NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MICHAEL A. SMITH, Plaintiff, v. DEPUY ORTHOPAEDICS, INC., et al., Defendants.	Civil Action No. 11-4139 (JAP) **OPINION**

PISANO, District Judge

This is a products liability action in which Plaintiff Michael A. Smith ("Plaintiff") had a total right knee replacement and a P.F.C. Sigma Rotating Platform Knee ("RP Knee") was implanted in his body. Defendants Depuy Orthopaedics, Inc. et al. ("Defendants")'s Motion for Summary Judgment [docket # 18] and Plaintiff's Cross-Motion for a Continuance [docket # 21] are presently before the Court. The issue is whether Plaintiff's claims are preempted because the RP Knee was subject to the Food & Drug Administration's ("FDA") Pre-Market Approval ("PMA") process. After reviewing the parties' papers and hearing oral argument on January 30, 2013, this Court grants Defendants' Motion for Summary Judgment because Plaintiff's claims are preempted since the RP Knee was subject to the rigorous PMA process and denies Plaintiff's Motion for a Continuance because further discovery would not preclude summary judgment. *See* Fed. R. Civ. P. 78.

I. BACKGROUND

A. Class III Medical Devices & Premarket Approval

The RP Knee is regulated by the FDA through the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). Declaration of Janet Johnson, Defendants' Director of Regulatory Affairs ("Johnson Dec."), ¶ 14. *See* 21 U.S.C. § 301 et seq. The statute establishes three classes of medical devices "intended for human use." 21 U.S.C. § 360c(a)(1). Class I devices are devices in which general controls, like labeling requirements, "are sufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A)(i). Examples of Class I devices are "tongue depressors, slings, and general instruments." Johnson Dec., ¶ 16. Class II devices "cannot be classified as a class I device because . . . general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device"; instead, special controls must be established "to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines . . . , [and] recommendations . . . ." 21 U.S.C. § 360c(a)(1)(B). Powered wheelchairs are Class II devices. *See Reigel v. Medtronic*, 552 U.S. 312, 316 (2008). Class III devices are "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 "presents a potential unreasonable risk of illness or injury . . . ." 21 U.S.C. § 360c(a)(1)(C)(ii). Class III devices, such as the RP Knee, receive the most federal regulation and must undergo the PMA process "to provide reasonable assurance of . . . [the device's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C).

The PMA process is rigorous and involves several steps. *See Reigel*, 552 U.S. at 317. First, because a PMA application must include data from clinical investigations in humans, a manufacturer has to seek permission to conduct the clinical investigations by applying for an Investigational Device Exemption ("IDE"). *See* 21 C.F.R. § 812.1. "An approved . . . IDE permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device." *Id.* The IDE application must include, among other things, the following: (1) a complete report of prior investigations of the device; and (2) "[a] description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 812.20.

Second, after the clinical investigations and testing have been concluded and the research gathered, a person may file an application for PMA. *See* 21 U.S.C. § 360e(c)(1). The PMA application requires a summary of "data and information," including (1) a "general description of the . . . condition the device will . . . treat . . . including a description of the patient population for which the device is intended"; (2) an "explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device" as well as a "brief description of the manufacturing process . . . if it will significantly enhance the reader's understanding of the device"; (3) alternative practices or procedures for treating the condition the device seeks to treat; (4) a description of the device's marketing history; (5) a summary of the nonclinical laboratory studies and "clinical investigations involving human subjects"; and (6) a "discussion demonstrating that

the data and information in the application constitute valid scientific evidence . . . and provide reasonable assurance that the device is safe and effective for its intended use." 21 C.F.R. § 814.20(b)(3). Additionally, the PMA application must contain a "complete description" of the device, "including pictorial representations"; the functional "components or ingredients of the device"; the "properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a . . . condition"; the "principles of operation of the device"; and the "methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device . . . ." 21 C.F.R. § 814.20(b)(4). Moreover, the applicant must submit to the FDA "[c]opies of all proposed labeling for the device." 21 C.F.R. § 814.20(b)(10); *see also* 21 U.S.C. § 360e(c)(1).

The FDA will review the PMA application after it is accepted for filing. 21 C.F.R. § 814.44(a). Once accepted for filing, the FDA may refer the application to an advisory panel unless it decides "that the application substantially duplicates information previously reviewed by a panel." *Id.* Then, the advisory panel submits a "report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation." 21 U.S.C. § 360e(c)(3); *see also* 21 C.F.R. § 814.44(b). The FDA reviews the PMA application and the advisory panel's report and recommendation "[w]ithin 180 days after receipt of [the] . . . application that is accepted for filing and to which the applicant does not submit a major amendment . . . ." 21 C.F.R. § 814.40; *see also* 21 C.F.R. § 814.44(c). The FDA "spends an average of 1,200 hours reviewing each application . . . ." *Reigel*, 552 U.S. at 318.

The FDA then grants or denies PMA. It grants the application "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* If the FDA cannot approve the application as submitted, it "may send an 'approvable letter' indicating that the

device could be approved if the applicant submitted specified information or agreed to certain conditions or restrictions." *Id.* at 319. Alternatively, the FDA may send a "not approvable" letter, which lists "the grounds that justify denial and, where practical, measures that the applicant could undertake to make the device approvable." *Id.* The "approvable letter and the not approvable letter" give the applicant the opportunity to amend or withdraw its application or to consider the letter a denial of PMA approval. 21 C.F.R. § 814.40.

If a PMA application is approved[1], the holder of the PMA approval must comply with all requirements contained in the Code of Federal Regulations and the "device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. The "FDA may impose postapproval requirements," which may include "periodic reporting on the safety, effectiveness, and reliability of the device for its intended use." 21 C.F.R. § 814.82(a). Moreover, the manufacturer of the PMA device must submit a report and information to the FDA whenever it becomes aware that the device reasonably caused death or serious bodily injury and has malfunctioned and could likely cause or contribute to death or serious bodily injury. 21 U.S.C. § 360i(a). Furthermore, "[c]hanges to a Class III product, its manufacture, labeling, or any other matter affecting safety or effectiveness must be pre-approved by the FDA" through a supplemental application for PMA. Johnson Dec., ¶ 19.

[1] The FDA will deny approval if it finds one of the following: (1) "lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;" (2) "lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;" (3) "the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title;" (4) "the proposed labeling is false or misleading"; or (5) "such device is not shown to conform in all respects to a performance standard in effect under section 360d" of this statute. 21 U.S.C. § 360e(d)(2).

B. The RP Knee is Subject to Premarket Approval

The RP Knee, a Class III medical device, went through the PMA process outlined above. On July 14, 1980, Defendants filed their IDE application for the RP Knee with the FDA. Johnson Dec., ¶ 22. Defendants' IDE application included "(a) all relevant publications and research studies concerning the proposed device and its material and design; (b) a detailed proposal for the method and manner of conducting the clinical studies including the methods and materials to be used for Informed Patient Consent; (c) a detailed description of the proposed product and its manufacturing processes and controls; and (d) investigational labeling." *Id.* On August 19, 1980, the FDA sent Defendants a letter, allowing the clinical investigations to begin provided it received more information regarding certain deficiencies. Johnson Dec., Ex. 2. The clinical studies began in late 1980 after a group of "orthopaedic surgeons was registered and certified as qualified to conduct the clinical studies." Johnson Dec., ¶ 24. The studies involved "surgical implantation of the RP Knee . . . in over 800 patients who, after informed consent, agreed to participate in the human clinical study." *Id.* The study was monitored by "individuals certified to the FDA as being qualified to perform these duties." *Id.*

After completing the clinical investigation, Defendants filed their PMA application on August 12, 1983. *Id.* at ¶ 25. The application was "more than 2,000 pages, and included information and descriptions of the device, manufacturing, quality control procedures, and . . . data from the clinical studies." *Id.* at ¶ 26; *see also* Johnson Dec., Ex. 3. On September 12, 1983, the FDA accepted Defendants' PMA application for review. Johnson Dec., ¶ 27. Subsequently, the FDA's "Office of Device Evaluation and Office of Science and Technology in the Center for Devices and Radiological Health and the Office of Legal Counsel reviewed the data and information" in the application, and Dr. Seth Greenwald from Case Western Reserve

University conducted mechanical testing of the RP Knee. *Id.* at ¶ 27–28. Additionally, the FDA submitted the application to an advisory panel to make a recommendation regarding the safety and effectiveness of the device. *Id.* at ¶ 29. On July 11, 1984, the advisory panel recommended that the FDA approve the RP Knee. *Id.* After that, the FDA conducted further review of the application, "including review of the labeling of the device." *Id.* at ¶ 30. The FDA then approved the RP Knee for use in the LCS Total Knee System.[2] *Id.* at ¶ 31.

In 1996, Defendants introduced the P.F.C. Sigma Knee, which at the time was a fixed-bearing system containing four components: (1) a femoral piece that the surgeon fit over the femur; (2) a patella or kneecap; (3) a tibial tray that the surgeon fit onto the tibia; and (4) a tibial insert. Supplemental Declaration of Janet Johnson ("Johnson Supp. Dec."), ¶ 2. This fixed-bearing P.F.C. Sigma Knee was "cleared by the FDA through the 510(k) Premarket Notification process." *Id.* The 510(k) process is different from PMA because under the 510(k) process, the FDA must find that a new device is "'substantially equivalent' to another device exempt from premarket approval" instead of making a determination regarding the safety and effectiveness of the device. *Reigel*, 552 U.S. at 317. The device is not "formally reviewed . . . for safety or efficacy," and the FDA "does not require that a device . . . take any particular form for any particular reason" unlike the PMA process, which requires the device "to be made with almost no deviations from the specifications in its approval application . . . ." *Id.* at 323 (internal quotations omitted). The FDA completes its review under the 510(k) process "in an average of

[2] Prior to 1985, the rotating platform technology used in the RP Knee was called the "New Jersey Total Knee System." *Id.* at ¶ 20. In 1985, the name of the product changed to "New Jersey LCS Total Knee System," and in 1998, the name changed again to "LCS Total Knee System." *Id.*

only 20 hours," *Gross v. Stryker*, 858 F. Supp. 2d 466, 484 (W.D. Pa. 2012), and most devices undergo the 510(k) process instead of the more rigorous PMA process.[3]

On February 11, 2000, Defendants submitted a supplement to the PMA application ("Supplement 69"), seeking approval of the RP Knee for use in the P.F.C. Sigma Knee System with rotating platform technology.[4] Johnson Dec., ¶ 31; Johnson Dec., Ex. 4; Johnson Supp. Dec., ¶ 3. The rotating platform technology allowed the knee joint to mimic the movement of a knee and was "designed to be used with the 510(k)-cleared femoral and patella components of the existing PFC Sigma fixed bearing knee system . . . ." Johnson Supp. Dec., ¶ 3–4. The supplement contained "similar types of product engineering, testing, and proposed labeling information as the original RP [Knee] PMA application," and it "passed through the same process of requests for additional information and modification of texts of package inserts and surgical technique instructions." Johnson Dec., ¶ 31. On March 16, 2000, the FDA approved Defendants' PMA supplement. Johnson Dec., Ex. 5. The "FDA's PMA approval acknowledged that certain components of the PMA-approved device had also been previously cleared through the 510(k) process" when it recognized that Defendants sought "approval for a design modification to the proximal articular surface of the LCS Rotating Platform Bearings to match the geometry of the P.F.C. Sigma femoral components," which were approved in the 510(k) process. *Id.*; Johnson Supp. Dec., ¶ 5.

On May 11, 2000, Defendants submitted another PMA application supplement for the RP Knee ("Supplement 74"), requesting approval of "modified tibial trays and bearings." Johnson

[3] For example, in 2005, "the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices." *Reigel*, 552 U.S. at 317.

[4] Because the P.F.C. Sigma Knee System, which is at issue here, and the LCS Total Knee System use the same technology, the Court will refer to both of them as the "RP Knee." *See* Johnson Dec., ¶ 20.

Dec., Ex. 6. This supplement "contained similar types of product engineering, testing, and proposed labeling information as the original RP PMA application," and it "passed through the same FDA process of requests for additional information and modification of texts of package inserts and surgical technique instructions." Johnson Dec., ¶ 33. On June 22, 2000, the FDA approved Supplement 74. Johnson Dec., Ex. 7. The components in this Supplement "were also included as part of the RP Knee construct that the FDA reviewed and considered at the time the RP Knee was granted PMA approval, despite their prior 510(k) clearance." Johnson Supp. Dec., ¶ 5.

On February 8, 2006, Defendants submitted a "Special Changes Being Effected Supplement" ("Supplement 95") to the PMA, notifying the FDA that an "additional inspection . . . [was] being added to the Kemet process for certain product codes . . . to inspect the platform thickness prior to polishing." Johnson Dec., Ex. 8. Defendants asserted that this "additional inspection is a change to the manufacturing that could 'provide additional assurance of purity, identity, strength, or reliability . . . .'" *Id.* This supplement "contained similar types of product engineering, testing, and proposed labeling information as the original RP PMA application," and it "passed through the same FDA process of requests for additional information and modification of package inserts and surgical technique instructions." Johnson Dec., ¶ 35. On February 22, 2006, the FDA approved Supplement 95. Johnson Dec., Ex. 9.

Since 1980, Defendants have submitted and the FDA has approved "thousands of pages of testing results, clinical data, product descriptions, process controls and validations, and investigation reports" regarding the RP Knee. Johnson Dec., ¶ 38. In fact, as required by federal statute, Defendants submit annual reports to the FDA regarding the RP Knee. *Id.* at ¶ 37.

C. Plaintiff's Claims

On or about October 15, 2007, Plaintiff underwent a total right knee replacement (Compl. ¶ 20). During this procedure, a RP Knee, which included a RP tibial insert, MBT (RP) tibial tray, oval dome patella, and femoral component, were implanted in Plaintiff's body. Johnson Supp. Dec., ¶ 6. The RP tibial insert received PMA approval through Supplements 69 and 74, and the tibial tray received PMA approval under Supplements 74 and 95. *Id.* at ¶ 7. The FDA initially cleared the patella and femoral components during the 510(k) Pre-Market Notification process, and they were also approved "as part of the RP Knee construct that the FDA reviewed and considered at the time the RP Knee was granted PMA approval . . . ." *Id.* In mid-2008, Plaintiff allegedly experienced "chronic pain with swelling and locking of the joint" (Compl. ¶ 21). As a result, on May 29, 2008, Plaintiff allegedly "underwent a bone scan of the right knee, which confirmed loosening of the femoral and tibial components" (Compl. ¶ 22), and on July 20, 2009, Plaintiff underwent a second surgery to revise the loose knee implant (Compl. ¶ 23). During this surgery, the doctor implanted a femoral component, tibial cemented stem, Sigma femoral adapter, Sigma femoral adapter bolt, distal augmentations, posterior augmentation combo, and tibial insert. Johnson Supp. Dec., ¶ 8. The surgeon left the tibial tray from the first surgery in place. *Id.* The tibial insert received PMA through Supplements 69 and 74, and the rest of the components implanted during the second surgery were "initially cleared through the FDA's 510(k) process" and then "included as part of the RP Knee construct that the FDA reviewed and considered at the time the RP Knee was granted PMA approval . . . ." *Id.* at ¶¶9–10.

Plaintiff alleges that on June 29, 2010, he "developed a snapping behind the patella-femoral joint" (Compl. ¶ 24). As a result, on July 19, 2011, Plaintiff filed a Complaint against

Defendants, the designer, manufacturer, distributor, seller, and marketer of the knee, and alleged the following causes of action: (1) manufacturing defect, pursuant to N.J.S.A. 2A:58C-1 et seq.; (2) design defect, pursuant to N.J.S.A. 2A:58C-1 et seq.; (3) failure to warn, pursuant to N.J.S.A. 2A:58C-1 et seq.; (4) negligence, pursuant to N.J.S.A. 2A:58C-1 et seq.; (5) breach of express warranty; (6) breach of implied warranty, pursuant to N.J.S.A. 2A:58C-1 et seq.; (7) negligent misrepresentation; (8) fraudulent misrepresentation; (9) fraudulent concealment; (10) fraud and deceit; (11) violation of Virginia Consumer Protection Act, Va. Code Ann. 59.1-196 et seq.; and (12) punitive damages (Compl. ¶¶69–178).

On August 1, 2012, the parties participated in a telephonic initial scheduling conference before the Magistrate Judge, at which time Defendants "reiterated a prior written request for permission to file" a motion for summary judgment on preemption grounds instead of going forward with discovery. Declaration of Melanie H. Muhlstock ("Muhlstock Dec."), ¶ 6. The Judge granted Defendants' request, although it declared that some discovery could go forward. *Id.* On August 7, 2012, the Magistrate Judge entered a pre-trial scheduling order, ordering that "summary judgment motions on the issue of pre-emption" be filed by August 24, 2012, and ordering that "discovery, except for the production of manufacturing records requested by Plaintiff, is stayed pending the summary judgment motions" [docket # 17].

On August 8, 2012, Plaintiff sent Defendants a Request for the Production of Documents. Muhlstock Dec., Ex. 3. Plaintiff attached the "chart stickers" from his surgical procedures to the Request and sought "any and all documents related to Defendants' seeking and obtaining regulatory approval to market and sell the knee systems generally, and each of the component parts specifically . . . ." *Id.* Plaintiff specifically asked for all 510(k) and PMA "submissions, supplements, . . . amendments . . . and supporting documents provided to the" FDA as well as

"any documents received by Defendants from the FDA regarding approval to market and sell" the knee systems and devices. *Id.*

On August 22, 2012, Defendants responded to Plaintiff's Request for the Production of Documents and produced more than 3,000 documents. Declaration of Jennifer Lamont ("Lamont Dec."), Ex. A; Muhlstock Dec., Ex. 4. Defendants produced the "PMA submissions" for the tibial insert and tibial tray as well as the "510(k) PreMarket Notification submissions" for the patella and femoral components. Muhlstock Dec., Ex. 4. In addition, Defendants produced "the Device History Records, Device Master Records, and Package Inserts for the subject components at issue in this litigation." *Id.* Plaintiff's counsel alleges these responses are deficient because they "completely ignore the components implanted in Plaintiff on July 20, 2009, and explicitly decline to provide regulatory and manufacturing documents for any components implanted other than those implanted during the first surgery." Muhlstock Dec., ¶ 18. Moreover, Plaintiff's counsel has articulated that further discovery is necessary regarding "whether the prosthesis and its component parts implanted in Plaintiff on July 20, 2009 were approved under the 'PMA' process, the '510(k)' process, or otherwise . . . ." *Id.* at ¶ 19.

On August 24, 2012, Defendants filed the Summary Judgment Motion currently at issue [docket # 18]. On October 14, 2012, Plaintiff's counsel, for the first time, requested additional discovery regarding documents related to the July 20, 2009 surgery. Lamont Dec., ¶ 3. Plaintiff filed its Cross-Motion for a Continuance on October 15, 2012 [docket # 21].

II. DISCUSSION

A. Summary Judgment Standard

To prevail on a motion for summary judgment, the moving party must establish "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a genuine dispute of material fact exists, the court must view the facts in the light most favorable to the nonmoving party and extend all reasonable inferences to that party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Stephens v. Kerrigan*, 122 F.3d 171, 176–77 (3d Cir. 1997). The Court is not required to "weigh the evidence and determine the truth of the matter" but instead need only determine whether a genuine issue necessitates a trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248.

On a summary judgment motion, the moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party makes this showing, the burden shifts to the nonmoving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. The nonmoving party must then offer admissible evidence that establishes a genuine issue of material fact, *id.*, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co.*, 475 U.S. at 586.

B. Motion for Summary Judgment

Defendants argue that their Motion for Summary Judgment should be granted because federal preemption bars Plaintiff's Complaint. Defendants explain that Plaintiff's state law

causes of action are preempted by *Reigel v. Medtronic*, 552 U.S. 312 (2008), because the RP Knee was approved under the PMA process. Defendants rely on *Reigel* and cite numerous cases from this Court, the Third Circuit, and other jurisdictions to support their argument.

Plaintiff, however, asserts that the Motion for Summary Judgment should be denied because issues of material fact exist. First, Plaintiff contends that there is a question of fact regarding whether the device enjoys preemption under *Reigel* because the patella and femoral components of the RP Knee were approved through the 510(k) process. Moreover, Plaintiff argues that he properly pled claims that are parallel to federal violations and therefore, *Reigel* preemption does not apply. Plaintiff explains that the claims are parallel because the conduct that gives rise to the state law causes of action also violates the FDCA. Lastly, Plaintiff requests leave to amend his Complaint if he inadequately pled any of his state law claims by failing to allege the violation of a parallel federal regulation.

Defendants filed a reply brief, arguing that there are no genuine issues of material fact. Defendants assert that although some components of the RP Knee were approved under the 510(k) process, these components were also included as part of the RP Knee when it went through the PMA process. In addition, Defendants contend that Plaintiff has not pled any parallel claims. Defendants explain that PMA regulations are not equivalent to state common law claims and therefore, the two are not parallel. Furthermore, Defendants argue that amending the Complaint is futile because it will not cure any deficiencies.

The MDA contain an express pre-emption provision, which provides:

> 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.
>
> [21 U.S.C. § 360k(a).]

Thus, a state law is preempted if: (1) "the Federal Government has established requirements applicable to" the device; and (2) plaintiff's claims are based upon state "requirements . . . that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Reigel*, 522 U.S. at 321–22.

Applying the first step of the *Reigel* analysis, the federal government has established requirements that are "specific to individual devices" through the PMA process. *Id.* at 322–23; *see also Gross*, 858 F. Supp. 2d at 485 (same); *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 450 (E.D. Pa. 2011) (stating that "premarket approval . . . imposes 'requirements' under MDA"); *Cornett v. Johnson & Johnson*, 211 N.J. 362, 38 (2012) (stating the "totality of the [premarket] approval represents a specific federal requirement"). Here, the federal government has established requirements specific to the RP Knee because the RP Knee received PMA. Thus, the FDA found that the RP Knee "offers a reasonable assurance of safety and effectiveness." *Reigel*, 522 U.S. at 323.

The second step of the *Reigel* analysis requires this Court to decide whether Plaintiff's claims are based on state requirements that are different from or in addition to the federal PMA requirements and whether those requirements relate to safety and effectiveness.

Plaintiff's manufacturing defect, design defect, failure to warn, negligence, and breach of implied warranty claims are brought pursuant to New Jersey's Product Liability Act ("PLA"), N.J.S.A. 2A:58-C-1 et seq. That statute holds a "manufacturer or seller of a product" liable

> only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.
>
> [N.J.S.A. 2A:58C-2.]

Additionally, the statute provides that a "manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction." N.J.S.A. 2A:58C-4.

This statute, therefore, imposes state requirements that are different from or in addition to the federal requirements outlined by PMA and they relate to safety and effectiveness. The statute specifically states that a manufacturer is liable *only if* the claimant proves that the device was not reasonably fit, suitable or safe for its intended purpose because it deviated from design specifications, etc. However, the FDA determined, by granting PMA, that the RP Knee was safe and effective as manufactured and designed in the PMA application. As a result, Plaintiff's claims based on this statute — manufacturing defect, design defect, failure to warn, negligence, and breach of implied warranty — are preempted because the PLA imposes state requirements that are different from the federal requirements outlined in the RP Knee's PMA. *See also Gross*, 858 F. Supp. 2d at 490 (stating that breach of implied warranty is a state claim "that imposes requirements that are different, or in addition to, specific federal requirements"); *Bentzley*, 827 F. Supp. 2d at 453 (deciding that design defect claims are preempted); *Hayes v. Howmedica Osteonics Corp.*, 2009 WL 6841859, *6 (D.N.J. Dec. 15, 2009) (finding that a failure to warn

claim is preempted); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243, *3 (D.N.J. Mar. 5, 2009) (holding that "the MDA preempts products liability claims, including" failure to warn, defective design, negligence, and breach of implied warranty); *Mayen v. Tigges*, 2012 WL 3553378, *1 (N.Y. Sup. Ct. Aug. 17, 2012) (holding, in a case concerning the RP Knee, that Plaintiff's state law claims were preempted by the FDA through the PMA process).

Similarly, in *Desai v. Sorin CRM USA, Inc.*, 2013 WL 163298 (D.N.J. Jan. 15, 2013), this Court held that Plaintiffs' PLA claims were preempted. There, Defendants argued that Plaintiffs' PLA claims were preempted while Plaintiffs asserted that the PLA claims were parallel, and if necessary, they could amend their compliant to include a claim under the PLA for Defendants' alleged deviation from federal requirements. *Id.* at *3. The Court held that Plaintiff's claims were "expressly preempted" because "Plaintiffs' claims of, *inter alia*, negligence, defective design, and failure to warn stem from state common law," and "Plaintiffs would only be able to prevail on the New Jersey PLA claims if they proved that" the device "as designed, manufactured, and distributed, was defective and unreasonably dangerous." *Id.* at *5. The Court explained that "liability would necessitate a finding that the [device] . . . — designed, manufactured, and labeled in a way that the FDA deemed safe and effective — was both defective and unreasonably dangerous." *Id.* This determination is "a requirement different from, or in addition to, the standard required by federal authorities." *Id.* (internal quotations omitted).

Thus, Plaintiff's PLA claims are preempted because the RP Knee received PMA. Plaintiff would be able to prevail on his PLA claims only if he proved that the RP Knee was "defective and unreasonably dangerous," a finding that would contradict the FDA's determination that the device is safe and effective.

In addition, Plaintiff states a cause of action for breach of express warranty, alleging that "Defendants expressly warranted that the" RP Knee "was a safe and effective orthopedic device" and that the RP Knee "did not conform to these express representations . . . ." Compl. ¶¶ 97–98. For Plaintiff to be successful on this breach of express warranty claim, he would have to show that the RP Knee was unsafe or ineffective; this would directly conflict with the FDA's grant of PMA based on its finding that the RP Knee was safe and effective. *See Williams v. Cyberonics, Inc.*, 388 Fed. Appx. 169, 171 (3d Cir. 2010) (stating that "[s]uccess on appellants' breach of warranty claims would require them to show that the VNS Therapy System device was unsafe or ineffective despite the PMA process, thereby interfering with the requirements already established by the MDA, which has preempted safety and effectiveness determinations for a device"). Moreover, Plaintiff's breach of express warranty claim is similar to an express warranty claim alleging that the device's label is inaccurate and insufficient, and these express warranty claims based on labeling are preempted. *See Cornett*, 211 N.J. at 392–93. Thus, Plaintiff's breach of express warranty claim is preempted.

Moreover, Plaintiff alleges negligent misrepresentation, fraudulent misrepresentation, fraudulent concealment, fraud and deceit, and a violation of Virginia's Consumer Protection Act. Specifically, Plaintiff alleges the following: (1) that "Defendants should have known that their . . . [RP Knee] failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Defendants negligently misrepresented to the Plaintiff and/or his physicians that its device was safe and met all applicable design and manufacturing requirements"; (2) that Defendants falsely and fraudulently represented to Plaintiff, the community, and the FDA that the RP Knee "has been tested and was found to be safe and/or effective for knee replacement treatment," but these representations were false and made with the

intent of defrauding and deceiving Plaintiff and the public; (3) that "Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that" the product was unsafe, defective, manufactured negligently, defectively, and improperly, and was designed negligently, defectively, and improperly; (4) that Defendants "intentionally omitted certain" testing results and research to the public, and the information it did distribute contained false and misleading representations, including that the RP Knee was safe and effective; and (5) that Defendants violated the Virginia Consumer Protection Act by using "deception, fraud, false promise, misrepresentation and/or unfair practices in their packaging, labeling, distributing, marketing, promoting and selling of the" RP Knee. Compl. ¶¶ 108, 112, 113, 115, 125, 134–141, 165.

These "[g]eneralized common law theories of liability . . . are precisely the type of claims the MDA sought to preempt." *Williams*, 388 Fed. Appx. at 171; *see also Reigel*, 552 U.S. at 323–24 (declaring that "reference to a State's 'requirements' includes its common-law duties"); *Delaney*, 2009 WL 564243, at *3 (D.N.J. Mar. 5, 2009) (stating claims are "expressly preempted because they assert 'general tort duties of care'"). Additionally, "state law claims brought by individuals based on intentional misrepresentations to the FDA during or after the PMA process are barred" because "only the federal government is authorized to sue for failure to comply with the MDA provisions, including providing false or misleading information." *Cornett*, 211 N.J. at 385 (discussing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)).

Here, Plaintiff's claims have a common theme — Defendants misrepresented that the RP Knee was safe — which directly contradicts the FDA's finding that the RP Knee is safe and effective, a determination made in the PMA process. Because these allegations question the safety of the device and would require the Court to find that Defendants misrepresented that the

device was safe and effective to succeed, they are preempted. *See*, *e.g.*, *Cooley v. Medtronic, Inc.*, 2012 WL 1380265, *5 (E.D. Ky. 2012) (determining that Plaintiff's negligent misrepresentation, intentional misrepresentation, fraud, and constructive fraud claims are preempted because "they would each require a finding that Medtronic's statements about the safety and effectiveness of the ICD devices were false or misleading").

In addition, these claims are preempted because they are subsumed by the PLA. The PLA encompasses "virtually all possible causes of action relating to harms caused by consumer and other products." *Delaney*, 2009 WL 564243, at *7. A product liability action is defined by the PLA as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. 2A:58C-1b(3). Because the negligent misrepresentation, fraudulent misrepresentation, fraudulent concealment, fraud and deceit, and Virginia Consumer Protection Act claims concern a product — the RP Knee — they are subsumed by the PLA, and as demonstrated above, the PLA imposes state requirements that are different from or in addition to the federal requirements imposed by PMA, meaning these causes of action are preempted.

Lastly, Plaintiff seeks actual and punitive damages under the common law, the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9 et seq., and the PLA, N.J.S.A. 2A:58C-1 et seq. Yet, because all of Plaintiff's claims have been preempted under *Reigel*, Plaintiff's punitive damages request is denied. *Hayes*, 2009 WL 6841859, at *8; *see also Gross*, 858 F. Supp. 2d at 503.

Thus, Defendants have met their burden of establishing that there is no genuine issue of material fact and that they are entitled to judgment as a matter of law because all of Plaintiff's claims are preempted under *Reigel*.

Plaintiff, however, attempts to show that there is a genuine issue of material fact regarding whether the RP Knee is preempted under *Reigel* because: (1) certain components of the RP Knee were approved under the 510(k) process instead of the PMA process; and (2) Plaintiff's claims are parallel to federal violations.

First, Plaintiff has not shown a genuine issue of material fact because although some components of the RP Knee were approved through the 510(k) process, the entire device received PMA. "[A] device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption." *Gross*, 858 F. Supp. 2d at 487; *Bentzley*, 827 F. Supp. 2d at 452 (stating "Plaintiff's contention that, in considering a preemption issue, the Court must break a medical device into its component parts, is without legal support"). Therefore, although the patella and femoral components of the RP Knee were initially approved through the 510(k) process, the RP Knee as a whole received PMA. As a result, the patella and femoral components still underwent the PMA process as components of the RP Knee. Consequently, Plaintiff has not shown a genuine issue of material fact regarding preemption.

Second, Plaintiff has not created a genuine issue of material fact because his claims are not parallel to federal violations. "State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Reigel*, 552 U.S. at 330. State claims "premised on a violation of FDA regulations," however, are parallel to federal requirements, and thus, are not preempted. *Id.*; *see also Bentzley*, 827 F. Supp. 2d at 452; *Banner v. Cyberonics, Inc.*, 2010 WL 455286, *3 (D.N.J. Feb. 4, 2010); *Cornett*, 211 N.J. at 384.

"To properly allege parallel claims, [a] complaint must set forth facts showing 'action or inaction in [defendants'] efforts to take part in the PMA process or implement its results."

Gross, 858 F. Supp. 2d at 492. A plaintiff cannot plead "non-specific regulations as a basis for a parallel claim" because this is inconsistent with *Reigel* and the pleading requirements under *Twombly*, *Iqbal*, and *Fowler*. *Desai*, 2013 WL 163298, at *7. "[B]road references to federal regulations in pleadings are insufficient"; instead, "[t]his Court requires a greater level of specificity in pleading a parallel claim . . . ." *Id.* at *6–7; *see also Gross*, 858 F. Supp. 2d at 495–96, 500.

In *Desai*, Plaintiffs, similar to Plaintiff here, argued that their claims were parallel state claims under the PLA and sought to amend their Complaint, if necessary, to "explicitly include a claim under the New Jersey PLA for Defendants' alleged deviation from the federal requirements . . . ." *Desai*, 2013 WL 263398, at *5. This Court, however, found that the claims were not parallel because Plaintiffs' allegations failed "to assert the facts necessary, or indeed, any facts at all, to establish a claim that would parallel a violation of federal law, or even meet the federal pleading standard." *Id.* at *6. This Court explained that the allegations "are devoid of any explanation as to how [defendants] allegedly violated federal regulations in its design or manufacture of the [device], or even what about the device is 'defective' or 'unreasonably dangerous.'" *Id.* The Complaint did not contain "specific wrongdoing on the part of [defendants], other than to conclusory state that it is liable for all of Plaintiff's damages." *Id.*

Here, none of Plaintiff's claims are parallel to federal requirements because none of the claims are adequately pled with the specificity required for parallel claims. For example, regarding Plaintiff's manufacturing defect claim under the PLA, Plaintiff alleges that the RP Knee was "defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these devices" (Compl. ¶ 71). This claim is not parallel to federal requirements because Plaintiff

merely asserts a "broad reference" to the RP Knee deviating from federal requirements and does not plead with specificity, as required by *Reigel* and the federal pleading requirements. *See Desai*, 2013 WL 163298, at *6–7. In addition, as demonstrated above, to succeed on this claim, Plaintiff would have to show that the RP Knee was unsafe and ineffective, thereby contradicting the FDA's findings through the PMA process. *See supra* pp. 16–18. Consequently, Plaintiff's manufacturing defect claim is not parallel but different from the federal requirements. Moreover, regarding Plaintiff's breach of express warranty claim, Plaintiff alleges that "Defendants' conduct . . . , including but not limited to their failure to adequately design and manufacture, as well as their continued marketing and distribution of the [RP Knee] when they knew or should have known of the serious health risks it created and/or their failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages" (Compl. ¶ 100). Again, Plaintiff does not plead this claim with the specificity required for parallel claims — it is unclear which federal requirements Defendants failed to comply with and what actions allegedly caused the failure. Thus, Plaintiff's claims are not parallel to the federal requirements, and Plaintiff is not seeking damages for a violation of federal claims.[5]

Thus, Plaintiff has failed to establish a genuine issue of material fact regarding whether the RP Knee is preempted because it does not matter that some of the components of the RP Knee went through the 510(k) process prior to undergoing the PMA process and Plaintiff's claims are not parallel to the federal requirements. As demonstrated above, all of Plaintiff's claims are preempted under *Reigel*, and Defendants are entitled to judgment as a matter of law. As such, Defendants' Motion for Summary Judgment should be granted.

[5] Although none of Plaintiff's claims are parallel, this Court chose to use the manufacturing defect and breach of express warranty claims as examples because Plaintiff discussed these claims on page 19 of his brief [docket # 21].

Plaintiff requests leave to amend his Complaint to cure any defects if the Court finds that he inadequately pled his state law claims by failing to allege a violation of a parallel federal regulation. Defendants, however, argue that Plaintiff's request for leave to amend should be denied because it is futile since Plaintiff cannot plead viable claims against Defendants due to *Reigel* preemption.

"A party may amend its pleading once as a matter of course within: (A) 21 days after serving it, or (B) if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier." Fed. R. Civ. P. 15(a)(1). After this, "a party may amend its pleading only with the opposing party's written consent or the court's leave," and "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The following grounds, however, "could justify a denial of leave to amend": undue delay, bad faith, dilatory motive, prejudice, and futility. *Shane v. Fauver*, 213 F. 3d 113, 115 (3d Cir. 2000). In assessing futility, the Court applies the Rule 12(b)(6) standard. *Id.* Thus, futility exists when "the complaint, as amended, would fail to state a claim upon which relief could be granted." *Id.*

Here, this Court denies Plaintiff's request for leave to amend because of futility. Plaintiff's claims have all been expressly preempted, and his claims are not parallel. Any proposed amended claims in which Plaintiff seeks to allege a parallel violation would fail to state a claim because Defendants have not violated a federal regulation. *See Reigel*, 552 U.S. at 330 (stating preemption "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because these state claims are parallel). As stated above, to "properly allege parallel claims, the complaint must set forth facts showing 'action or inaction in [defendants'] efforts to take part in the PMA process or implement its results."

Gross, 858 F. Supp. 2d at 492. Plaintiff, here, would be unable to state a claim and show inaction regarding Defendants' efforts to take part in the PMA process because the facts clearly show that Defendants went through the PMA process and received PMA for the device. "This Court confesses it's unable to discern how a plaintiff pleads around the 360k preemption." *Hayes*, 2009 WL 6841859, at *6.

Thus, Defendants' Motion for Summary Judgment is granted. All of Plaintiff's claims are preempted, and Plaintiff has failed to show a genuine issue of material fact, meaning Defendants are entitled to judgment as a matter of law. Lastly, this Court denied Plaintiff leave to amend his Complaint because to do so would be futile.

C. Cross-Motion for a Continuance

Plaintiff filed a Cross-Motion for a Continuance pursuant to Rule 56(d), arguing that the Court should deny summary judgment as premature because "significant discovery remains outstanding that is necessary to the adjudication of the issues presented" (Pb7[6]). Plaintiff asserts that he needs further discovery regarding whether the components implanted in the July 20, 2009 surgery received PMA or were approved through another process because Defendants just discussed what was implanted in the first surgery on October 15, 2007. Additionally, Plaintiff contends that the documents Defendants produced and Ms. Johnson's Declaration ignore that some of the components used in the October 15, 2007 surgery went through the 510(k) process as opposed to the PMA process. Plaintiff states that he needs to take the deposition of Ms. Johnson to find out how components cleared through the 510(k) process went under the PMA process such that they deserve preemption. Moreover, Plaintiff seeks leave to serve Interrogatories on these issues.

[6] "Pb7" is a citation to page 7 of Plaintiff's brief [docket # 21].

Defendants, however, argue that the Cross-Motion for a Continuance should be denied because: (1) there are no questions of fact regarding the regulatory status of the RP Knee, and (2) the Muhlstock Declaration, on which Plaintiff bases their Cross-Motion, is deficient. Defendants assert that the Cross-Motion should be denied because additional discovery will not preclude summary judgment since discovery reveals that certain components of the RP Knee were approved under the 510(k) process and then received PMA as part of the RP Knee. In addition, Defendants argue that the Muhlstock Declaration is deficient since it failed to describe how the information regarding regulatory status would preclude summary judgment. Therefore, Defendants point out that Plaintiff cannot meet the requirements for a Rule 56(d) continuance.

Federal Rule of Civil Procedure 56(d) provides: "[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order." The nonmovant's motion "must identify with specificity what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained." *Lunderstadt v. Colafella*, 885 F.2d 66, 71 (3d Cir. 1989) (internal quotation omitted). The "affidavit must set forth more than bare conclusions or mere conjecture regarding facts that *may* be uncovered through discovery." *New Cmty. Corp. v. Arthur J. Gallagher Risk Mgmt. Servs. Inc.*, 2011 WL 4020941, *3 (D.N.J. Sept. 9, 2011), *report and recommendation adopted* 2011 WL 1594293 (D.N.J. Sept. 30, 2011).

Although this Court granted Defendants' Motion for Summary Judgment, thereby concluding that further discovery is not needed, it will explain why Plaintiff's Cross-Motion must be denied. The Cross-Motion must be denied because the Muhlstock Declaration submitted

with Plaintiff's brief is deficient since it does not explain how further discovery would preclude summary judgment. First, the Muhlstock Declaration clearly identifies what information is sought: (1) "outstanding discovery . . . with respect to the device implanted in Plaintiff's knee during his October 15, 2007 surgery"; (2) discovery regarding "whether the prosthesis and its component parts implanted in Plaintiff on July 20, 2009 were approved under the" PMA or 501(k) process; (3) Ms. Johnson's deposition "to inquire as to if, how and why components cleared pursuant to the 510(k) process have somehow undergone the rigors of the PMA" process; and (4) leave to serve Interrogatories "targeted to the distinct regulatory approval/clearance issues . . . ." *See* Muhlstock Dec., ¶¶ 19, 22, 23. Moreover, the declaration identifies why this information has not previously been obtained — because Defendants' response to Plaintiff's Request for Production of Documents was inadequate. *See* Muhlstock Dec., ¶ 18. Yet, the Declaration does not discuss how the discovery sought would preclude summary judgment because it will not preclude summary judgment. *See S. Jersey Gas Co. v. Mueller Co., Ltd.*, 2010 WL 2160060, *5 (D.N.J. May 26, 2010) (stating "South Jersey Gas does not indicate how the information sought would preclude summary judgment because it will not"), *aff'd*, 429 Fed. Appx. 128 (3d Cir. 2011). Plaintiff seeks further discovery regarding whether the components of the RP Knee were approved under the 510(k) or PMA process. As demonstrated above, certain components of the RP Knee were first approved under the 510(k) process and then received PMA as part of the RP Knee. *See supra* p. 21. Thus, further discovery regarding what process certain components underwent would not preclude summary judgment because all of the components were part of the RP Knee when it received PMA; the fact that certain components first underwent the 510(k) process does not create a genuine issue of material fact. *See New Cmty. Corp.*, 2011 WL 4020941, at *3 (stating the party "requesting a continuance must . . .

demonstrate how that discovery will create a genuine issue of material fact"). As a result, Plaintiff's Cross-Motion for a Continuance must be denied.

III. CONCLUSION

For these reasons, the Court grants Defendants' Motion for Summary Judgment and denies Plaintiff's Cross-Motion for a Continuance. An Order accompanies this Opinion.

Dated: March 18, 2013

/s/ Joel A. Pisano
JOEL A. PISANO
United States District Judge