IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

No. 99-41089

BILLYE JEANNE MARTIN,

Plaintiff-Appellant,

versus

MEDTRONIC, INC.,

Defendant-Appellee.

No. 99-41090

LIBRA SALAZAR,

Plaintiff-Appellant,

versus

MEDTRONIC, INC.,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Texas

June 18, 2001

Before REYNALDO G. GARZA, JOLLY, and HIGGINBOTHAM, Circuit Judges.

E. GRADY JOLLY, Circuit Judge:

In this consolidated appeal,[1] we address a question of federal preemption: whether, based on Medtronic's compliance with the Food and Drug Administration's ("FDA") rigorous premarket approval procedure ("PMA"), the plaintiffs' Texas common law products liability tort claims are preempted by 21 U.S.C. § 360k, the Medical Devices Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). We have addressed this issue before. In Stamps v. Collagen Corp., 984 F.2d 1416, 1422 (5th Cir. 1993), we held that similar state product liability claims were preempted. Since we decided Stamps, however, the Supreme Court has spoken on the issue. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 477, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). The Supreme Court did not specifically decide the case before us, yet spoke in a way that overruled Stamps in part. Lohr is a difficult opinion to apply in this case; first, because it involves a process far less specific in its requirements than the PMA process involved in both this case and Stamps, and second, because on points important to this appeal, the Lohr court was fractured. In any event, we ultimately determine that for purposes of deciding this appeal, Stamps is binding precedent that controls the outcome of the case. Accordingly, we hold that the

[1]The cases have been consolidated for the purposes of appeal only. The appellants, however, brief their appeal as if the district court considered their cases on a consolidated basis. Therefore, we treat the procedural history in the same manner.

Texas state product liability claims in this case are preempted by the MDA, and we affirm the judgment of the district court dismissing the complaint.

I

Billye Jeanne Martin and Libra Salazar each claim that they were injured by Medtronic's defective pacemaker (Model 4004). They allege that the pacemaker contained a defective "ventricular lead," the wire that carries current into the heart muscle. Their product liability claims include negligence, gross negligence, strict liability, breach of warranty, and violation of the Texas Deceptive Trade Practices Act; all claims are based on alleged deficiencies in the safety and effectiveness of the design, manufacturing process, warnings, and labeling of the lead.

The district court initially granted Medtronic's motion for summary judgment only in part, finding that the MDA preempted Salazar's and Martin's design, manufacturing process, and warning claims. The district court reasoned that in all these areas, the FDA, through its PMA procedure,[2] had approved Medtronic's product. The district court, however, denied summary judgment on the

[2] Under the FDA's PMA process, the manufacturer of the medical device must submit a detailed application to the FDA, including information on product specifications, manufacturing, intended use and proposed labeling. Qualified experts review each application and prepare a report and recommendation. The FDA then has six months to accept or reject the application. See 21 U.S.C. § 360e; Stamps v. Collagen Corp., 984 F.2d 1416, 1419 (5th Cir. 1993).

plaintiffs' claims that Medtronic had deviated from FDA requirements. Following further discovery, Medtronic renewed its summary judgment motion. The district court then granted the renewed motion, finding that appellants failed to produce evidence of alleged deviations, and entered judgment dismissing each complaint. These appeals, now consolidated, present the single issue of whether the FDA's PMA procedure preempts the state law tort claims.

II

We begin our consideration of this question of preemption by making a few preliminary observations that serve to place in context the even more precise issue before us--to what extent is our case today decided by precedents of this court and the Supreme Court. The MDA classifies medical devices into three categories based on the degree of risk they pose to the public. Class I devices pose little or no risk to public health and are subject only to general controls on manufacturing. Class II devices are potentially more harmful and may be subject to regulations and product specifications. Class III devices, the most strictly regulated, are "[d]evices that either 'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing

impairment of human health.'" Lohr, 518 U.S. at 477 (quoting 21 U.S.C. § 360c(a)(1)(C)).

A pacemaker is classified as a "Class III" medical device. As such, it must undergo an indisputably thorough, rigorous, and costly premarket review (some 1,200 FDA man-hours at hundreds of thousands of dollars in cost) by the FDA. Under this PMA process, the manufacturer must give the FDA a "reasonable assurance" that the product is safe and effective. Although this term does not sound excessively demanding, the PMA process is rigorous. It requires manufacturers to submit detailed information regarding the safety and efficacy of their devices. This includes, among other things, full reports of all information that is known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for manufacturing and installation of the device. See 21 U.S.C. § 360e(c)(1) (describing the components of a PMA application). The FDA then reviews the application, spending an average of 1,200 hours on each submission before granting marketing approval. The statutory basis for this process, and its exceptions, are set forth at length in Lohr, 518 U.S. at 477, and need not be reiterated here.

It is central to our resolution of this appeal that we have held that § 360k preempts these state products liability claims

when the device manufacturer complies with the FDA's PMA process. See Stamps, 984 F.2d at 1422. In this appeal, it is not disputed that Medtronic has complied with the FDA's PMA process in the creation of its pacemakers. Thus, based on the holding of Stamps, the claims here should be preempted.

But yet there is a twist. After Stamps, the Supreme Court considered the scope of MDA preemption of state law claims in the "§ 510(k) notification" process,[3] an exception to the far more demanding PMA review process. See Lohr, 518 U.S. 470. The § 510(k) process allows improvements to existing devices to be rapidly introduced into the market by foregoing the extensive review in the PMA process. Id. at 478. While the PMA process requires an inquiry into the risks and efficacy of each device through a variety of reports and submissions, as described above, the § 501(k) process only requires the manufacturer to show that the device is "substantially equivalent" to devices already on the market. Under the § 501(k) process, the manufacturer must submit proposed labeling, labels, and advertisements that describe the device, its intended use and the directions for its use; a statement indicating how the device is similar to or different from comparable products; a statement that the submitter believes that

[3]The section number refers to the original section of the MDA containing the provision.

the information is accurate and complete; and any additional information necessary for the FDA Commissioner to make a determination as to whether the device is "substantially equivalent." See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S.Ct. 1012, 1016, 148 L.Ed.2d 854 (2001); 21 C.F.R. §§ 807.87, 807.92. The manufacturer does not have to submit information on the safety or efficacy of the device. In contrast to the 1,200 hours that it takes to complete a PMA review, a § 510(k) review takes an average of 20 hours. Lohr, 518 U.S. at 479. As the Supreme Court has noted, "[t]he § 510(k) notification process is by no means comparable to the PMA process." Id. at 478-79.

Lohr, however, is highly relevant to this appeal because it considered in some detail the preemption statute that is applicable both to the § 510(k) process and the PMA process. Notwithstanding its relevance, the Supreme Court decision must be more than merely illuminating with respect to the case before us, because a panel of this court can only overrule a prior panel decision if "such overruling is unequivocally directed by controlling Supreme Court precedent." United States v. Zuniga-Salinas, 945 F.2d 1302, 1306 (5th Cir. 1991). This means that Stamps should apply to this case unless "an intervening Supreme Court case explicitly or implicitly overrul[es] that prior precedent." United States v. Short, 181

F.3d 620, 624 (5th Cir. 1999). Thus, the first, and ultimately only, question we face is the degree to which Stamps retains precedential value after the Supreme Court's decision in Lohr.

A

To resolve the impact of Lohr on our precedent in Stamps, we begin by setting out the relevant statutory and regulatory language that we must consider. Section 360k(a) ("General Rule") is the preemption provision of the MDA governing the extent to which the MDA preempts state law. It applies both to situations arising under the § 510(k) process and the PMA process. It states:

> [N]o 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(a). The FDA has promulgated regulations interpreting § 360k, which state:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d).

B

With both the statute and the regulations in mind, we turn to consider the intervening Supreme Court decision, Medtronic Inc. v. Lohr, 518 U.S. 470. In Lohr, the Supreme Court considered whether state tort claims were preempted when the FDA subjected the medical device to § 510(k) notification under the MDA, a process, as we have noted, far less thorough than the PMA process presented in this case.[4] In a five to four decision, the Court held that the state tort claims in that § 510(k) case were not preempted. The Court, however, fractured over the question of whether the preemption section of the MDA would ever preempt general state law tort claims.

The facts underlying the plaintiffs' claims in Lohr are similar to the facts in our case: Lohr and her husband sued on state law claims over a defective lead in a pacemaker. Their complaint alleged both negligence and strict liability claims for defective design, failure to warn, and negligent manufacturing. Unlike our case, however, which involves a rigorous review under

[4]As the Supreme Court itself has observed, the PMA process and the § 510(k) process are clearly distinguishable. See Lohr, 518 U.S. at 493 (noting that substantially equivalent devices have "never been formally reviewed under the MDA for safety or efficacy" and that the FDA does not consider the § 510(k) process "official FDA approval"); Buckman, 121 S.Ct. at 1017 ("Admittedly, the § 510(k) process lacks the PMA review's rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device.").

the PMA process, Medtronic began marketing the pacemaker lead in Lohr after the FDA had found only that the device was "substantially equivalent" to devices already on the market under § 510(k). Indeed, the FDA itself "emphasized . . . that [the § 510(k) notification process] should not be construed as an endorsement of the pacemaker lead's safety." Lohr, 518 U.S. at 480.

The Court's reasoning largely focused on the requirements of the FDA's regulation interpreting § 360k, cited and quoted earlier in this opinion. The Court observed that certain factors must be present, according to the regulations, before § 360k would preempt state requirements. First, there must be a state requirement specifically developed with respect to medical devices that is different from or in addition to federal requirements. Second, the state requirement must relate to the safety or effectiveness of the device, or "'other matter included in a requirement applicable to the device.'" Lohr, 518 U.S. at 500 (quoting 21 U.S.C. § 360k(a)). State requirements of "'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement for a specific device.'" Id. Third, the federal requirement must be specific to the particular device. The Court held that because neither the federal requirements relating to the § 510(k) notification procedure nor the state common law

requirements were specific to the device, Lohr's tort claims were not preempted.

Although the Court concluded that Lohr's tort claims were not preempted, the majority split on the broader question of whether the duties enforced by common law actions could ever be "requirements" for the purpose of preemption. The four justice plurality written by Justice Stevens, distinguishing the MDA from the statute in Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), found that general common law actions were not the "requirements" that Congress was concerned about when it enacted the preemption provision. Thus, Justice Stevens concluded that "§ 360k(a) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." Lohr, 518 U.S. at 491. That, however, was only a plurality.

The meaning of Lohr as applied to our case becomes confusing at this point. Concurring with only parts of the majority writing, Justice Breyer found that the MDA could in fact preempt state tort suits. Relying on Cipollone, in which the "Court made clear that similar language 'easily' encompassed tort actions," he reasoned that a state requirement that takes the form of a duty of care is essentially no different from a state statute or regulation. Id. at 504 (Breyer, J., concurring). Justice Breyer noted, however,

that the FDA promulgated a regulation that allows preemption when there are "'specific [federal] requirements applicable to a particular device.'" Id. at 506 (quoting 21 C.F.R. § 808.1(d) (1995)). Because the FDA requirements relating to design, manufacturing and labeling in the § 510(k) notification process at issue in Lohr were "not 'specific' in any relevant sense," Justice Breyer concluded that the FDA did not intend the § 510(k) notification procedures to preempt state tort claims. Id. at 507.

The four justices concurring in part and dissenting in part, relying on the § 360k preemption language and not the FDA's regulations, concluded that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." Id. at 509 (O'Connor, J., concurring in part, dissenting in part). Justice O'Connor noted that a majority of the Court in Cipollone agreed that state common law damages actions do impose "requirements," and that the rationale behind that decision was equally applicable in Lohr. Id. at 510. Thus, given Justice Breyer's concurrence, five justices would agree that state common law actions do impose "requirements" that can be preempted under the statute, as found in Cipollone.

Because only parts of Justice Stevens's opinion commanded a majority, extracting the final meaning of Lohr is no easy task.

Assessing Lohr in the light of the three requirements for preemption described above, the Court first held that general common law duties do not impose requirements that are different from or in addition to the § 501(k) process. The Court offers no clear guidance on when the common law may satisfy the second factor, that is, that the state requirement relate to the safety or effectiveness of the device or establish a "substantive requirement" for a specific device. Although Justice Breyer's concurrence very specifically disavows the view that common law duties cannot provide substantive requirements for the purpose of preemption, neither his concurrence nor the plurality opinion offers much help to us in developing the point. As to the third factor, the Court held that the FDA's "substantially equivalent" determination under the § 501(k) process is not a federal regulation specific to a particular device, at least under the facts of Lohr. Because these holdings do not explicitly or implicitly decide the case before us, we must compare Lohr with Stamps, the circuit precedent that we are required to follow.

C

Our decision in Stamps, 984 F.2d 1416, which relies on Cipollone and predates Lohr, held that state tort claims in that case were preempted under the MDA. In Stamps, the plaintiff contracted a rare autoimmune disease from being injected with

defendant's Class III products. She then filed suit alleging defective design, inadequate warnings, and negligent failure to warn. Because the FDA scrutinized the labeling, design, and manufacturing of a product during the PMA process, we determined that each of these state claims covered an area stringently regulated by the FDA.

We then addressed the question of whether state tort claims could be considered state "requirements" under § 360k. Relying on the Supreme Court's preemption doctrine as laid out in Cipollone, 505 U.S. 504, we noted that the term "requirements" in § 360k(a) "'sweeps broadly' and encompasses common law tort actions within its preemptive scope." Stamps, 984 F.2d at 1421. Thus, the specific duties in Texas tort liability create requirements in addition to the strict requirements of the Class III PMA process. Stamps concluded that "[s]tate tort causes of action–-to the extent they relate to safety, effectiveness, or other MDA requirements--constitute requirements 'different from, or in addition to' the Class III process; they are, therefore, preempted." Stamps, 984 F.2d at 1424.

III

When we turn to consider the impact of Lohr on the precedential effect of Stamps, we can immediately conclude that the

Supreme Court did not explicitly overrule the case. Neither do we think that Lohr implicitly requires us to disregard Stamps as controlling precedent.[5] Although Stamps gave § 360k a somewhat broader preemptive scope than the Supreme Court's opinion in Lohr,[6] none of the components of the preemption test in Lohr contradict the holding in Stamps as applied here. As noted above, the Supreme Court held that for preemption under § 360k, there must be a state requirement--which does not exclude common law tort duties--with

[5] In fact, after Lohr, both the Sixth and the Seventh Circuits determined that the PMA process constitutes specific federal requirements that preempt state tort suits. Kemp v. Medtronic, 231 F.3d 216, 226-227 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902, 913 (7th Cir. 1997). These decision parallel our reasoning in Stamps. Although not all courts have found that common law tort suits relating to the device are preempted by the PMA process, see Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999) (finding that plaintiffs' state law tort claims were not preempted by Medtronic's compliance with the FDA's PMA process), Brooks v. Howmedica, Inc., 236 F.3d 956 (8th Cir. 2001) (finding that the PMA process constitutes specific federal requirements and common law tort suits can constitute specific state requirements but finding no conflict between them), vacated and reh'g en banc granted by 246 F.3d 1149 (8th Cir. 2001), our question is not whether the panel in Stamps correctly decided the case, but whether the Supreme Court overruled Stamps. As long as Stamps is not inconsistent with the law set out in Lohr, this panel has no authority to overrule it.

[6] For instance, Stamps notes that "section 360(k). . . 'sweeps broadly' and encompasses common law tort actions within its preemptive scope." Stamps, 984 F.2d at 1421. In contrast, Lohr remarks on the FDA's "narrow understanding" of § 360k and finds that "it is impossible to ignore [the statutory and regulatory language's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." Lohr, 518 U.S. at 500, n. 18.

respect to a medical device that relates to the safety or efficiency of a device, or establishes a substantive requirement for the device, that is different from or in addition to a specific federal requirement. Lohr, 518 U.S. at 500. Stamps is not contrary to these criteria.

A

First, Stamps found that common law tort suits can impose state requirements for the purposes of preemption. Stamps, 984 F.2d at 1423. Although not part of the holding of Lohr, a majority of the justices in Lohr clearly agreed with this proposition. See 518 U.S. at 509 ("I conclude that state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA")(O'Connor, J., dissenting). Id. at 503 ("[T]he MDA will sometimes pre-empt a state-law tort suit.")(Breyer, J., concurring). Thus, it seems clear that Lohr did not overrule our holding in Stamps that state tort suits can constitute specific state requirements for the purposes of preemption.

B

Second, Stamps found that common law duties could be preempted "to the extent that they relate[d] to safety, effectiveness, or other MDA requirements." Stamps, 984 F.2d at 1423. With some similarity, Lohr observed that state requirements must, "with

respect to" medical devices, establish a "substantive requirement for a specific device," and must relate to the "safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Lohr, 518 U.S. at 500. The Lohr majority opinion did not articulate when common law requirements may become "substantive requirements" or under what circumstances they are considered to be "specifically developed 'with respect to' medical devices." Id. at 501. To determine whether Stamps's understanding of common law duties as state requirements is consistent with Lohr, we must therefore consider Justice Stevens's opinion in the light of Justice Breyer's concurrence.

Justice Breyer joined in the majority's finding that "general state common-law requirements in this suit were not specifically developed 'with respect to' medical devices," and that "these state requirements escape preemption . . . because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." Lohr, 518 U.S. at 501. Justice Breyer's separate concurrence, however, which recognizes that common law tort suits may be preempted, does not support a conclusion that common law claims are invariably too general for preemption. Indeed, Justice Breyer noted that he "basically agree[d] with Justice O'Connor's

discussion" of whether the MDA can preempt a state law tort suit Id. at 503, which observed that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." Id. at 509. Furthermore, Justice Breyer specifically disavowed the portions of the opinion finding that "[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device,'" Id. at 502 (plurality) (citing CFR § 808.1(d)(6)(ii)(1995)), and that the term "'[r]equirement appears to presume that the State is imposing a specific duty on the manufacturer." Id. at 487. As noted by the Ninth Circuit, these apparently conflicting positions make analysis difficult:

> [I]t makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law "requirements" which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements.

Papike v. Tambrands Inc., 107 F.3d 737, 742 (9th Cir. 1997).

Of course, we are plainly bound to follow the majority opinion in Lohr; yet, we cannot fully grasp the opinion's interpretation of when state common law requirements are considered "specifically developed with respect to medical devices" without Justice Breyer's concurrence. The majority opinion says that general common law

obligations are not a threat to federal requirements. Id. at 501. Justice Breyer joins in the opinion, but, in his concurrence, he points out that these general common law requirements are not a threat because there is no potential for them to conflict with the federal requirements at issue in Lohr, namely, the requirements under the § 501(k) process. He also notes that while common law duties may seem general, they can result in the imposition of standards that are very device-specific. Justice Breyer takes the position that there is no preemption in Lohr because there is no conflict between the § 501(k) process and general common law duties. See Lohr, 518 U.S. at 508 (Breyer, J., concurring)("I can find no actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state-law tort suit"). Justice Breyer's emphasis on the juxtaposition of the state and federal duties suggests that the Court would be less sanguine about the generality of common law duties if the federal requirements were specific, say, as in the PMA process.[7]

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[7]Justice Breyer even notes that "it is possible that the plurality also agrees" that

> insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.

Lohr, 518 U.S. at 504-05 (Breyer, J. concurring). This observation suggests that it was important to Lohr's conclusion that both state and federal requirements were general.

We think it is important to read the portion of the majority opinion addressing specific state requirements narrowly to avoid adopting as controlling law the broadly worded plurality opinion. Using Justice Breyer's concurrence as a guide, we can conclude only that general duties of care can generate specific requirements that conflict with specific FDA requirements. We read Justice Breyer's special concurrence to recognize that, although a manufacturer's general duty of care to avoid foreseeable dangers may be too general to merit preemption when there is no specific federal requirement, the proof required to establish a particularly alleged common law claim can be specific enough that the claim becomes preempted as an "additional" or "different" requirement than the FDA requirement.[8] This reasoning is consistent with the majority opinion; while the general duty, standing on its own, is not a threat to federal requirements and is not developed specifically "with respect to" medical devices, the elements needed to prove a violation of that general duty may be very specifically tailored to the device, and the state court action may therefore threaten specific federal requirements. Because the federal § 510(k)

[8]However, common law duties that incorporate the PMA process, such as the general duty to take due care to comply with the PMA process in labeling or manufacturing, will never contain specific requirements that are additional to or different from federal requirements. Therefore, claims based on those duties are not preempted. See Lohr, 518 U.S. at 495.

requirements were not specific, it was unnecessary in Lohr to reach that conflict. For instance, as an example of a general common law duty, the majority opinion uses a "general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use." Id. at 501. While this duty does not seem "developed with respect to" a medical device specifically, proving a violation of that duty would require a jury to determine precisely what information users should have been provided. Those determinations would not conflict with the § 510(k) process, because that process does not determine or approve what information consumers of the product should be provided. On the other hand, however, a jury's determination may directly conflict with FDA determinations and approvals made during the PMA review process.

Thus, reading the language in the majority opinion through the lens of Justice Breyer's concurrence, we cannot say that Lohr overruled the holding of Stamps that common law tort claims challenging the safety or effectiveness of a device create specific requirements under state law. After Lohr, however, we need to consider more than whether the common law duties relate to safety, effectiveness, or other MDA requirements; we need to focus on whether the specific requirements imposed by those common law duties threaten to interfere with specific federal requirements.

C

Third, Stamps interpreted state tort causes of action as requirements "different from, or in addition to" the PMA process, thereby meriting preemption. Stamps, 984 F.2d at 1423. This holding reflects a comparison of state and federal requirements and a consideration of how additional state common law requirements could undermine the FDA's detailed PMA review process. On the other hand, Lohr compared common law duties with the § 510(k) process, which imposes relatively minor disclosure requirements, and found that preemption was not appropriate. Given the difference between the intensive PMA review and the minimal requirements under the § 510(k) process, Lohr does not call into question the holding of Stamps, that common law duties can impose requirements different from or in addition to the PMA process.

Stamps, however, specifically disagreed with the proposition that "the lack of direct conflict between the state and federal regulations compel[led] a finding of no preemption." Id. at 1424. On the other hand, this proposition seems to have been adopted by the Supreme Court; Lohr notes that "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Lohr, 518 U.S. at 495. This language tells us that tort suits based on a manufacturer's failure to follow the FDA's regulations and procedures are not preempted. Indeed, that is

precisely what the district court held in this case, and that holding has not been appealed. In the context of the PMA process, we agree that state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted. Thus, Lohr narrows the language in Stamps's preemption analysis to allow for state actions that parallel federal requirements. This holding of Lohr, although overruling Stamps in that specific matter, does not, however, overrule Stamps as it applies to the case before us.

D

Fourth, Stamps held that the PMA process imposed specific federal requirements as to labeling, manufacturing, and design for the purposes of preemption.[9] Here, too, there is no conflict with Lohr. Although Lohr considered the application of the identical FDA regulation governing labeling, the labeling requirements in Lohr under the § 510(k) process were general; as it did not go through the PMA process, the labeling in Lohr was not specifically reviewed by the FDA.

[9]During the PMA process, the FDA reviews the proposed labeling as well as the ingredients, components, methods, controls, and facilities used in the manufacture and processing of the device. 21 U.S.C. § 360e(c)(1)(B)-(C),(F). If any element of the manufacturing does not comply with regulations, or labeling is found to be false or misleading, the application for approval is denied. Id. § 360e(d)(2)(A)-(D).

On its face, therefore, Lohr is limited to a finding that the § 501(k) process does not create specific federal requirements that conflict with state tort actions. Indeed, the plurality's opinion itself seems to leave this suggestion when it notes at several points in the course of its writing the very significant differences between the FDA's § 510(k) approval and a PMA approval. See, e.g., 518 U.S. at 492-94 (noting that the § 510(k) process "is focused on equivalence, not safety. As a result, substantial equivalence determinations provide little protection to the public") (internal quotations and citations omitted).[10] The PMA is specifically focused on safety and requires a significant weighing of considerations specific to the device before approval is granted. Thus, the fact that the § 510(k) process did not preempt state causes of action in Lohr does not indicate that the PMA process cannot preempt state tort causes of action.

Thus, for all these reasons, we are fully convinced that Stamps has not been overruled and remains viable authority in this circuit to the extent that we have described. Instead of overruling Stamps, Lohr should be read to implicitly affirm our holding in Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995), in which we reached the same conclusion as did the Court in Lohr, that

[10] See also id. at 480 ("The agency emphasized, however, that this determination [of substantial equivalence] should not be construed as an endorsement of the pacemaker lead's safety.").

the § 510(k) process did not create preemptive "requirements." 518 U.S. at 484 n.6.[11] We think that our separate preemption treatment of the differing processes to device approval is further reflection and acknowledgment of the fact that the PMA process is of an order that is a magnitude apart from § 510(k) approval.

In sum, we simply cannot read Lohr as establishing a new rule of law that contradicts our preexisting case law as it applies in this appeal. Thus, although the broad holding of Stamps that the PMA process preempts state tort causes of action to the extent that they relate to safety, effectiveness or other MDA requirements is narrowed by Lohr's finding that preemption requires substantive requirements imposed by common law duties to threaten federal requirements, Stamps remains controlling precedent for the purpose of this appeal.

IV

We turn now to apply Stamps, as narrowed by Lohr, to the case before us. The plaintiffs allege that Medtronic breached state law duties by designing a pacemaker lead that contained certain materials, by labeling the lead with certain warnings, and by manufacturing the lead in a certain way. The design of the lead,

[11]Our decision in Feldt explicitly discusses our decision in Stamps, 61 F.3d at 435, but, after analyzing the § 510(k) process, states, "there are, in short, no requirements or prohibitions specifically regarding the design of non-PMA Class III devices." Id. at 438.

the labeling on the lead, and the manner of manufacturing of the lead were all submitted to the FDA in great detail and approved by the FDA in the PMA process. Like the inadequate labeling, failure to warn, and defective design claims in Stamps, the plaintiffs' claims that the district court found to be preempted relate to areas specifically covered in the PMA process, and seek to impose requirements that are different from and, indeed, conflict with the PMA process.

The district court specifically found those claims that paralleled the federal process--the claims that Medtronic did not adequately comply with the PMA process--were not preempted under § 360k. This finding comports with Lohr, that general duties of care that parallel federal requirements are not "different from, or in addition to" federal requirements, and are therefore not preempted.

In Stamps, our circuit spoke to the precise question presented in this appeal. And we have concluded here that the Supreme Court's fractured ruling in Lohr does nothing to upset Stamps's binding authority as respects this particular appeal. We therefore reaffirm that a medical device manufacturer's compliance with the FDA's PMA process will preempt state tort law claims brought with respect to that approved device and relating to safety,

effectiveness or other MDA requirements when the substantive requirements imposed by those claims potentially conflict with PMA approval. Thus, the plaintiffs' tort law claims relating to design, manufacturing process, and failure to warn are preempted by the MDA.

V

For the reasons stated above, the judgment of the district court is

A F F I R M E D.