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Be Careful What You Ask For: The FDA's Denials of Citizen Petitions Confirms There Is No Such Thing as a Limited Premarket Approval

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BE CAREFUL WHAT YOU ASK FOR: THE FDA'S DENIALS OF CITIZEN PETITIONS CONFIRMS THERE IS NO SUCH THING AS A LIMITED PREMARKET APPROVAL

David T. Schultz† and D. Scott Aberson††

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I. INTRODUCTION

A Class III medical device, by definition, “support[s] or sustain[s] human life” or “presents a potential unreasonable risk of illness or injury.”¹ As a result, the decision to authorize the sale of Class III devices through the premarket approval process requires a

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difficult and time-consuming cost-benefit analysis—i.e., “weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”

Congress placed exclusive responsibility for conducting this cost-benefit analysis of medical devices in the hands of the Food and Drug Administration (“FDA”). If the FDA determines the benefits of the device outweigh its risks, the device is deemed to be safe and effective. To ensure manufacturers are not subjected to a standard of care inconsistent with, or additional to, those imposed by the FDA, Congress explicitly preempted any conflicting or additional state requirements related to the safety and effectiveness of a device.

In *Riegel v. Medtronic, Inc.*, the United States Supreme Court clarified that, for devices receiving premarket approval, state common-law claims or causes of action, such as negligence and strict liability, impose “addition[al]” requirements related to the “safety or effectiveness of the device” and are therefore expressly preempted by § 360k(a). In the years since *Riegel* was decided, courts across the country have broadly enforced this statutory prohibition and dismissed all manner of claims that seek to impose requirements that are “different from, or in addition to” the standards imposed by the FDA. In an attempt to survive preemption, plaintiffs in some medical device cases have attempted to separate out the allegedly defective aspect or component parts of a premarket approved medical device, arguing the FDA somehow limited its premarket approval to only certain aspects or components of a particular medical device or system. Several courts have now addressed the issue, appropriately rejecting this argument and concluding that premarket approval applies to the entire device or system. Not to be deterred, plaintiffs in medical device cases have filed citizen petitions with the FDA, requesting that the FDA “clarify” its approval letters to limit the scope of the premarket approval (“PMA”) to only certain components of the medical devices. The FDA’s denials of these requests to amend its approval letters coupled with its assurances it had indeed approved

the entire system demonstrates that, consistent with judicial precedent, there is simply no such thing as a limited PMA.

This article begins by discussing the statutory and regulatory background related to the regulation of medical devices. Next, it addresses the approval processes for Class III medical devices. Part IV of this article provides a brief history of preemption under the Medical Device Act. Part V of this article examines recent court decisions holding that premarket approval of medical devices applies to all aspects and components of the medical device system—i.e., that attempting to separate the component parts of a medical device system for purposes of preemption is not appropriate. Finally, this article discusses the FDA’s recent denials of plaintiffs’ citizen petitions in medical device cases as evidence that the FDA intends premarket approval to apply to an entire medical device.

II. STATUTORY AND REGULATORY BACKGROUND

The Federal Food, Drug, and Cosmetic Act (“FDCA”) has long required the FDA to approve the introduction of new drugs into the market. But unlike the situation with new drugs, for many years the FDA generally lacked authority to regulate the introduction of new medical devices; instead, “the introduction of new medical devices was left largely for the States to supervise as they saw fit.” That all changed when Congress enacted the
Medical Device Amendments of 1976\(^{15}\) ("MDA"), "which swept back some state obligations" and expanded the FDA’s authority to regulate medical devices.\(^{16}\)

The MDA established three regulatory classes of medical devices, with varying levels of oversight depending on the risks the devices in each class present\(^{17}\) and the "level of control necessary to assure the safety and effectiveness of the device[s]."\(^{18}\) Class I medical devices pose the lowest risk and are therefore subject to the lowest level of government oversight: "general controls," such as labeling requirements and generally applicable design and manufacturing standards.\(^{19}\) Class II medical devices are devices that cannot be classified as Class I devices because the "general controls" applicable to all devices "are insufficient to provide [a] reasonable assurance of the safety and effectiveness of the device."\(^{20}\) Thus, while Class II devices may be marketed without advance approval,\(^{21}\) these devices are subject to "special controls," such as performance standards, postmarket surveillance measures, and development and dissemination of guidelines.\(^{22}\) Class III devices

\(\text{Medical devices when the Medical Device Amendments of 1976 was enacted).}\)

16. Riegel, 552 U.S. at 316. The FDA’s expanded authority as it relates to medical devices was due, in part, to advances in medical technologies and consumer and regulatory concerns over injuries that resulted from such devices:

As technologies advanced and medicine relied to an increasing degree on a vast array of medical equipment “[f]rom bedpans to brainscans,” including kidney dialysis units, artificial heart valves, and heart pacemakers, policymakers and the public became concerned about the increasingly severe injuries that resulted from the failure of such devices.

Lohr, 518 U.S. at 475–76 (citations omitted) (quoting SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE H. COMM. ON ENERGY AND COMMERCE, 98TH CONG., MEDICAL DEVICE REGULATION: THE FDA’S NEGLECTED CHILD 1 (Comm. Print 1983)).

17. 21 U.S.C. § 360c (2006); Riegel, 552 U.S. at 316; see also Classify Your Medical Device, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm (last updated Dec. 3, 2012) ("[C]lassification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned.").

18. Classify Your Medical Device, supra note 17 (stating that medical devices are assigned to one of three classes “based on the level of control necessary to assure the safety and effectiveness of the device”); see also 21 U.S.C. § 360c. According to the FDA’s website, it has established classifications for approximately 1700 different generic types of devices. Classify Your Medical Device, supra note 17.

19. 21 U.S.C. § 360c(a)(1)(A)(i); Riegel, 552 U.S. at 316; Classify Your Medical Device, supra note 17.
have the greatest risk and receive the most federal oversight. In general, a medical device is assigned to Class III if neither general nor special controls would provide a “reasonable assurance of its safety and effectiveness,” and the device “is 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” or “presents a potential unreasonable risk of illness or injury.”

III. CLASS III MEDICAL DEVICE APPROVAL

Class III medical devices “incur the FDA’s strictest regulation” and must receive FDA approval before they may be sold. The FDA has two different processes by which it approves new Class III medical devices. Most devices are approved based on applications urging “substantial equivalence” to pre-existing medical devices, commonly known as the § 510(k) process. Alternatively, medical devices may be approved through the FDA’s premarket approval process, a rigorous process that requires a manufacturer to submit what is typically a multivolume application. Specifically, the

23. Riegel, 552 U.S. at 317; Classify Your Medical Device, supra note 17.
26. Pre-existing medical devices are those that were already on the market when the 1976 Medical Device Amendments were enacted.
27. 21 U.S.C. § 360c(f)(1)(A); Riegel, 552 U.S. at 317. The § 510(k) process “imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a ‘premarket notification’ to the FDA.” Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996). If the FDA concludes the medical “device is ‘substantially equivalent’ to a pre-existing device, it can be marketed without further regulatory analysis.” Id. The § 510(k) process stems from Congress’ concerns about both preventing manufacturers of grandfathered medical devices—i.e., pre-1976 devices that were allowed to remain on the market without FDA approval due to concerns about the impact of withdrawing those devices from the market while the FDA completed premarket approval—from monopolizing the market while new devices await premarket approval, and ensuring that improvements to existing devices can be rapidly introduced into the market. Id. at 477–78.
29. See id.; see also Premarket Approval, supra note 25 (“PMA is the most stringent type of device marketing application required by FDA. The applicant
application for premarket approval must contain, among other things, “full reports of all information” concerning investigations of the device’s safety and effectiveness that have been “published or [are] known to or which 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 “specimens of the labeling proposed to be used for such device.”

The FDA spends several hundred hours reviewing each PMA application, “weig[hing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.” If the FDA is not satisfied with the information provided, it may request additional relevant data from the manufacturer. It also may refer the application to a panel of outside experts. The FDA’s review also includes an evaluation of the device’s proposed labeling for purposes of evaluating the device’s safety and effectiveness under the conditions of use set forth on the label, as well as a determination that the device’s proposed labeling is neither false nor misleading.

After completing its review, the FDA must issue an order either granting or denying premarket approval. The FDA “grants premarket approval only if it finds there is a ‘reasonable assurance’ of the device’s ‘safety and effectiveness.’” In addition, the FDA

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30. 21 U.S.C. § 360e(c)(1).
31. Riegel, 552 U.S. at 318 (“The FDA spends an average of 1,200 hours reviewing each application.”). By contrast, the § 510(k) review is, on average, completed in just 20 hours. Lohr, 518 U.S. at 479.
32. Riegel, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). It is because of this balancing test that the FDA may “approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives.” Id.
33. Id. (citing 21 U.S.C. § 360e(c)(1)(G)).
34. Id. (citing 21 C.F.R. § 814.44(a) (2007)).
35. Id. (citing 21 U.S.C. § 360c(a)(2)(B)).
36. Id. (citing 21 U.S.C. § 360e(d)(1)(A)).
37. 21 U.S.C. § 360c(d)(1)(A)(i)–(ii). Although FDA regulations provide that the FDA’s order must be issued within 180 days after the FDA’s receipt of a premarket approval application, the FDA’s review time is typically longer. Id.; Premarket Approval, supra note 25.
38. Riegel, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(d)). If the FDA determines it cannot approve the medical device’s design, manufacturing
may “condition approval on adherence to performance standards,” 39 “restrictions upon sale or distribution, or compliance with other requirements.” 40 It may also “impose device-specific restrictions by regulation.” 41

The FDA’s regulation of medical devices does not end with granting the PMA application. “Once a device has received premarket approval, the MDA 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.” 42 If a manufacturer wishes to make changes—e.g., altering an existing device or developing and manufacturing a next-generation version of an existing device—the manufacturer must submit an application for supplemental premarket approval and may implement the changes only after the FDA grants that approval. 43 An application for supplemental premarket approval is evaluated under the same exacting criteria as an initial application. 44 Moreover, the entire PMA submission, including all prior supplements, are “before” the FDA “at the time the supplement is reviewed.” 45

methods, or labeling in its proposed form, “it may send an ‘approvable letter’ indicating that the device could be approved if the applicant submitted specified information or agreed to certain conditions or restrictions.” Id. at 319 (citing 21 C.F.R. § 814.44(e)). “Alternatively, the agency may send a ‘not approvable’ letter, listing the grounds that justify denial and, where practical, measures that the applicant could undertake to make the device approvable.” Id. (citing 21 C.F.R. § 814.44(f)). “The FDA thus has quite broad authority to approve, deny, and effectuate modifications of an application throughout the PMA process.” Riegel v. Medtronic, Inc., 451 F.3d 104, 110 (2d Cir. 2006). Medical devices are subject to various reporting requirements after receiving premarket approval, including: (1) “the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of”; and (2) the obligation to “report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred.” Riegel, 552 U.S. at 319 (citing 21 C.F.R. §§ 814.84(b)(2), 803.50(a)). “The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.” Id. at 319–20 (citing 21 U.S.C. § 360e(c)(1)).

39. Riegel, 552 U.S. at 319 (citing 21 C.F.R. § 861.1(b)(3)).
40. Id. (citing 21 C.F.R. § 814.82).
41. Id. (citing 21 U.S.C. § 360(j)(c)(1)).
42. Id. (citing 21 U.S.C. § 360e(d) (6)(A) (i)).
43. Id. (citing 21 U.S.C. § 360(e)(d) (6); 21 C.F.R. § 814.39(c)).
44. Id.
45. Premarket Approval of Medical Devices, 51 Fed. Reg. 26,342, 26,354 (July
IV. PREEMPTION UNDER THE MEDICAL DEVICE ACT

The MDA includes an express preemption provision in § 360k that provides:

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.46

In Medtronic, Inc. v. Lohr, the United States Supreme Court held that state common-law tort claims involving medical devices that receive FDA approval through the § 510(k) process are not preempted by § 360k of the MDA.47 But in doing so, the Court declined to conclude that common-law duties are never “requirements” within the meaning of § 360k and that the statute thus could never preempt common-law actions.48 That is, the Court

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46. 21 U.S.C. § 360k(a). The exception contained in subsection (b) states: Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

Id. § 360k(b).


48. Id. at 502–03 (“[W]e do not respond directly to this argument . . . . [S]ince none of the [plaintiffs’] claims is pre-empted in this suit, we need not resolve hypothetical cases that may arise in the future. . . . Until such a case arises, we see no need to determine whether the statute explicitly pre-empts such a claim.”).
left open the question of whether § 360k preempts state common-law tort claims regarding medical devices receiving premarket approval, as opposed to those devices that were approved through the § 510(k) process. 49 Following Lohr, the majority of circuits addressing this question held that common-law tort claims involving medical devices receiving premarket approval are preempted. 50

In Riegel v. Medtronic, Inc., the United States Supreme Court clarified how this preemption provision is to be applied. 51 First, a court must determine whether the FDA has established requirements applicable to the particular medical device in question. 52 The Court in Riegel held that the premarket approval process does impose certain federal “requirements” upon the subject medical devices because “the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness” and because “the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application.” 53 Therefore, for all devices receiving premarket approval, this first prong is met. 54

Second, for those devices that undergo the PMA process, a

51. 552 U.S. 312, 321–22 (2008). In Riegel, the plaintiff brought a lawsuit in the United States District Court for the Northern District of New York alleging that a balloon catheter marketed by defendant for use in coronary angioplasty procedures—which had received FDA premarket approval—was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused plaintiff to suffer injuries. Id. at 320. “The District Court held that the MDA pre-empted [plaintiff’s] claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter . . . .” Id. at 312. Accordingly, the district court dismissed these claims. See id. at 321. On appeal, the United States Court of Appeals for the Second Circuit affirmed the district court’s summary judgment dismissal of plaintiff’s strict liability; breach of implied warranty; and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims. Riegel, 451 F.3d at 106.
52. Riegel, 552 U.S. at 321.
53. Id. at 322–23.
54. See id. The Court distinguished devices approved through the less rigorous § 510(k) process, which have not undergone review for safety or efficacy under the MDA, but instead are simply reviewed for equivalence. Id. at 323.
court must then determine whether the plaintiff’s state law claims impose “requirement[s]” that are “‘different from, or in addition to’ federal requirements and that ‘relate[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.’”55 The Court concluded that the state tort claims for negligence and strict liability at issue in *Riegel* met the second part of this test because the claims imposed “requirements” additional to those federally imposed through the PMA process.56 The Court noted, however, that “parallel” state claims, or those that simply provide a damages remedy for claims premised on a violation of federal regulations but do not add to federal requirements, are not preempted by § 360k.57

Since *Riegel*, “courts across the country have applied [§] 360k(a) broadly,” preempts claims ranging from strict products liability and negligence to breach of warranty, failure to warn and manufacturing and design defect, and negligence per se.58 Nonetheless, parties embroiled in medical device litigation

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55. *Id.* (quoting 21 U.S.C. § 360k(a) (2006)).
56. *Id.* at 323–24.
57. *Id.* at 330.
continue to dispute the extent to which state common-law tort claims involving medical devices that received premarket approval are preempted, with much of plaintiffs’ efforts focused on avoiding preemption by demonstrating the state claims being asserted are “parallel.”

V. RECENT JUDICIAL DECISIONS HOLD THAT PREMARKET APPROVAL OF MEDICAL DEVICES APPLIES TO ALL ASPECTS AND COMPONENTS OF THE DEVICE

Despite the significant attention still being paid to the issue of “parallel” claims, some plaintiffs recently have attempted to avoid preemption by separating out the allegedly defective aspect or component of the medical device at issue and arguing that a different preemption analysis should apply to that particular aspect or component. This argument arises most often in cases involving a medical device or system where certain components of the device warn, and statutory fraud preempted by MDA); Covert v. Stryker Corp., No. 1:08CV447, 2009 WL 2424559, at *1, *8 (M.D.N.C. Aug. 5, 2009) (holding claims for failure to warn, defective design, defective manufacture, negligence, express warranty, and implied warranty preempted by MDA); Riley v. Cordis Corp., 625 F. Supp. 2d 769, 780–89 (D. Minn. 2009) (holding claims for failure to warn, manufacturing defect, implied warranty, express warranty, misrepresentation, and fraud preempted by MDA); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 282–87 (E.D.N.Y. 2009) (holding claims for negligence, defective design, manufacturing defect, failure to warn, express warranty, and implied warranty preempted by MDA); Clark v. Medtronic, Inc., 572 F. Supp. 2d 1090, 1093–95 (D. Minn. 2008) (holding claims for negligence and failure to warn preempted by MDA); Blanco v. Baxter Healthcare Corp., 70 Cal. Rptr. 3d 566, 578–82 (Cal. App. 2008) (holding claims for negligence, strict liability, and breach of implied warranty preempted by MDA); Colombini v. Westchester Cnty. Health Care Corp., No. 11101/2002, 2009 WL 2170250, at *1, *5 (N.Y. Sup. Ct. July 6, 2009) (holding claims for negligent design, negligent manufacture, negligent failure to warn, breach of warranty, and strict products liability preempted by MDA).


60. See, e.g., Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013) (en banc) (holding negligence claim based on alleged failure to report to the FDA known risks associated with medical device was not preempted by § 360k of the MDA because the state-law duty of care “parallels” a federal-law duty imposed by the MDA).
or system (or predecessor device components) were initially approved through the separate § 510(k) process.

For example, in Lewkut v. Stryker Corp., plaintiff received an artificial hip replacement system manufactured by defendant on or about November 15, 2006. The hip replacement system, called a Howmedica Osteonics Trident System (“Trident System”), consisted of several components, including an Osteonics Trident PSL Acetabular Shell (“acetabular shell” or “acetabular cup”). After his surgery, plaintiff began experiencing pain in his thigh, groin, and hip, which persisted for some time. Plaintiff was subsequently advised by his doctor that his pain was caused by a failure in his hip prosthesis. Plaintiff asserted his pain was due to loosening of the acetabular shell component of his hip prosthesis, caused by residues that remained on the shell after manufacturing and packaging. “It [was] undisputed that the acetabular shell received § 510(k) approval and was commercially available well before [p]laintiff received his hip replacement.” The acetabular shell was later incorporated into the Trident System, which received premarket approval on or about February 3, 2003, approximately three-and-a-half years before plaintiff received the device.

Plaintiff sued defendant alleging manufacturing, design, and marketing defects in the acetabular shell. Defendant subsequently moved to dismiss plaintiff’s claims, arguing they were preempted under § 360k(a). In response, plaintiff contended his claims were not preempted because the acetabular shell was not part of the Trident System that was approved via the PMA process, but instead was FDA-approved only through the § 510(k) process.

The United States District Court for the Southern District of Texas disagreed, concluding instead that the Trident System

62. Id.
63. Id.
64. Id.
65. Id. at 652.
66. Id.
67. Id.
68. Id. Specifically, plaintiff asserted claims for relief under strict liability, negligence, and the Texas Deceptive Trade Practices Act. Id. Plaintiff sought actual and punitive damages. Id.
69. Id. at 652–53.
70. Id. at 654.
approved through the PMA process included the acetabular shell.\textsuperscript{71} The fact that the acetabular shell was previously approved through the § 510(k) process did not affect the court’s analysis:

\textquote{That the acetabular shell was previously approved through only the § 510(k) process, and was commercially available when the Trident System was approved, does not change the fact that it was later subject to the more rigorous scrutiny of the PMA process as a component of the Trident System. Because the Trident System went through the PMA process, and the acetabular shell was part of this system, the first part of the \textit{Riegel} test is satisfied.}\textsuperscript{72}

The district court also concluded that because the state law claims alleged by plaintiff imposed requirements in addition to those imposed by the MDA, they were preempted.\textsuperscript{73} Accordingly, the court dismissed plaintiff’s claims.\textsuperscript{74}

In \textit{Cornwell v. Stryker Corp.}, plaintiff filed claims against defendant alleging defects in the Trident System’s acetabular shell caused plaintiff pain and forced him to undergo a revision of his total hip replacement.\textsuperscript{75} As in \textit{Lewkut}, plaintiff contended that his claims were not preempted because the acetabular cup component of the Trident System was initially approved via the § 510(k) process, not the PMA process.\textsuperscript{76} The United States District Court for the District of Idaho rejected plaintiff’s argument, instead concluding “the record in this case supports that the Trident System, including its component parts, received PMA approval under the PMA process.”\textsuperscript{77} Accordingly, the court held that plaintiff’s product liability claims were preempted.\textsuperscript{78}

The courts in \textit{Lewkut} and \textit{Cornwell} do not stand alone. In fact, several other courts dealing with claims relating to the Trident System have similarly held that when the system received premarket approval, all of the device’s components, including the acetabular shell, received premarket approval.\textsuperscript{79} This line of analysis is not

\textsuperscript{71.} Id. at 656.
\textsuperscript{72.} Id. at 657.
\textsuperscript{73.} Id. at 660.
\textsuperscript{74.} Id.
\textsuperscript{76.} Id. at *3.
\textsuperscript{77.} Id. at *8.
\textsuperscript{78.} Id. at *9.
limited, however, to just those cases involving Stryker’s Trident System. Indeed, courts in cases involving other medical devices have similarly found that attempting to separate the component parts of a medical device or system that has received premarket approval for purposes of preemption is simply not appropriate.80

VI. THE FDA’S DENIAL OF CITIZEN PETITIONS CONFIRMS THERE IS NO SUCH THING AS A LIMITED PREMARKET APPROVAL

Not to be deterred, plaintiffs in Duggan v. Medtronic, Inc. advanced the argument one step further, this time asking the FDA to weigh in on the meaning of its PMA letter as it related to the question of whether the FDA’s premarket approval of a Paradigm Real Time System applied to all aspects and components of the system.81

On June 15, 1999, the FDA granted premarket approval to a Medtronic medical device called the MiniMed Continuous Glucose Monitoring System, a device that aids diabetics by monitoring blood glucose levels.82 “[T]hrough a series of premarket approval

(“Trident System, in its entirety, received premarket approval.”); Bass v. Stryker Corp., No. 4:09CV632Y, 2010 U.S. Dist. LEXIS 90226, at *12 (N.D. Tex. Aug. 31, 2010), aff’d in part, rev’d in part, 2012 U.S. App. LEXIS 1789 (5th Cir. Jan. 31, 2012) (holding defendant had established that the acetabular shell, as a component of the Trident System, “was subject to the rigorous premarket-approval review on which the Supreme Court’s analysis in Riegel was based, causing claims based on the Shell to be preempted under § 360k(a)”); Lemelle v. Stryker Orthopaedics, 698 F. Supp. 2d 668 (W.D. La. 2010) (dismissing state law product liability claims against the Trident System, including those involving acetabular shells); Funk v. Stryker Corp., 673 F. Supp. 2d 522, 531 (S.D. Tex. 2009) (“[I]n nearly all of the prior district court cases addressing preemption of claims involving the Trident, both the plaintiffs and the defendants agreed it was a Class III device approved through the PMA process.”); Delaney v. Stryker Orthopaedics, No. 08-03120, 2009 WL 564243, at *4 (D.N.J. Mar. 5, 2009) (noting that additional discovery was not warranted because defendant had sufficiently demonstrated that the entire Trident System underwent the PMA process); Bausch v. Stryker Corp., No. 08C4248, 2008 WL 5157940, at *3 (N.D. Ill. Dec. 9, 2008), rev’d, 630 F.3d 546 (7th Cir. 2010) (noting that Trident, including the acetabular shell, was subjected to the process of premarket approval and therefore subject to federal regulations).

80. See, e.g., Bentzley v. Medtronic, Inc., 827 F. Supp. 2d 443, 452 (E.D. Pa. 2011) (“Plaintiff’s contention that, in considering a preemption issue, the Court must break a medical device into its component parts, is without legal support.”); Riley v. Cordis Corp., 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (“It makes no sense—indeed, it would probably be impossible—to pick apart the components of a medical device and apply different preemption analyses to different components.”).


82. Id. at 469.
supplements, this [glucose] sensor came to include a monitor to display the data [obtained] from the sensor; Medtronic named the device Guardian RT. Medtronic also marketed Model MMT-515/715 insulin pumps, Class III medical devices that deliver insulin to a patient either automatically or based on patient input. The MMT-515/715 insulin pumps were approved in 2004 via the § 510(k) process.

Medtronic subsequently developed the Paradigm Real Time System: a combination of the Guardian RT glucose monitor and the next generation Model MMT-522/722 insulin pumps that allowed the glucose sensor to send data to the pump for viewing on the pump’s monitor. The Paradigm Real Time System was submitted to the FDA on October 4, 2005, as a supplement to the prior PMA application for the MiniMed Continuous Glucose Monitoring System. In its application, Medtronic described the Paradigm Real Time System as an “integration of the 515/715 pump with the Guardian RT.” The supplemental PMA application was approved by the FDA on April 7, 2006.

Plaintiff Judith Duggan utilized a Medtronic Model MMT-522 insulin pump to treat her diabetes. Plaintiffs filed suit against defendant Medtronic claiming the insulin pump used by Ms. Duggan was defective and caused her to suffer physical injuries. Medtronic subsequently moved for summary judgment, arguing that, because the MMT-522 pump received premarket approval, plaintiffs’ state-law tort claims were preempted by § 360k(a) of the MDA. Plaintiffs disagreed, instead contending that, while the FDA granted premarket approval for certain components of the Paradigm Real Time System, the FDA had not granted premarket approval for the MMT-522 pump, the part of the system that
allegedly injured Ms. Duggan. Plaintiffs argued that because the MMT-522 pump was substantially identical to the MMT-515 pump, which entered the market through the § 510(k) process, state law claims specifically and exclusively targeting the insulin pump component of the system should not be preempted. “Acknowledging that when premarket approval is granted to a system it applies to all devices within the system, [plaintiffs also contended] the FDA did not approve the Paradigm [Real Time] System as a system.” Finally, plaintiffs argued that the language in the FDA approval letter for the Paradigm Real Time System shows the FDA did not intend to grant premarket approval to the entire system.

Interestingly, plaintiffs filed a citizen petition with the FDA regarding the meaning of the premarket approval letter. But the FDA denied plaintiffs’ petition. In its letter denying plaintiffs’ citizen petition, the FDA made clear it intended to grant premarket approval to the entire Paradigm Real Time System, including the MMT-522 pump: “FDA approved the PMA supplement for the Paradigm System, including both the 522 pump and the Guardian RT sensor, on April 7, 2006.” The FDA further explained:

The approval reflected FDA’s finding that the PMA supplement for the Paradigm System and the original PMA for the Guardian RT sensor provided a reasonable assurance of safety and effectiveness for the Paradigm System. Because the approval letter, as issued, applies to the Paradigm System as a whole, we deny your request to amend the approval letter by adding the following language: “This approval is limited solely to the ability of the pump to accept data from the sensor and the ability

93. Id. at 471.
94. Id.
95. Id.
96. Id. at 472.
97. Id. Plaintiffs also filed a request for testimony with the FDA, which the FDA denied, and issued a subpoena to the FDA for a deposition, which the FDA moved to quash. Id. at 472 & n.1. In its memorandum in support of its motion to quash, the FDA argued, in part, that complying with the subpoena would be unduly burdensome because the FDA’s citizen petition response obviated plaintiffs need for testimony regarding the scope and content of the approval letter. Motion to Quash at 28, Duggan, 840 F. Supp. 2d 466 (No. 1:09-cv-12046). Plaintiffs subsequently withdrew their subpoena. Duggan, 840 F. Supp. 2d at 472 n.1.
98. Duggan, 840 F. Supp. 2d at 472.
99. Id.
for the sensor to communicate directly to the pump, and this approval does not extend to the pump itself.\textsuperscript{100} Based on these facts, the court concluded that the Paradigm Real Time System, including the MMT-522 pump, was granted premarket approval, and plaintiffs’ state law claims were preempted under the MDA; therefore, the court granted Medtronic’s motion for summary judgment.\textsuperscript{101}

The FDA’s denial of plaintiffs’ citizen petition in \textit{Duggan} is not the only instance of that occurring with respect to Medtronic’s Paradigm Real Time System. In \textit{Bentzley v. Medtronic, Inc.}, plaintiff Paul Bentzley, who like Ms. Duggan utilized a Medtronic Model MMT-522 insulin pump to treat his diabetes, filed a lawsuit after he was hospitalized for diabetic ketoacidosis alleging that his insulin pump malfunctioned.\textsuperscript{102} Defendants moved for summary judgment, arguing that plaintiff’s MMT-522 pump received premarket approval and that plaintiff’s claims were therefore preempted by § 360k(a) of the MDA.\textsuperscript{103} Plaintiff responded by claiming, in part, that his MMT-522 pump was “separate and apart” from the Paradigm Real Time System and thus was not approved through the PMA process.\textsuperscript{104}

As in \textit{Duggan}, plaintiff sought to bolster his claim by filing a citizen petition with the FDA requesting clarification of the scope of the FDA’s April 7, 2006 letter granting premarket approval of the Paradigm Real Time System.\textsuperscript{105} Specifically, plaintiff sought to amend the letter by adding the exact same language suggested by plaintiffs’ counsel in \textit{Duggan}: “This approval is limited solely to the ability of the pump to accept data from the sensor and the ability for the sensor to communicate directly to the pump, and this


\textsuperscript{101} \textit{Duggan}, 840 F. Supp. 2d at 473. In doing so, the court observed: “To the extent there was any ambiguity about the scope of the approval letter, this rejection of the Citizen Petition is the cherry on the icing.” \textit{Id.} at 472.

\textsuperscript{102} 827 F. Supp. 2d 443, 448 (E.D. Pa. 2011). Specifically, plaintiff asserted claims for strict liability, marketing defect, design defect, manufacturing defect, breach of express warranty, breach of implied warranty of fitness for a particular purpose, breach of implied warranty of merchantability, negligence, and punitive damages. \textit{Id.}

\textsuperscript{103} \textit{Id.} at 449.

\textsuperscript{104} \textit{Id.} at 450, 451.

\textsuperscript{105} \textit{Id.} at 451.
approval does not extend to the pump itself.”

On September 23, 2011—the same day the FDA denied plaintiff’s citizen petition in *Duggan*—the FDA responded by letter and rejected plaintiff’s citizen petition. Like the FDA’s letter to Ms. Duggan’s counsel, the FDA first noted that “[t]he Paradigm [Real Time] System consists of the Paradigm MMT-522/722 external insulin infusion pump (‘the 522 Pump’) and a continuous glucose monitor, the Guardian RT sensor.”

The FDA further observed that “Medtronic modified the 515 Pump and the Guardian RT sensor and combined them to create the Paradigm System.”

The FDA’s letter concluded:

> Accordingly, FDA approved the PMA supplement for the Paradigm System, including both the 522 pump and the Guardian RT sensor, on April 7, 2006. . . . Because the approval letter, as issued, applies to the Paradigm System as a whole, we deny [plaintiff’s] request to amend the approval letter by adding the [suggested] language . . . .

Relying in part on the rejection of plaintiff’s citizen petition, the United States District Court for the Eastern District of Pennsylvania held that the entire Paradigm Real Time System, including plaintiff’s Model MMT-522 pump, received premarket approval.

The following principle can be gleaned from the FDA’s denials of the citizen petitions in *Duggan* and *Bentzley*: the FDA’s grant of premarket approval to a medical device or system applies to all aspects and components of that device or system. This is consistent with what courts have previously held, and means that state law claims involving medical devices or systems receiving premarket approval can only survive going forward if they are truly parallel and do not impose different or additional requirements on the device.

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106. *Id.* (citation omitted).
107. *Id.*
108. *Id.* (citation omitted).
109. *Id.* (citation omitted).
110. *Id.* (citation omitted).
111. *Id.* at 451–52 (“Because the FDA granted premarket approval for the MMT-522 System, the Court finds that the Federal Government has established requirements applicable to the relevant device.”).
VII. CONCLUSION

The FDA’s denials of the citizen petitions in *Duggan* and *Bentzley*, along with recent judicial decisions consistently holding that premarket approval of medical devices applies to all aspects and components of the medical device system at issue, have likely sounded the death knell for any future arguments by plaintiffs that the FDA granted manufacturers limited premarket approvals that do not apply to all aspects and components of a medical device or system. Indeed, the only time such an argument would seem appropriate is when the PMA letter itself clearly and expressly limits the approval to only certain aspects or components of the medical device or system. As a result, moving forward it seems likely the future of medical device litigation, as it relates to the issue of preemption, will be focused almost exclusively on the question of whether the state claims being asserted by plaintiffs are parallel.