claims fail because Plaintiffs failed to allege the element of privity. (Doc. 9.)

Plaintiffs concede that federal preemption applies to most state law claims concerning Class III medical devices approved through a PMA. (Doc. 24, pp. 3–8.) Nonetheless, Plaintiffs argue that the Court should deny Defendants' Motion because Defendants cannot establish at the pleading stage that the Cormet System "underwent" the PMA. (*Id.* at 3–4.) Plaintiffs also effectively concede that they have not properly alleged a "parallel" manufacturing defect claim. (*Id.* at 6 n.4.) Plaintiffs state that they will request leave to amend their Complaint to state such a claim, but they require discovery to determine "the circumstances surrounding the exact nature of the manufacturing defect." (*Id.* at 4, 8.) Plaintiffs further contend that they require discovery concerning: (1) "the facts presented by" Corin; and (2) whether Corin "has complied with Post

Market Approval requirements." (*Id.*)

The Court rejects the Plaintiffs' argument that the Court should disregard the PMA Documents and the documents available on the FDA website. Plaintiffs failed to cite any legal authority to support their argument and they did not question that the FDA website is a source of public documents "whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Accordingly, like other courts faced with this issue (*see infra* p. 6), this Court takes judicial notice of the documents that are publicly available on the FDA website which reflect that the Cormet System is a Class III device that has successfully undergone the PMA process. (*See* FDA, Medical Devices, Databases http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=14466 (last visited Nov. 6, 2014)).

Through the PMA, the Federal Government has established "requirements applicable" to the Cormet System; thus, Plaintiffs' claims are due to be dismissed if they impose requirements for the Cormet System that differ from those imposed by the FDA. *Riegel*, 552 U.S. at 324–26. The five strict liability claims asserted by Plaintiff do impose such differing requirements. *See Lederman*, 950 F. Supp. 2d at 1251 (granting motion to dismiss Florida product liability claims based on preemption); *McClelland*, 944 F. Supp. 2d at 1200–01 (dismissing second amended complaint with prejudice because negligence claim related to medical device was preempted); *Kaiser*, 944 F. Supp. 2d at 1192 (granting motion to dismiss amended complaint because claims concerning medical device were preempted and denying as futile the request for leave to assert a claim for breach of warranty); *see also Stokes v. I-Flow Corp.*, No. 6:12-cv-991-Orl-36DAB, 2013 WL 1715427, at *7 (M.D. Fla. Apr. 8, 2013) (granting motion to dismiss based on preemption where plaintiff failed to allege that the medical device

violated "particular" federal regulations). Accordingly, Plaintiffs claims are preempted under § 360k and *Riegel*.

Again, Plaintiffs concede that they have not yet alleged a parallel claim, but they indicate a desire to do so.[7] (*See* Doc. 24, pp. 4 & 8.) In an abundance of caution, the Court will permit Plaintiffs one opportunity to amend their Complaint, if they can do so in accordance with their obligations under Rule 11 without discovery to determine "the circumstances surrounding the exact nature of the manufacturing defect." (Doc. 24, pp. 4, 8.)

CONCLUSION

Accordingly, it is hereby **ORDERED AND ADJUDGED**:

1. Corin USA Limited's Motion to Dismiss Plaintiffs' Complaint (Doc. 9) is **GRANTED**.
2. Plaintiffs' Complaint (Doc. 2) is **DISMISSED**.
3. On or before November 28, 2014, Plaintiffs may file an Amended Complaint in conformance with this Order.
4. If Plaintiffs do not file an Amended Complaint in the time prescribed by this Order, this action will be **CLOSED** without further notice.

DONE AND ORDERED in Chambers in Orlando, Florida, on November 7, 2014.

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[7] In making this request, Plaintiffs have not pointed to any Florida law recognizing a private cause of action to enforce the FDCA. Other litigants before Plaintiffs have similarly failed to identify Florida law that would support "a private cause of action to enforce the FDA." *See Kaiser v. Depuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1192 (M.D. Fla. 2013) (dismissing parallel claim absent Florida law supporting such a cause of action); *see also Lederman v. Howmedica Osteonics Corps.*, 950 F. Supp. 2d 1246, 1250, n.1 (M.D. Fla. 2013) (noting that defendant's argument that Florida law does not recognize a parallel claim is well-taken but premature); *Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264, 1268 (S.D. Fla. 2010) (granting summary judgment in favor of defendant where plaintiff failed to "identify a Florida law that supports" a parallel claim).

ROY B. DALTON JR.
United States District Judge

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