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LESLIE AND VINCENT MULLIN	:	SUPERIOR COURT
	:	COMPLEX LITIGATION DOCKET
V.	:	JUDICIAL DISTRICT OF
	:	WATERBURY
GUIDANT CORPORATION	:	APRIL 2008

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COMPLEX LITIGATION
400 GRAND ST
WATERBURY CT 06702

SUMMARY RULING ON THE DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

STATEMENT OF THE CASE

The plaintiffs Leslie and Vincent Mullin brought this case against the defendant Guidant Corporation under Connecticut's product liability statute, General Statutes § 52-572m et. seq. The complaint alleges that in July 1999, the plaintiff Leslie Mullin suffered a heart attack from ventricular fibrillation. She survived, and to guard against similar events and as part of her treatment, she was prescribed and implanted with a Guidant Ventak Mini Model 1793 (MINI), manufactured by the defendant.[1] After the implantation, the MINI began to beep, indicating that the device had entered a default mode. The MINI was determined to have suffered a defect, and was replaced, at the defendant's expense, with another model defibrillator also manufactured by the defendant. The complaint is in two counts. In the first count, Leslie Mullin claims that the defendant is liable under the product liability statute on various grounds including the following: that the MINI was defective and unreasonably dangerous in nature and design; that the defendant failed appropriately to evaluate the safety of the product; that the defendant breached warranties

[1]According to the plaintiffs' expert witness, Jeffrey Kluger, M.D., the MINI is an automatic, implantable cardioverter defibrillator (ICD) that "shocks a life threatening rhythm" by delivering an electrical impulse that converts a rapid rhythm back to normal, and is regarded as a life-saving, complicated electronic device.

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that the product was safe and effective for its intended use; that the defendant failed to warn or provide written directions about the inherent dangers of the product; and that the "defendant failed adequately to evaluate and address human factors as they relate to the product." In the second count of the complaint, the plaintiff Vincent Mullin asserts a claim for loss of consortium.

Pending before the court is the defendant's motion for summary judgment. One of the bases of the defendant's motion is that the plaintiffs' tort claims are preempted by federal statute, the Medical Device Amendments of 1976, 21 U.S.C. 360k (MDA). The court viewed this claim as implicating the court's subject matter jurisdiction, and directed the parties to submit evidence on the applicability of the MDA, or more specifically, on the defendant's claim that the MINI had undergone the premarket approval process of the MDA and had been approved by the Food and Drug Administration (FDA). See generally, *Standard Tallow Corporation v. Jowdy*, 190 Conn. 48, 56, 459 A.2d 503 (1983) (evidentiary hearing may be necessary to determine the court's jurisdiction). In response to this direction, the defendant submitted the affidavit of Lisa Becker, Director of Regulatory Affairs at Boston Scientific Rhythm Management, and supporting documentation. At a hearing held on April 7, 2008, the parties submitted the preemption issue for disposition based on written submissions, without offering or requesting the presentation of any further evidence.

Based on the parties' submissions and arguments, the court finds that the MINI is governed by the MDA. Consequently, the court concludes that the plaintiffs' product liability and loss of consortium claims are preempted by the MDA and the complaint must be dismissed.

DISCUSSION

The court's consideration of the defendant's motion for summary judgment is governed by

Sections 17- 44 through 17-51 of the Practice Book and rules so well established that they need not be repeated here. See *Connecticut Medical Insurance Co. v. Kulikowski*, 286 Conn. 1, 4 - 5 (2008). The court recognizes that a motion to dismiss, rather than a motion for summary judgment, is the appropriate motion for raising jurisdictional claims. However, when the court's subject matter jurisdiction is implicated, the court is required to address the issue regardless of the factual setting of the implication or the procedural motion through which it is raised. *Evans v. General Motors Corp.*, Superior Court, Complex Litigation Docket, Judicial District of Waterbury, Docket No. 94-0156090 (Sept. 13, 2007, *Stevens, J.*) 44 C.L.R. 216. Thus, the Appellate Court has indicated that a motion for summary judgment contesting subject matter jurisdiction should be treated as a motion to dismiss. See *Lewis v. Chelsea G.C.A. Realty Partnership*, 86 Conn. App. 596, 607, 862 A.2d 368 (2004), cert. denied, 273 Conn. 909, 870 A.2d 1079 (2005) (form of judgment for lack of subject matter jurisdiction raised through summary judgment motion should be judgment of dismissal).

As a general rule, "[f]ederal preemption implicates the court's jurisdiction. The question of preemption is one of federal law, arising under the supremacy clause of the United States constitution. Determining whether Congress has exercised its power to preempt state law is a question of legislative intent. Absent an explicit statement that Congress intends to preempt state law, courts should infer such intent where Congress has legislated comprehensively to occupy an entire field of regulation, leaving no room for the States to supplement federal law or where the state law at issue conflicts with federal law, either because it is impossible to comply with both or because the state law stands as an obstacle to the accomplishment and execution of congressional objectives." (Citations omitted; internal quotation marks omitted.) Id. at 601; accord *Times Mirror*

Co. v. Division of Public Utility Control, 192 Conn. 506, 510-11, 473 A.2d 768 (1984).[2]

Based on the defendant's submissions, the court finds, and the plaintiffs essentially concede, that the MINI underwent the MDA's premarket approval process, and the device was approved by the FDA under the MDA and applicable federal regulations.

The MDA includes an express preemption provision that states:

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

21 U.S.C. 360k. The court finds this language to be clear and unambiguous. The court further finds that the United States Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. __, 128 S. Ct. 999 (2008), is on point and controlling. In *Riegel*, supra, 128 S. Ct. 1011, the Supreme Court held that state product liability laws and common law torts are "different from, or in addition to the requirements imposed by the MDA . . . ." Therefore, such state laws are preempted by the MDA, which subjects medical devices such as the MINI to the premarket review and approval process of that statute.

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[2]In this context, such preemption has been described as ordinary or defensive preemption and has been categorized as express preemption, field preemption or conflict preemption. See *Sullivan v. American Airlines, Inc.*, 424 F.3d 267, 272-73 (2d Cir. 2005). The defendant apparently contends that the express preemption at issue here does not implicate the court's subject matter jurisdiction. This argument is unclear, but in any event is rejected.

The plaintiffs contend that they still may argue under *Riegel* that the defendant failed to follow federal regulations applicable to the MINI approval, but there are no such allegations contained in the plaintiffs' complaint. "[A] plaintiff cannot, under the guise of fortifying the complaint, present an entirely new cause of action or expand the scope of his cause of action [even] by means of a counter-affidavit. . . . The issue must be one which the party opposing the motion is entitled to litigate under his pleadings and the mere existence of a factual dispute apart from the pleadings is not enough to preclude summary judgment." (Internal quotation marks omitted.) *Collum v. Chapin*, 40 Conn. App. 449, 453, 671 A.2d 1329 (1996); accord, *Labow v. Rubin*, 95 Conn. App. 454, 471, 897 A.2d 136 (2006).

Therefore, for the foregoing reasons, the defendant's motion is hereby granted, and the court issues an order dismissing the complaint.[3]

So ordered this 8th day of April, 2008.

STEVENS, J.

[3]Assuming *arguendo* that jurisdiction existed, the court further notes alternatively that the complaint also fails because the plaintiffs' claims require expert testimony, and the plaintiffs provided no such evidence to support their claims. The plaintiffs' expert, Dr. Kluger, testified at his deposition that the MINI experienced a random component failure and not a design or manufacturing defect; as an electrical device, the MINI is subject to being affected by innumerable factors normally occurring in the environment. According to Dr. Kluger, the MINI performed as designed in response to the undetermined complication by reverting to feedback or safety mode.