SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

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DEBRA RIOLO and THOMAS RIOLO Index No: 24494/09

Plaintiffs,

-against-

MICHELLE POLIDORO, M.D., P.C., MICHELLE POLIDORO, M.D., CONCEPTUS, INC. and SOUTHSIDE HOSPITAL,

Defendants.

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MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR DISMISAL AND/OR SUMMARY JUDGMENT BASED UPON FEDERAL PRE-EMPTION/LACK OF SUBJECT MATTER JURISDICTION

Respectfully submitted,
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INTRODUCTION

This memorandum of law is respectfully submitted in support of Conceptus' motion for dismissal/summary judgment pursuant to CPLR 3211(a)(2) and CPLR 3212(b) based upon federal pre-emption of all claims asserted against Conceptus and therefore lack of subject matter jurisdiction. The basis for the motion is that Essure device at issue in this litigation, as a matter of public record, is a Class III device under the Medical Device Act of 1976, 21 USC § 360K(a), subject to premarket approval by the FDA, which approval was granted in 2002 (see enclosed affidavit of Gregory E. Lichwardt and exhibits thereto) and published at 68 Fed. Reg. 62812 (2003) (Ex. "G" to Fogel Aff.). Accordingly, plaintiffs' claims in this matter against Conceptus for common law negligence (third cause of action), breach of warranty (fourth cause of action), strict product liability (fifth and third causes of action) and loss of consortium based upon the forgoing claims (sixth cause of action) are pre-empted by the federal statute and must be dismissed. *Riegel v Medtronic, Inc.,* 552 U.S. 312 (2008); *Mitaro v. Medtronic, Inc.*, 73 A.D.3d 1142, 900 N.Y.S.2d 899 (2d Dep't 2010).

FACTS

This action is a product liability/medical malpractice litigation in which the plaintiff, Mrs. Riolo, claims personal injury by co-defendant medical providers and/or Conceptus' product, the Essure System, a permanent contraception device. Plaintiffs' claims against Conceptus are based upon theories of common law negligence (third cause of action), breach of warranty (fourth cause of action), strict product liability (fifth and third causes of action) and loss of consortium based upon the forgoing claims (sixth cause of action).

According to plaintiffs' bills of particulars to the medical malpractice co-defendants

(Fogel Aff. Ex. "D') and interrogatory responses to Conceptus (Fogel Aff. Ex. "E"), on or about November 26, 2007, Mrs. Riolo underwent a voluntary sterilization procedure. Co-defendant Dr. Polidoro attempted to insert the Essure system in Mrs. Riolo at Southside Hospital in Bay Shore, for the intended purpose of permanent contraception. Plaintiffs claim Mrs. Riolo suffered personal injury as a result, including but not limited to a supracervical hysterectomy.

The U.S. Food and Drug Administration (FDA) approved the Essure system on or about Nov. 4, 2002 as a Class III device under the Medical Device Act of 1976 [hereinafter "MDA"], 21 USC § 360K(a) under the premarket approval (PMA) procedure specified in the statute. As set forth more fully below, PMA is a rigorous process in which the FDA spends an average of 1200 man hours reviewing each voluminous application and that is not including any review of a panel of outside experts that may be required for each application. *Riegel v Medtronic, Inc.,* 552 U.S. 312, 318 (2008), The FDA published the approval at 68 Fed. Reg. 62812 (2003) (Fogel Aff., Ex. "G").

ARGUMENT

In *Riegel v Medtronic, Inc.,* 552 U.S. 312 (2008), the court held that state and common law personal injury claims are pre-empted by federal law for Class III, PMA medical devices.

> Premarket approval is a "rigorous" process [citation omitted]. A manufacturer must submit what is typically a multivolume application [citation omitted]. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; " a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling [citation omitted]. Before deciding whether to

> approve the application, the agency may refer it to a panel of outside experts [citation omitted] and may request additional data from the manufacturer [citation omitted].
>
> … [The FDA] may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives…
>
> The premarket approval process includes a review of the devices proposed labeling…
>
> Once a device has received premarket approval, the [federal statute] forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling or any other attribute, that would affect safety or effectiveness [citations omitted]. If the applicant wishes to make a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application [citation omitted. 55 U.S. at 317-319.

The Supreme Court goes on to explain that the federal MDA statute clearly pre-empts state law and state agencies and that it would be ridiculous to exempt from pre-emption, common law claims to be considered by a jury with no expertise and that such a jury's decision on particular set of facts should have greater authority than a state agency with presumed expertise. 55 U.S. at 321-330. Accordingly, the Court expressly held that common law claims against PMA Class III devices for product liability, negligence, strict product liability and breach of warranty are pre-empted by federal law pursuant to the MDA. *Id.*

In *Mitaro v. Medtronic, Inc.*, 73 A.D.3d 1142, 900 N.Y.S.2d 899 (2d Dep't 2010), the Second Department, relying on *Riegel*, dismissed as pre-empted, common law product liability, negligence and breach of warranty claims against a Class III PMA device, holding that plaintiffs arguments against pre-emption had no merit in view of *Reigel*.

The case before the court has nothing to distinguish it from the controlling U.S. Supreme Court and New York Appellate Division precedent. The causes of action based upon negligence, product liability, strict product liability, breach of warranty and loss of consortium derived from those claims must also be dismissed as preempted.

CONCLUSION

Wherefore, Conceptus requests that the court issue an order dismissing the complaint for lack of subject matter jurisdiction pursuant to CPLR 3211(a)(2) and/or granting Conceptus summary judgment pursuant to CPLR 3212(b), and further granting such other and further relief as the court deems just and proper.

Dated: Islip, N.Y.
April 15, 2011

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