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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

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RIEGEL, INDIVIDUALLY AND AS ADMINISTRATOR OF ESTATE OF RIEGEL *v.* MEDTRONIC, INC.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

No. 06–179. Argued December 4, 2007—Decided February 20, 2008

The Medical Device Amendments of 1976 (MDA) created a scheme of federal safety oversight for medical devices while sweeping back state oversight schemes. The statute provides that a State shall not "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 [federal law] 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" relevant federal law. 21 U. S. C. §360k(a). The MDA calls for federal oversight of medical devices that varies with the type of device at issue. The most extensive oversight is reserved for Class III devices that undergo the premarket approval process. These devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness. Manufacturers may not make changes to such devices that would affect safety or effectiveness unless they first seek and obtain permission from the FDA.

Charles Riegel and his wife, petitioner Donna Riegel, brought suit against respondent Medtronic after a Medtronic catheter ruptured in Charles Riegel's coronary artery during heart surgery. The catheter is a Class III device that received FDA premarket approval. The Riegels alleged that the device was designed, labeled, and manufactured in a manner that violated New York common law. The District Court held that the MDA pre-empted the Riegels' claims of strict liability; breach of implied warranty; and negligence in the design,

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testing, inspection, distribution, labeling, marketing, and sale of the catheter, and their claim of negligent manufacturing insofar as the claim was not premised on the theory that Medtronic had violated federal law. The Second Circuit affirmed.

Held: The MDA's pre-emption clause bars common-law claims challenging the safety or effectiveness of a medical device marketed in a form that received premarket approval from the FDA. Pp. 8–17.

(a) The Federal Government has established "requirement[s] applicable . . . to" Medtronic's catheter within §360k(a)(1)'s meaning. In *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 495, 500–501, the Court interpreted the MDA's pre-emption provision in a manner "substantially informed" by an FDA regulation, 21 CFR §808.1(d), which says that state requirements are pre-empted only when the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device" under federal law. Premarket approval imposes "specific requirements applicable to a particular device." The FDA requires that a device that has received premarket approval be marketed without significant deviations from the specifications in the device's approval application, for the reason that the FDA has determined that those specifications provide a reasonable assurance of safety and effectiveness. Pp. 8–10.

(b) Petitioner's common-law claims are pre-empted because they are based upon New York "requirement[s]" with respect to Medtronic's catheter that are "different from, or in addition to" the federal ones, and that relate to safety and effectiveness, §360k(a). Pp. 10–17.

(i) Common-law negligence and strict-liability claims impose "requirement[s]" under the ordinary meaning of that term, see, *e.g., Lohr, supra,* at 503–505, 512, *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504, 521–523, 548–549. There is nothing in the MDA that contradicts this normal meaning. Pp. 10–12.

(ii) The Court rejects petitioner's contention that the duties underlying her state-law tort claims are not pre-empted because general common-law duties are not requirements maintained "with respect to devices." Petitioner's suit depends upon New York's "continu[ing] in effect" general tort duties "with respect to" Medtronic's catheter. Title 21 CFR §808.1(d)(1)—which states that MDA pre-emption does not extend to "[s]tate or local requirements of general applicability [whose] purpose . . . relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices"—does not alter the Court's interpretation. Pp. 14–17.

(c) The Court declines to address in the first instance petitioner's argument that this lawsuit raises "parallel" claims that are not pre-empted by §360k under *Lohr, supra,* at 495, 513. P. 17.

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451 F. 3d 104, affirmed.

SCALIA, J., delivered the opinion of the Court, in which ROBERTS, C. J., and KENNEDY, SOUTER, THOMAS, BREYER, and ALITO, JJ., joined, and in which STEVENS, J., joined except for Parts III–A and III–B. STEVENS, J., filed an opinion concurring in part and concurring in the judgment. GINSBURG, J., filed a dissenting opinion.