**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF TEXAS**
**DALLAS DIVISION**

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| IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITIGATION<br><br>This Order Relates to:<br>*Alicea* – 3:15-cv-03489-K<br>*Barzel* – 3:16-cv-01245-K<br>*Buonaiuto* – 3:14-cv-02750-K<br>*Heroth* – 3:12-cv-04647-K<br>*Kirschner* – 3:16-cv-01526-K<br>*Miura* – 3:13-cv-04119-K<br>*Stevens* – 3:14-cv-01776-K<br>*Stevens* – 3:14-cv-02341-K | MDL Docket No.<br><br>3:11-MD-2244-K |

**ORDER**

Before the Court are the following motions:

1. Defendants' Motion for Summary Judgment as to all Claims Relying on a Theory That DePuy Should Have Sought Premarket Approval or That all Metal-on-Metal Implants are Defective [*Heroth* Doc. 31; *Miura* Doc. 36; *Stevens* Doc. 31; *Stevens* Doc. 31; *Bounaiuto* Doc. 33; *Alicea* Doc. 32; *Barzel* Doc. 34; *Kirschner* Doc. 29]

2. Defendants Motion for Summary Judgment as to Plaintiffs Claims Based on a Theory of Manufacturing Defect [*Heroth* Doc. 32; *Miura* Doc. 37; *Stevens* Doc. 32; *Stevens* Doc. 32; *Bounaiuto* Doc. 34; *Alicea* Doc. 33; *Barzel* Doc. 35; *Kirschner* Doc. 30]

3. Defendants' Motion for Partial Summary Judgment as to Plaintiffs' Express Warranty Claims [*Heroth* Doc. 33; *Miura* Doc. 38; *Stevens* Doc. 33; *Stevens* Doc. 33; *Bounaiuto* Doc. 35; *Alicea* Doc. 34; *Barzel* Doc. 36; *Kirschner* Doc. 31]

4. Defendants' Motion for Summary Judgment as to Plaintiffs' Design-Defect Claims [*Heroth* Doc. 34; *Miura* Doc. 39; *Stevens* Doc. 34; *Stevens* Doc. 34; *Bounaiuto* Doc. 36; *Alicea* Doc. 35; *Barzel* Doc. 37; *Kirschner* Doc. 32]

5. Johnson & Johnson's Motion for Summary Judgment [*Heroth* Doc. 36; *Miura* Doc. 41; *Stevens* Doc. 36; *Stevens* Doc. 36; *Bounaiuto* Doc. 38; *Alicea* Doc. 37; *Barzel* Doc. 39; *Kirschner* Doc. 34]

The Court carefully considered the parties' briefing and the applicable law. For the reasons stated herein, the Court DENIES the motions.

## I. Factual and Procedural Background

Pursuant to 28 U.S.C. §1407, the United States Judicial Panel on Multidistrict Litigation ordered coordinated or consolidated pretrial proceedings in this Court of all actions involving the Pinnacle Acetabular Cup System hip implants ("Pinnacle Device"), which Defendant DePuy Orthopaedics, Inc. ("DePuy") manufactured.

The lawsuits in this MDL relate to the design, development, manufacture, and distribution of the Pinnacle Device in the United States. Plaintiffs assert claims against Depuy, as well as Depuy Products, Inc., Depuy Synthes, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., and Johnson & Johnson International (collectively, the "Defendants"). The Pinnacle Device is used to replace diseased hip joints and was intended to provide pain-free natural motion over a longer period of time than other hip-replacement devices. Plaintiffs claim that the Pinnacle Devices have not so functioned but have instead caused significant health problems in many implantees. The Pinnacle Device MDL—MDL No. 2244—now involves over 9,100 cases.

Over the pendency of this MDL, the Court has held three prior bellwether trials. In September and October 2014, the Court held the first bellwether trial, involving a Montana plaintiff and her husband [No. 3:12-cv-04975-K] (the "*Paoli*" bellwether). The Court held a second bellwether trial in January through March 2016, consolidating five cases brought by Texas plaintiffs [*Aoki* – 3:13-cv-1071-K; *Christopher* – 3:14-cv-1994-K; *Greer* – 3:12-cv-1672-K; *Klusmann* – 3:11-cv-2800-K; *Peterson* – 3:11-cv-1941-K] (collectively, the "*Aoki*" bellwether). On September 20, 2016, the Court consolidated for trial six California cases (collectively, the "*Andrews*" bellwether) subject to this Order. The trial was held from October 3, 2016, to November 30, 2016.

The Motions currently before the Court relate to the cases selected to be prepared for the fourth bellwether trial in this multidistrict litigation ("MDL") involving the Pinnacle Device. On November 8, 2016, the Court selected nine New York cases [*Alicea* – 3:15-cv-03489-K; *Barzel* – 3:16-cv-01245-K; *Buonaiuto* – 3:14-cv-02750-K; *Cousin* – 3:13-md-02244-K; *Heroth* – 3:12-cv-04647-K; *Kirschner* – 3:16-cv-01526-K; *Miura* – 3:13-cv-04119-K; *Stevens* – 3:14-cv-01776-K; *Stevens* – 3:14-cv-02341-K] and one New Jersey case [*Riedhammer* – 3:11-cv-02460-K] to be prepared for the fourth bellwether trial. Order on Bellwether Trials [3:11-md-2244-K (Doc. 713)]. Plaintiff Cousin's case was later voluntarily dismissed. Stipulation of Dismissal with Prejudice [3:13-md-02244-K (Doc. 28)]. Riedhammer's case was withdrawn. Notice of Withdrawal [3:11-cv-2460-K (Doc. 41)]. Accordingly, eight cases remain for the fourth bellwether trial.

On February 3, 2017, all Plaintiffs filed Amended Complaints asserting the same nine causes of action against Defendants: negligence, strict liability, fraud, negligent misrepresentation, fraudulent business acts and practices, breach of express and implied warranty. *See, e.g.*, Am. Compl. and Jury Trial Demand ("Am. Compl.") [*Alicea*, 3:15-cv-03489-K (Doc. 14)]. Some Plaintiffs also assert a tenth claim for loss of consortium. Defendants seek summary judgment on Plaintiffs' claims.

## II. Summary Judgment Standard

This Court shall grant summary judgment if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). An issue as to a material fact is genuine if a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The Court considers all evidence in the light most favorable to the party resisting the motion. *Trevino v. Celanese Corp.*, 701 F.2d 397, 407 (5th Cir. 1983).

## III. Analysis

### A. Defendants' Motions for Summary Judgment on Plaintiffs' Design Defect Claims

Defendants argue that summary judgment is proper on Plaintiffs' design defect claims because (1) Plaintiffs have no evidence of a feasible, safer alternative design and (2) because such claims are purportedly preempted by federal law.

#### 1. Alternative Design

Defendants first argue that Plaintiffs have no evidence of a feasible, safer alternative design, as required to succeed on a design defect claim under New York law. To state a claim for strict liability design defect under New York law, Plaintiffs must show that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *S.F. v. Archer Daniels Midland Co.*, 594 F. App'x 11, 12 (2d Cir. 2014) (citations omitted). An alternative design supports a design defect claim if it "fairly corresponds" to the defective product. *Adams v. Genie Indus., Inc.*, 14 N.Y.3d 535, 539-540, 929 N.E.2d 380 (N.Y. 2010). Plaintiffs argue in response that their evidence demonstrates (1) that hip implants incorporating a cross-linked poly liner fairly correspond to and function better than the Pinnacle MoM implants and (2) that Plaintiffs' alternative design is not "a different product altogether" because it merely requires a modification to the Pinnacle MoM implant as Defendants' own literature contemplates.

Defendants argue that Plaintiffs' reference to these alternative liners identify different products altogether and not an alternative design. Defendants advanced a version of their argument in their Partial Motion to Dismiss Plaintiffs' First Amended Complaints in this bellwether, which this Court denied. The Court again finds that Defendants' argument is unavailing. Following Defendants' reasoning, any change to a device would create a new product, making it impossible to propose an alternative

design. Further, Plaintiffs' summary judgment evidence raises a genuine issue of material fact that an alternative design was feasible.

**2. Federal Preemption**

Defendants next contend that summary judgment is proper on Plaintiffs' design defect claims because they are preempted by federal law. Specifically, Defendants argue that the Supreme Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580-81 (2011) supports summary judgment on Plaintiff's design defect claims because an impossible conflict between state and federal law, as the Pinnacle Device is subject to federal regulation and no change can be made to the design of a device without FDA permission. Defendants allege that it is impossible to independently comply with both state and federal requirements, and as such, Plaintiffs' state law design defect claims are preempted under *Mensing*. The *Mensing* matter, however, involved the preemption of failure-to-warn claims for generic prescription drugs which required FDA evaluation on the drugs and accompanying warnings prior to marketing.

As this Court observed in the *Aoki* and *Andrews* bellwethers, the FDA evaluation process for prescription drugs differs from the process applicable to the Pinnacle Device. Generally, product manufacturers have two options when seeking product approval from the FDA: a pre-market approval ("PMA") process, and a substantial equivalence "grandfathering" standard (the "510(k)" process). In *Medtronic v. Lohr*, 518 U.S. 470 (1996), the Supreme Court held that the 510(k) clearance process, by which the Pinnacle Device was approved, does not preempt state-law design defect

claims. The FDA never passed on the original design of the device and imposed no requirements for safety or otherwise on it. The FDA merely determined whether the Pinnacle Device was substantially equivalent to a grandfathered device. Defendants, therefore, could not have been subject to conflicting state and federal design requirements that would give rise to preemption.

Defendants also attempt to argue that Plaintiffs' design defect claims are "impliedly preempted" as the 510(k) clearance process prohibits a manufacturer's unilateral change after approval. However, this product restriction is not equivalent to impossibility; it is neither a "duty of sameness" for generic drugs that prohibits changes or a coexisting "state-law duty to change the label and . . . federal law duty to keep the label the same." *Mensing*, 131 S. Ct. at 2578. Rather, *Lohr* controls; "[t]he FDA's 'substantially equivalent' determination as well as its continuing authority to exclude a device from the market do not amount to a specific, federally enforceable design requirement" running in conflict with state liability law. *Lohr*, 518 U.S. at 471. With the 510(k) process, manufacturers enjoy the benefit of being able to "rapidly introduce [devices] into the market," but that benefit comes at the cost of "hav[ing] to defend itself against state-law claims" when those devices cause harm. *Id.*, at 478, 494. The 510(k) process does not give rise to express or implied preemption.

Because Plaintiffs' claims are not preempted by federal law and Plaintiffs have raised a genuine issue of material fact regarding the existence of a safer alternative

design, the Court DENIES Defendants' Motion for Summary Judgment on Plaintiffs' design defect claims.

**B. Defendants' Motions for Summary Judgment on Plaintiffs' Manufacturing Defect Claims**

Defendants advance two arguments in moving for summary judgment on Plaintiffs' manufacturing defect claims. First, on Plaintiffs' theory that the products deviate from specification in that citric acid rather than nitric acid was used to passivate the femoral head and Ultamet liner, Defendants argue that Plaintiffs' manufacturing defect claims fail as a matter of law because: (1) this uniform characteristic of the Pinnacle Ultamet product line does not constitute a manufacturing defect under New York law; and (2) even if it did, Plaintiffs have no expert evidence that it caused any alleged injury. Second, Defendants argue that Plaintiffs fail to raise a genuine issue of material fact on their theory that a significant percentage of Pinnacle MoM Device components failed to comply with dimensional specifications because their component parts were either undersized or oversized.

To prevail on a manufacturing defect claim based on either negligence or strict liability, a plaintiff must show that a specific product unit was defective as a result of "some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in the construction," and that the defect was the cause of the plaintiff's injury. *Gunn v. Hytrol Conveyor Co.*, No. 10-CV-00043, 2013 WL 2249241, at *7 (E.D.N.Y. May 22, 2013) (quoting *Colon ex rel. Molina v. BIC USA*, Inc., 199 F.Supp.2d 53, 85 (S.D.N.Y. 2001); *Caprara v. Chrysler Corp.*, 52 N.Y.2d 114,

129 (N.Y. 1981)). A manufacturing defect exists "when the unit in question deviates in quality and other performance standards from all of the other identical units." *Id.* (citing *Perazone v. Sears, Roebuck & Co.*, 515 N.Y.2d 908, 911 (3d Dep't 1987)). "The crux of a strict liability manufacturing defect claim is the product's failure to perform as expected due to an error in the manufacturing process that resulted in a defect." *Derienzo v. Trek Bicycle Corp.*, 376 F.Supp.2d 537, 560 (S.D.N.Y. 2005) (quoting *Rainbow v. Albert Elia Building Co.*, 436 N.Y.S.2d 480 (4th Dep't 1981), aff'd, 56 N.Y.2d 550 (N.Y.1982)).

In response to Defendants' first argument, Plaintiffs point to evidence that Defendants used citric acid to passivate each Plaintiff's femoral head and Ultamet liner. Plaintiffs argue that these actions were inconsistent with Defendants' specifications. Specifically, Plaintiffs point out that Defendants' own expert, Nick Sheppard, confirmed the existence of a manufacturing defect in Plaintiffs' implanted products. So, Plaintiffs effectively raise a question of whether "some mishap in the manufacturing process itself occurred." *Gunn*, 2013 WL 2249241 at *7.

Plaintiffs similarly cite evidence that raises a genuine issue of material fact on their theory that a significant percentage of Pinnacle MoM Device components failed to comply with dimensional specifications because their component parts were either undersized or oversized. Specifically, Plaintiffs point to Defendants' Corrective and Preventive Action ("CAPA") in 2008 in which Defendants determined that a significant percentage of Pinnacle MoM Device components failed to comply with

dimensional specifications. Plaintiffs argue that through the CAPA, Defendants discovered that component parts manufactured in their DePuy Leeds manufacturing facility were either undersized or oversized, detrimentally affecting the clearance of its hip prosthesis devices and in clear deviation from its own product specifications submitted to the FDA. Plaintiffs again point to Defendants' expert's testimony to further support their manufacturing defect contentions.

Summary judgment is not proper given the fact issues that exist on Plaintiffs' manufacturing defect claims. Accordingly, Defendants' Motion for Summary Judgment on Plaintiffs' manufacturing defect claims is DENIED.

### C. Defendants' Motions for Summary Judgment on Premarket Approval and Metal-on-Metal Defect Issues

Defendants seek summary judgment on all claims to the extent that claims rely on evidence or argument that (1) Defendants should have sought premarket approval instead of relying on the § 510(k) substantial-equivalence clearance process; or (2) all metal-on-metal hip implants are inherently defective.

Defendants contend that these claims are preempted by federal law. First, Defendants contend that the FDA has the exclusive authority to determine what submissions should be made to that agency to receive clearance to market a drug, and Plaintiffs' position that Defendants should have used the alternate, more rigorous clearance process interferes with the FDA's authority. Second, Defendants also contend that any claim that metal-on-metal devices are inherently defective is contrary to the FDA's decision to permit such devices and is preempted under the MDA.

As discussed above, product manufacturers may seek FDA approval through either the PMA or 510(k) process. Both Plaintiffs and Defendants acknowledge that both procedures are lawful mechanisms for obtaining FDA approval. Accordingly, Defendants argue that any state law imposing liability on Defendants for using the 510(k) process rather than the more rigorous PMA process are preempted, as they interfere with the FDA's authority to determine its own clearance procedures. However, there is a significant difference in the effects of the PMA and 510(k) processes; products undergoing the PMA process are preempted from claims under state law as to the design and manufacture of the product where products undergoing the 510(k) process are not.

While DePuy had the right to proceed under the 510(k) process—and Plaintiffs do not assert that Defendants are per se liable because of that election—nothing in the law permits that process to be used as a shield against inquiry regarding the approval process. Defendants argue that imposing liability for a device approved under the 510(k) process would discourage manufacturers from using the process, cause more device manufacturers to elect the slower and more onerous PMA process, and defeat the 510(k) purpose of rapid product availability to consumers. However, it is the manufacturer's benefit to "rapidly introduce [devices] into the market" under the 510(k) process which bears with it the cost of "hav[ing] to defend itself against state-law claims" when those devices cause harm. *Lohr*, 518 U.S. at 494.

Defendants also contend that any claim that metal-on-metal devices are inherently defective is contrary to the FDA's decision to permit such devices and is preempted under the MDA. Generally speaking, common law claims regarding medical devices that have received premarket approval are preempted. *Riegel v. Medtronic, Inc.*, 522 U.S. 312 (2008). However, this preemption applies specifically to items cleared through the rigorous PMA process, rather than the alternative 510(k) "grandfathering" practice. As noted by Plaintiffs, the FDA has approved three "hip resurfacing implants" under the PMA process. *See Christiansen v. Wright Med. Tech., Inc.*, 2015 U.S. Dist. LEXIS 15601 *4 (Aug. 31, 2015). The PMA process is specific to individual devices, however, and so is PMA preemption. The fact that a different metal-on-metal device has been approved does not preclude claims that the products at issue are defective and cannot support an argument that such claims are preempted. *Id.* at *112-13.

Defendants' Motion for Summary Judgment on premarket approval and inherent defect issues is DENIED.

**D. Defendants' Motions for Summary Judgment on Plaintiffs' Warranty Claims**

Defendants seek summary judgment on Plaintiffs' claims for breach of express warranty, breach of the implied warranty of fitness for a particular purpose, and breach of the implied warranty of merchantability based on privity of contract between Plaintiffs and Defendants. Defendants also seek summary judgment on Plaintiffs' claim for breach of the implied warranty of merchantability, as Defendants contend

there is no evidence that any of the Plaintiffs or their physicians selected the Pinnacle Device for a special or particular purpose separate and apart from its ordinary purpose as a hip implant.

To prevail on a claim for breach of express warranty under New York law, Plaintiffs must allege "there was an affirmation of fact or promise by the seller, the natural tendency of which was to induce the buyer to purchase and that the warranty was relied upon to the [P]laintiffs' detriment." *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 625 (S.D.N.Y. 2012) (citations omitted). Further, the "affirmation of fact or promise must have been 'false or misleading when made.'" *Id.* (citations omitted). Defendants argue that Plaintiffs lack evidence of a specific affirmation of fact necessary to succeed on a breach of express warranty claim and that Plaintiffs' express warranty claim "boils down" to an allegation that Defendants generally warranted that the Pinnacle Device was safe to use.

Plaintiffs claim in response that Defendants marketed the Pinnacle Device as "uniquely designed to meet the demands of active patients," each of Plaintiffs' prescribing physicians advised them that the Pinnacle Device was the best choice, and Plaintiffs' physicians reached their opinions about the efficacy of the Pinnacle Device based at least in part on marketing and promotion by Defendants to hospitals and surgeons via written materials, the use of "celebrity endorser" surgeons, "seeding" studies in the medical literature, and through their network of sales representatives. Further, Plaintiffs' physicians indicated a "bias" after seeing Defendants'

advertisements, recalled studying Defendants' manuals, typically read promotional materials, or testified to relying on manufacturer representative statements.

A fact issue accordingly exists as to reliance on Defendants' representations and the privity necessary for Plaintiffs' breach of warranty claims. The Court therefore DENIES Defendants' Motion for Summary Judgment on Plaintiffs' warranty claims

**E. Defendant Johnson & Johnson's Motion for Summary Judgment**

In addition to each of the other motions for summary judgment addressed in this Order, Johnson & Johnson (J&J) filed a separate motion addressing its status as a party, rather than the merits of any cause of action (the "J&J Motion"). J&J argues that it is entitled to summary judgment on Plaintiffs' products liability and fraud-based claims because (1) it is a holding company that does not manufacture, distribute, or sell products like the Pinnacle Device; and (2) because Plaintiffs fail to identify a misrepresentation attributable to J&J on which Plaintiffs relied.

**1. Products Liability Claims**

J&J argues that it is entitled to summary judgment on Plaintiffs' products liability claims because it never manufactured or sold the Pinnacle Device. Under New York law, "a manufacturer of defective products who places them into the stream of commerce may be held strictly liable for injuries caused by its products, regardless of privity, foreseeability or due care. *Finerty v. Abex Corp.*, 27 N.Y.3d 236, 47-241 (N.Y. 2016) (citing *Sukljian v. Ross & Son Co.*, 69 N.Y.2d 89, 94, 511 N.Y.S.2d 821, 503 N.E.2d 1358 (N.Y. 1986); *Codling v. Paglia*, 32 N.Y.2d 330, 342, 345 N.Y.S.2d 461,

298 N.E.2d 622 (N.Y. 1973); *Amatulli v. Delhi Constr. Corp.*, 77 N.Y.2d 525, 532, 569 N.Y.S.2d 337, 571 N.E.2d 645 (N.Y. 1991)). Retailers and distributors of allegedly defective products can also be strictly liable where they are usually "in a position to exert pressure for the improved safety of products and can recover increased costs within their commercial dealings, or through contribution or indemnification in litigation," as a result of their continuing relationship with the manufacturers. *Finerty*, 27 N.Y.3d 236 at 241 (quoting *Sukljian*, 69 N.Y.2d at 95).

J&J reasons that it is neither a seller nor a manufacturer under New York law and that it is instead a holding company. Citing the New York Court of Appeals' holding in *Finerty*, J&J argues that summary judgment is appropriate because a parent company's presumed authority over a wholly owned subsidiary does not subject it to strict liability for a subsidiary's actions. *Finerty*, 27 N.Y.3d 236 at 241

Plaintiffs respond that their strict liability claims against J&J are not based merely upon its presumed authority over DePuy as its parent, nor on general allegations of guidance or facilitation. Instead, according to Plaintiffs, the evidence shows that J&J is strictly liable for Plaintiffs' product liability claims because it is an integral participant in the overall production and marketing enterprise of the Pinnacle Device. Plaintiffs also argue that J&J can be held directly liable for Plaintiffs' product liability claims under the apparent manufacturer doctrine and can be held liable for its own negligence.

Viewed in the light most favorable to Plaintiffs, the summary judgment evidence raises a genuine issue of material fact related to J&J's role in the production and

marketing of the pinnacle device. A jury could reasonably infer that J&J was responsible for placing the product in the marketplace. Accordingly, the Court DENIES J&J's motion for summary judgment on Plaintiffs' products liability claims.

**2. Fraud-Based Claims**

J&J argues that it is entitled to summary judgment on Plaintiffs' fraud-based claims because J&J never made a misrepresentation on which Plaintiffs or their physicians relied. J&J also contends that Plaintiffs fail to identify any concealment of information that it had a legal duty to disclose. Under New York law, such statements and concealments are necessary to Plaintiffs' claims for fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraudulent business acts and practices in violation of General Business Law § 349.

When taken in the light most favorable to the Plaintiffs, the summary judgment record raises issues with respect to the truthfulness of the fluid film lubrication theory that was introduced by J&J's procured "thought leaders" at the J&J organized and sponsored satellite broadcast to over 1,500 physicians, the truthfulness of numerous statements in DePuy's advertising materials and literature over which J&J had authority or sponsored, such as the 99.9% five-year survival rate, and the knowledge and concealment of device failures which DePuy was claiming as a substantially equivalent device to the Pinnacle Device.

J&J contends that these statements are insufficient to hold J&J liable for Plaintiffs' fraud-based claims. As Plaintiffs' point out, however, "one who misrepresents

for his gain and benefit, at the expense of human life, should be answerable in fraud for all the reasonable and foreseeable consequences of his deception." *Wechsler v. Hoffman-La Roche, Inc.*, 99 N.Y.S.2d 588, 590 (N.Y. Sup. Ct. 1950). In addition, "[m]isrepresentations of safety to the public at large, for the purpose of influencing the market of a product known to be defective, gives rise to a…cause of action for fraud." *Standish-Parkin*, 786 N.Y.S.2d at 15; *see Lead Indus. Ass'n*, 597 N.Y.S.2d at 177; *Young v. Robertshaw Controls Co.*, 481 N.Y.S.2d 891, 893 (N.Y. App. Div. 3d Dept. 1984). Additionally, "[l]iability for fraud may be premised on knowing participation in a scheme to defraud, even if that participation does not by itself suffice to constitute fraud." *Danna v. Malco Realty, Inc.*, 857 N.Y.S.2d 688, 689 (N.Y. App. Div. 2d Dept. 2008). Finally, Plaintiffs point to testimony of their implanting physicians indicating that physicians received J&J's representations and that the physicians' decisions to use the Pinnacle Device were based in part not on these alleged misrepresentations.

Viewed in the light most favorable to Plaintiffs, this evidence raises a genuine issue of material fact. The Court DENIES J&J's Motion for Summary Judgment as to Plaintiffs' fraud-based claims.

**SO ORDERED.**

Signed September 18th, 2017.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE