NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 09-3800

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DIANE M. WILLIAMS; KEITH M. WILLIAMS;
AUDREY KNIGHT, INDIVIDUALLY AND ON BEHALF
OF ALL OTHERS SIMILARLY SITUATED,

Appellants

v.

CYBERONICS, INC.

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On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D. C. No. 2-06-cv-05361)
District Judge: Hon. Anita B. Brody

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Submitted under Third Circuit LAR 34.1(a)
on May 11, 2010

Before: BARRY and ROTH, Circuit Judges
and HAYDEN*, District Judge

(Opinion filed: July 30, 2010)

*Honorable Katharine S. Hayden, United States District Judge for the District of New Jersey, sitting by designation.

O P I N I O N

ROTH, Circuit Judge:

This products liability case involves the malfunctioning of a medical device used to treat depression by electronically stimulating a nerve in the neck. Diane Williams, Keith Williams, and Audrey Knight appeal the District Court's order, granting manufacturer Cyberonics, Inc.'s, motion for summary judgment.[1] We exercise plenary review over a grant of summary judgment and apply the same standard as the District Court, drawing all inferences and viewing the facts in the light most favorable to the nonmoving party. *Horn v. Thoratec Corp.*, 376 F.3d 163, 165-66 (3d Cir. 2004). We assume the parties' familiarity with the factual and procedural history, which we describe only as necessary to explain our decision. We will affirm the District Court's order.

The device at issue here is the Vagus Nerve Stimulation (VNS) Therapy System manufactured by Cyberonics. The VNS Therapy System is a Class III medical device that was given premarket approval (PMA) after a rigorous review by the Food and Drug Administration (FDA), as required by the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (manufacturers of Class III medical devices must submit voluminous material to

[1] The appellants appeal only the District Court's ruling that the *Riegel* decision preempted state-based claims founded on alleged malfunction of Cyberonics' Class III medical device."

the FDA, which the FDA spends over 1,000 hours reviewing in depth and grants PMA only if the device is found to be safe and effective). The MDA contains an express preemption provision providing that "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." 21 U.S.C. § 360k(a). In *Riegel v. Medtronic, Inc.*, the Supreme Court held that state-imposed requirements are preempted by the MDA if (1) the Federal Government has established requirements applicable to the device and (2) the plaintiff's claims are based on state requirements related to safety and effectiveness that are "different from, or in addition to" the federal requirements. 552 U.S. 312, 321-22 (2008). Only the second prong is at issue here.

Appellants' allegations of strict products liability based on manufacturing defect and breach of warranty are pre-empted by the MDA. Generalized common law theories of liability, such as those advanced in appellants' complaint, are precisely the type of claims the MDA sought to preempt. *See id.* at 325 ("tort law, applied by juries under a negligence or strict-liability standard," is pre-empted by the MDA); *Horn*, 376 F.3d at 173 ("[I]t is firmly established that a 'requirement' under § 360k(a) can include legal requirements that arise out of state common-law damages actions."). Success 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. 21 U.S.C. § 360k(a); *see Riegel*, 552 U.S. at 325 (holding that state law that requires a manufacturer's devices "to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme").

Appellants also advance a strict products liability claim for a manufacturing defect based on the malfunction theory, which allows the trier-of-fact to infer a defect from the fact that the device malfunctioned. *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 255 (3d Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010) (stating that the malfunction theory permits a plaintiff to base a products liability claim on "circumstantial evidence of a manufacturing defect."). Although it is alleged that the VNS Therapy System stopped working for the Williamses and malfunctioned for Knight, appellants fail to explain how the device deviated from the FDA requirements. *See Riegel*, 552 U.S. at 330 (holding that strict liability claims under § 360k are not preempted if "premised on a violation of FDA regulations"); *Horn*, 376 F.3d at 179 (rejecting plaintiff's manufacturing defect claim because she did "not assert[] that [defendant] has in any way failed to conform with the FDA requirements prescribed by its PMA – nor that it deviated from, or violated, any of the FDA's federal statutes or regulations"). Rather, appellants seek to ground Cyberonics' liability on requirements that go beyond those established by the MDA. Accordingly, appellants' claims are preempted.

For the foregoing reasons, we will affirm the order of the District Court granting summary judgment in favor of Cyberonics.