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I. INTRODUCTION

Congress passed the Medical Device Amendments of 1976 (MDA) to amend the Federal Food, Drug, and Cosmetic Act (FDCA). The purpose of the MDA is to give the Food and Drug Administration (FDA) authority over medical devices and to authorize the FDA to promulgate regulations pertaining to these devices, thereby assuring their safety and effectiveness.

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The MDA contains an express preemption provision with respect to state law. 4 This provision declares that the MDA shall preempt any state law that is “different from, or in addition to” any provision of the MDA. 5 Courts have interpreted this provision inconsistently. 6 The FDA also has interpreted the MDA's preemption provision, albeit indirectly. 7 Some courts have relied upon FDA interpretations as being strongly suggestive of Congress' intended meaning with respect to the preemption provision. 8 Courts have, however, cited the FDA's interpretations for inconsistent propositions. 9 The ambiguity with respect to this preemption issue became more clear on June 26, 1996, when the Supreme Court handed down the decision in Medtronic, Inc. v. Lohr. 10

This Note has several goals. The first goal is to explain the context in which the Supreme Court decided Medtronic. The second goal is to explain the holding in Medtronic. The final goal is to discuss and interpret the future implications of the Medtronic decision.

To facilitate these goals, Part II of this Note details the background and threshold issues for analysis of preemption issues. Part III explains both the substantive and practical aspects of the MDA. Part IV analyzes federal appellate courts' treatment of the issue of whether the MDA preempts state tort claims. Part V explains the decision in Medtronic. Finally, Part VI illustrates how courts have interpreted cases involving MDA preemption issues since Medtronic and delineates the future implications of the decision.

5. Id.
6. See infra Part IV (discussing various interpretations of MDA preemption of state-law claims).
7. See infra Part IV.E (discussing the FDA's interpretation of the MDA's preemption provision).
8. See, e.g., Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392, 398 (4th Cir. 1995) (noting "that the FDA interprets the word 'requirement' in § 360k to include duties imposed by state common law"); see also Mitchell v. Collagen Corp., 67 F.3d 1268, 1275-76 (7th Cir. 1995) (noting that the "FDA regulation ... interprets the statute's preemptive sweep as encompassing state requirements established by 'statute, ordinance, regulation, or court decision'")
9. cert. granted and judgment vacated, 116 S. Ct. 2576 (1996); Martello v. Ciba Vision Corp., 42 F.3d 1167, 1168 (8th Cir. 1994) (stating that the FDA has interpreted section 360k(a) as preempting any state requirement, "whether established by statute, ordinance, regulation, or court decision"); cert. denied, 115 S. Ct. 2614 (1995); National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 991 (8th Cir. 1994) (claiming that "the FDA understands the statute to preempt state tort law"); Mendes v. Medtronic, Inc., 18 F.3d 13, 18 (1st Cir. 1994) (stating "[t]he common law, no less than agency regulations and statutes, can impose 'requirements' on a manufacturer").
10. See infra Parts IV.A-D.
II. PREEMPTION BACKGROUND

The doctrine of preemption arises out of the Supremacy Clause of the United States Constitution. The Supremacy Clause states, in pertinent part, that "the Laws of the United States which shall be made . . . under the Authority of the United States and of the several States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any . . . Laws of any State to the Contrary notwithstanding." 

The United States Supreme Court has interpreted this language to mean that federal law preempts, or takes precedence over, state law that is inconsistent with federal law. The phrase "Laws of the United States" has been interpreted to mean both statutes and authorized regulations. When courts consider issues arising under the Supremacy Clause regarding areas of law that the states traditionally occupy, courts are to "start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress." Based on this language, the Supreme Court has noted that "[t]he purpose of Congress is the ultimate touchstone" when undertaking a preemption analysis. When it enacts legislation, Congress may establish its intent to preempt state law in either an express or an implied manner.

11. See U.S. CONST. art. VI, cl. 2.
12. Id.
13. See Maryland v. Louisiana, 451 U.S. 725, 746 (1981) (noting that a state law in conflict with a federal law is without effect with respect to Article VI, Clause 2); Hines v. Davidowitz, 312 U.S. 52, 63 (1941) (quoting the Supremacy Clause and holding that a state may not add to or take away from the force and effect of a treaty or statute with respect to foreign affairs); M'Culloch v. Maryland, 17 U.S. 316, 427 (1819) (stating that a state law which conflicts with a federal law is "without effect," based on Article VI, Clause 2 of the United States Constitution).
17. See Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 152-53 (1982) (noting that congressional preemption may be implied or express); Malone, 435 U.S. at 505 (stating that congressional intent may be implied or found expressly in legislative history).
A. Express Preemption

Express preemption presents itself in one of two ways. First, Congress may declare federal legislation to have preemptive effect through the use of explicit statutory language. Where such express intent is present, the court's task in determining whether preemption exists has been described as an easy one. Second, a federal agency acting within its authority may expressly declare its intent to preempt the state law in question. The only difference between this situation and one in which Congress expressly preempts state law lies in who promulgated the regulation. In this type of preemption, a regulatory body, under the authority of Congress, creates the preemption language.

Often, the real question in these situations consists of determining whether a particular statute warrants the exercise of express or implied preemption principles. This determination is crucial because it carries...
substantive implications for the scope of preemption. 23

Courts determine the breadth of an express preemption provision by reliance upon express preemption principles and the language used by Congress, rather than by looking to the comprehensive nature of the statutory scheme in question. 24 Where Congress includes an express preemption provision, it is not necessary to infer congressional intent with respect to preemption. 25 However, where the statutory language is unclear as to the intended scope of the preemption provision, courts should examine legislative history to assist in determining the intended scope of the provision in question. 26

B. Implied Preemption

Implied preemption exists when Congress (or an agency with jurisdiction) has not made an express declaration with respect to preemption, but "federal law so thoroughly occupies a legislative field 'as to make reasonable the inference that Congress left no room for the States to supplement it.'" 27 Implied preemption is often divided into two general categories: field preemption and direct conflict preemption. 28

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23. See Gade, 505 U.S. at 104 n.2.
24. See Morales v. Trans World Airlines, Inc., 504 U.S. 374, 384 (1992). The Morales Court rejected an attempt to distinguish the preemption provision of the Airline Deregulation Act from ERISA's preemption provision on the ground that ERISA's preemption provision had a "wide and inclusive sweep" whereas the Airline Deregulation Act did not. Id.; see also CSX Transp., Inc. v. Easterwood, 507 U.S. 658 (1993) (holding that preemption exists only if the federal regulations substantially subsume the subject matter of the relevant state law).
27. Cipollone, 505 U.S. at 516 (quoting Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982)).
1. Field Preemption

Field preemption occurs in three situations. First, field preemption occurs when a federal regulation in a given area is so pervasive that it precludes supplementation by the states.9 Second, field preemption occurs when the federal interest in the field is "sufficiently dominant."31 Finally, field preemption occurs under circumstances in which "the object sought to be obtained by the federal law and the character of obligations imposed by it . . . reveal the same purpose."31

2. Direct Conflict Preemption

Preemption by means of direct conflict arises when "compliance with both federal and state regulations is a physical impossibility."32 Preemption by direct conflict also occurs when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."33 Finally, even if a federal and state law share a common goal, preemption may occur if the state law interferes with the methods that the federal statute is using to implement federal goals.4 The Supreme Court has noted that the existence of federal regulation, in and of itself, is not enough to warrant preemption of all state law in a given area.35

30. Rice, 331 U.S. at 230 (citing Hines v. Davidowitz, 312 U.S. 52, 65-68 (1940)).
31. Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 299-300 (1988) (holding that the Natural Gas Act regulated the field to the exclusion of state law); see also O'Melveny & Myers v. FDIC, 512 U.S. 79, 87 (1994) (reasoning that the creation of a special federal rule is not justified where there is no significant conflict between some federal policy or interest and the use of state law); Hillsborough County v. Automated Med. Lab., Inc., 471 U.S. 707, 713 (1985) (discussing preemption and the Supremacy Clause where state and federal law conflict); Fidelity Fed. Sav. & Loan Ass'n, 458 U.S. at 153 (holding that preemption principles are not inapplicable simply because real property law is a matter of special concern to the states).
34. See International Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987) (holding that the Clean Water Act preempted a Vermont nuisance law, because the Vermont law "would allow respondents to circumvent the [federally-imposed] permit system, thereby upsetting the balance of public and private interests so carefully addressed by the Act").
35. See Automated Med. Lab., 471 U.S. at 719. "Undoubtedly, every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law . . . . Instead, we must look for special features warranting preemption." Id.
III. THE MEDICAL DEVICE AMENDMENTS OF 1976

The MDA is regulatory legislation passed to protect the public from harm caused by the use of medical devices. The MDA was enacted for two reasons: to encourage the research and development of medical devices, and as a "knee-jerk" reaction to the Dalkon Shield tragedies of the 1960s and 1970s.

Prior to the enactment of the MDA, there were no federally established controls governing the marketing and sale of medical devices. As medical technology advanced in the 1950s and 1960s, the use of complex medical devices such as brain scans, kidney dialysis machines, and heart pacemakers and valves became more common in medical treatment. In the 1960s and early 1970s, tragedy struck when a large number of women suffered injury from the use of a contraceptive device known as the Dalkon Shield. Congress enacted the MDA largely in response to the

37. See id. at 2.
38. See id.
41. See Medtronic, 116 S. Ct. at 2246. The Court noted that use of the Dalkon Shield "resulted in a disturbingly high percentage of inadvertent pregnancies, serious infections, and even, in a few cases, death." Id. (citing Regulation of Medical Devices (Intrauterine Contraceptive Devices): Hearings Before a Subcomm. of the House Comm. on Gouv't Operations, 93rd Cong., 1st Sess. (1973)); see also Kennedy v. Collagen Corp., 67 F.3d 1453, 1455 (9th Cir. 1995) (stating that injuries were suffered by many women as a result of the use of the Dalkon Shield during the 1960s and 1970s), cert. denied, 116 S. Ct. 2579 (1996); In re A.H. Robins Co., 880 F.2d 709, 711 (4th Cir. 1986) ("The first action to come to trial against Robins charging injuries from the use of the Dalkon Shield arose in the state court in Kansas and resulted in a verdict in February 1975 in favor of the plaintiff in the amount of $85,000, including a $75,000 punitive award."). In a commentary on the Dalkon Shield crisis, the author notes that the legislative history of the MDA reveals concern over injuries caused by the use of IUDs such as the Dalkon Shield. See Mary G. Boguslaski, Classification and Performance Standards under the 1976 Medical Device Amendments, 40 FOOD DRUG COSM. L.J. 421, 423 (1985). "During the same time period, consumer advocates encouraged the public to voice a desire to weigh the
mounting government and consumer concern over such devices.\textsuperscript{42}

The United States Congress enacted the MDA to "provide for the safety and effectiveness of medical devices intended for human use."\textsuperscript{43} Congress noted two purposes underlying the enactment of the MDA.\textsuperscript{44} The first is to protect the public from harm by placing a regulatory scheme on medical devices to ensure their safety and effectiveness.\textsuperscript{45} The second purpose is to encourage the development of medical devices by creating a uniform scheme of regulation, thereby ensuring that development is economically feasible.\textsuperscript{46} The MDA functions as a federal scheme of regulation with respect to medical devices and gives the FDA comprehensive control over the use and introduction of such devices.\textsuperscript{47}

risks involved in using a product against perceived benefits themselves, rather than allowing FDA to determine the risk-benefit ratio, and, therefore, to determine the availability of products in the United States." \textit{Id.}

42. See Medtronic, 116 S. Ct. at 2246 (stating that products such as catheters, artificial heart valves, defibrillators, and pacemakers were attracting the attention of both consumers and legislators, and that the MDA was enacted as a response to concern over all of these products); see also Ministry of Health v. Shiley, 858 F. Supp. 1426, 1434 (C.D. Cal. 1994) (noting that the MDA was enacted largely in response to the public outcry following the injuries suffered in the 1960s and early 1970s by women using the Dalkon Shield); Gail H. Javitt, \textit{I've Got You Under My Skin – And I Can't Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices}, 49 FOOD & DRUG L.J. 553, 558 (1994) (stating that federal investigations into the Dalkon Shield injuries confirmed that the "pace of the [medical device] industry far exceeded the FDA's ability to control it").


44. See 21 U.S.C.A. §§ 360c(a)(1)(A)(i), 360c(a)(1)(B), 360e(d)(2), 360j(g)(1), 360k(a) (West Supp. 1997); see also Lohr v. Medtronic, 56 F.3d 1335, 1339 (11th Cir. 1995). In Medtronic, the Eleventh Circuit noted two competing congressional purposes for enacting the MDA. See \textit{id.} at 1339. The court also noted, however, that the two purposes should not be interpreted as Congress' exclusive motives in enacting the MDA, as legislative acts often have competing interests. See \textit{id.} at n.1.


46. See 21 U.S.C.A. §§ 360j(g)(1), 360k(a).

47. See Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392, 395 (9th Cir. 1995); Lewis v. Intermedics Intraocular, Inc., 56 F.3d 703, 704 (5th Cir. 1995) (stating that the MDA was enacted to vest regulatory power over medical devices in the FDA); Feldt v. Mentor Corp., 61 F.3d 431, 433 (5th Cir. 1995) (holding that since the enactment of the MDA, the FDA has had the authority to regulate the medical device industry and the entrance of such devices into the marketplace), cert. granted and judgment vacated by 116 S. Ct. 2575 (1996); Michael v. Shiley, Inc., 46 F.3d 1316, 1319 (3rd Cir. 1995) (characterizing the MDA as "a comprehensive extension of the FDA's authority beyond medical drug manufacturers to medical device manufacturers"); Mendes v. Medtronic, Inc., 18 F.3d 13, 14 (1st Cir. 1994)
The MDA grants a federal agency authority to regulate the medical device industry. This was the first instance that Congress granted any federal agency authority to regulate the medical device industry. The MDA establishes a classification scheme for all medical devices. Pursuant to the MDA, the FDA places medical devices into one of three classes based upon the level of risk associated with the device. The following section explains this classification scheme.

A. Classification of Medical Devices Based on Level of Risk

The MDA gives the FDA the power to classify medical devices intended for human use into one of three categories based on the level of risk the device poses to the public. These categories are Class I, Class II, and Class III. According to the MDA, this classification is to be based on the degree of regulation necessary to assure the safety and effectiveness of the device. The devices with the highest amount of risk associated with their use are classified as Class III devices, and they are the most heavily regulated under the MDA.

1. Class I Devices

Medical devices can receive Class I status in one of two ways. First, if a manufacturer can provide a reasonable assurance of the safety and effectiveness of the device, the device will receive Class I status. This is accomplished by showing that the device is controlled by another MDA section and that the controls within this section are sufficient to provide the

(explaining that the amendments gave the FDA comprehensive regulatory authority over medical devices for the first time); see also Committee of Dental Amalgam Mfrs. & Distrib. v. Stratton, 92 F.3d 807, 809 (9th Cir. 1996) (stating that the MDA grants broad authority to the FDA to regulate medical devices), cert. denied, 117 S. Ct. 754 (1997); Kennedy, 67 F.3d at 1455 (stating that the MDA gives broad powers of classification and regulation to the FDA).

48. See Michael, 46 F.3d at 1319 ("[Congress] granted the FDA new broad powers to regulate medical devices.").


51. See id.; see also Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2246 (1996).


53. See id.

54. See Medtronic, 116 S. Ct. at 2246 (referring to pacemakers as an example of a Class III device).

55. See 21 U.S.C. § 360c(a)(1)(A). The two means include devices for which controls are authorized and devices for which insufficient information exists to determine controls. See id.

necessary assurance of safety and effectiveness. Second, even if a device cannot be shown to be safe and effective by the previously described method, the device may receive Class I status if it is not used in a life-sustaining capacity or in a capacity in which it is of substantial importance in preventing the impairment of health. Examples of Class I devices include tongue depressors and crutches.

Class I designation is the lowest level of regulation applicable to devices falling under the MDA. Such devices are subject only to "general controls." General controls consist of regulations with respect to misbranding, registration, adulteration, good manufacturing practices,

57. See id. (cross-referencing a list of MDA sections that constitute "general controls"); see also infra notes 60-66 and accompanying text (discussing general controls).

58. See 21 U.S.C. § 360c(a)(1)(A)(i); see also Medtronic, 116 S. Ct. at 2246 (stating that "devices that present no unreasonable risk of illness or injury are designated Class I"); Committee of Dental Amalgam Mfrs. & Distribs. v. Stratton, 92 F.3d 807, 809 (9th Cir. 1996) (noting that "medical devices which pose little or no threat to public health are classified as Class I").


60. 21 U.S.C. § 360c(a)(1)(A) (1994); see also Medtronic, 116 S. Ct. at 2246; Duvall, 65 F.3d at 396; Michael, 46 F.3d at 1319.

61. See 21 U.S.C. § 352 (1994). A medical device is misbranded if it does not have a label indicating the following information: (1) name and place of business of the device manufacturer, (2) name of the packer or distributor of the device, (3) an accurate statement of the contents of the package, (4) correct name of the device, (5) directions for use, and (6) appropriate warnings. See id. § 352(b), (e)(1), (f). This section does, however, allow for reasonable variations from these requirements and allows the Secretary of the FDA to exempt small packages from the labeling requirements. See id. Additionally, a device that is labeled in a false or misleading manner is misbranded. See id. § 352(a).

62. See id. § 360. This section contains requirements regarding registration of device manufacturers. See id. The section also provides for the creation of a registration number system to identify manufacturers, allows the FDA to inspect any establishment registered under this section, and forces any manufacturer who wishes to introduce its device into the stream of commerce to file a report with the FDA. See id. § 360(e), (h), (k).

63. See id. § 351. This section defines adulteration of both drugs and medical devices. See id. Adulterated devices are as those devices which are: (1) not in conformity with certain described performance standards (specifically Class III devices), (2) banned under section 360f, and (3) not in conformity with certain manufacturing, packing, storage or installation requirements. See id. § 352(e), (g), (h). Any IDE device that is not in compliance with the requirements placed upon the device is also an adulterated device. See id. § 352(i); see also infra notes 108-12 and accompanying text (defining and discussing IDE devices).
notification and repair, replacement or refund, banned devices, and records and reports. These "general controls" apply to all devices regulated under the MDA.

2. **Class II Devices**

Class II devices are those devices that cannot be classified as Class I because they do not satisfy one of the two criteria discussed above for obtaining Class I status. Further, to receive Class II status, enough information must be available with respect to the device so that "special controls" may be established to ensure its safety and effectiveness. Special controls include promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, or any other actions that are deemed appropriate by the Secretary of the FDA. Examples of Class II devices include oxygen masks, bone conduction hearing aids, and tampons.

64. See 21 U.S.C. § 360f. This section gives the Secretary of the FDA the power to ban a medical device. See id. § 360f(a). The Secretary may ban a device if it is intended for human use and presents a substantial risk of causing illness or death. See id. § 360f(a)(1). The Secretary has the authority to notify all health professionals of a device found to be a substantial risk to health. See id. § 360h(a). The Secretary also has the power to recall any such device. See id. § 360h(e).

65. See id. § 360i. Under this section, the FDA requires device manufacturers to make reports to the FDA under a variety of circumstances. See id. For example, anytime a device manufacturer becomes aware that one of its devices may have caused or contributed to a serious injury or death, that manufacturer must make a report to the FDA. See id. § 360i(a)(1)(A). Moreover, section 360j provides that any requirement imposed under the previously explained sections remains in effect until it is changed. Id. § 360j(a). It exempts custom devices from sections 360d and 360e. See id. § 360j(b). This section also gives FDA authority to prescribe regulations that establish "good manufacturing practices" or GMPs. See id. § 360j(f). Finally, this section creates the exemption for IDE devices from various MDA sections. See id. § 360j(g).

66. See Feldt v. Mentor Corp., 61 F.3d 431, 433 (5th Cir. 1995) (stating "all classes of medical devices are subject to general controls, including labeling requirements and so-called good manufacturing practices"); Bianca I. Truitt, Injured Consumers and the FDA: Should Federal Preemption Protect Medical Device Manufacturers Under a Quasi-Governmental Immunity?, 15 J. LEGAL MED. 155, 157 (1994) (noting that the MDA imposes general, minimum controls on all three classes of medical devices).


68. See id.

69. See id.

70. See Kennedy v. Collagen Corp., 67 F.3d 1453, 1455 (9th Cir. 1995); Michael v. Shiley, Inc., 46 F.3d 1316, 1319 (3rd Cir. 1995).


72. See Kennedy, 67 F.3d at 1455.
If a Class II device is intended to support or sustain human life, then the Secretary must examine and identify the special controls that are necessary to provide adequate assurance of safety and effectiveness. The Secretary also must describe how the chosen controls provide the necessary safety assurance.

3. Class III Devices

A device is categorized as a Class III device when it meets the following criteria. First, there must be insufficient information with respect to the safety and effectiveness of the device for it to meet the requirements for Class I or II status. Second, the device must be one that is used to support or sustain human life and that presents a potentially unreasonable risk of either illness or injury. Third, the device must pass premarket approval unless an exception applies. Examples of Class III devices include pacemakers, cardiac catheters, heart valves, inflatable penile implants, and joint replacements.

B. Premarket Approval and Its Limited Application to Class III Devices

According to the MDA, all Class III devices must pass a rigorous approval process known as premarket approval (PMA). This process requires the manufacturer to submit a detailed application to the FDA. The application must include the following information: an outline of the device's components and properties; a description of the manufacturing process; a list of adverse events and their frequency; a summary of the clinical studies and their results; and a description of the expected risk to the patient.

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74. See id.
75. See id. § 360c(a)(1)(C).
76. See id. § 360c(a)(1)(C)(i). Insufficient information prohibits the establishment of a reasonable performance standard. See id. § 360c(a)(1)(C).
77. See id.; Committee of Dental Amalgam Mfrs. & Distribs. v. Stratton, 92 F.3d 807, 809 (9th Cir. 1996) (noting that Class III devices are “medical devices that pose a high risk of injury or that are implanted in the body”); Kennedy, 67 F.3d at 1455 (noting that “Class III devices are those devices which are implanted in the body or which pose a potentially unreasonable risk of injury”); Michael v. Shiley, Inc., 46 F.3d 1316, 1320 (3rd Cir. 1995) (stating that “Class III devices... include all devices which are to be implanted into people, which are used to sustain life, or which pose a potentially unreasonable risk of injury”).
78. See infra Part III.B-C (discussing the premarket approval process and its exceptions).
79. See Kennedy, 67 F.3d at 1455 (stating that pacemakers, heart valves and replacement joints are all examples of Class III devices); Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392, 396 (4th Cir. 1995) (noting that pacemakers, replacement heart valves, and inflatable penile implants are examples of Class III devices); Michael, 46 F.3d at 1320 (noting that the Shiley heart valve is an example of a Class III device).
process; safety data including human and animal testing results; a bibliography of all reports concerning the device’s safety and effectiveness; copies of all proposed labeling; description of the intended use of the product; and any other information requested by the FDA.\textsuperscript{81}

The FDA spends an average of 1200 hours reviewing each submission.\textsuperscript{82} The FDA also may refer the application to a panel of experts which can include nonvoting representatives of consumers and the medical device industry.\textsuperscript{83} Finally, the FDA must approve the application within 180 days unless one of four circumstances exists: (1) there is a failure to establish a reasonable assurance that the device is safe or effective under the recommended conditions of use; (2) the manufacturing methods do not conform to the requirements for good manufacturing practices; (3) the proposed labeling is false or misleading; or (4) the device does not conform to an applicable performance standard.\textsuperscript{84}

The PMA process is an important one. It is the means by which the FDA determines whether a Class III device is safe and effective for its intended use.\textsuperscript{85} The MDA’s policy of ensuring the safety and effectiveness of medical devices was of special concern with respect to Class III devices because of the life-supporting nature of such devices.\textsuperscript{86} Thus, the MDA requires that Class III devices be approved for marketing through the PMA process.\textsuperscript{87}

\textsuperscript{81} See id. § 360e(c)(1)(A)-(G) (1994); 21 C.F.R. § 814.20(b)(2)-(12); see also Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2246-47 (1996) (noting what is entailed in the PMA process); Kennedy, 67 F.3d at 1455-56; Duvall, 65 F.3d at 396; Feldt v. Mentor Corp., 61 F.3d 431, 433-34 (5th Cir. 1995); Michael, 46 F.3d at 1320.


\textsuperscript{85} See Kahan, supra note 82, at 512-14.

\textsuperscript{86} See Kahan, supra note 82, at 511-12. Congress established the PMA process as a heightened degree of scrutiny. See id. This stringent process arises as a result of the “risk-laden” products that comprise Class III devices. Id.; see also supra note 79 and accompanying text (giving examples of Class III life-supporting or -sustaining devices).

\textsuperscript{87} See supra note 80 and accompanying text (alluding to the high risk of Class III devices and the need for the PMA process).
C. Exceptions to Premarket Approval

There are three exceptions to the premarket approval process for Class III devices. These exceptions allow manufacturers to skip the rigorous PMA process altogether, thereby enabling manufacturers to sell certain devices to the public without any determination of their safety or effectiveness. These exceptions illustrate the balance the MDA seeks to strike between the policy of protecting the public and the policy of encouraging the development of medical devices. The next section will show that with respect to these exceptions, the balance looms precariously close to being tipped in favor of the economic interests of medical device manufacturers.

1. Grandfather Exception

The MDA allows all medical devices in use prior to the enactment of the MDA in 1976 to continue to be marketed without being subject to the PMA process. This is known as the grandfather exception. Congress created this exception to avoid the removal of existing medical devices from the marketplace. Technically, the MDA requires that at some point in the future, the manufacturers of these grandfathered devices will be forced to put their products through the PMA process. Up to this point, however, the FDA has not initiated, or even suggested, that any grandfathered devices be subject to the PMA process to establish their safety or effectiveness.

88. See 21 U.S.C. § 360e(b)(1)(A) (1994) (providing the grandfather loophole); id. § 360e(b)(1)(B)(i) (stating that the device is of a type already introduced or delivered); id. § 360e(b)(1)(B)(ii) (providing the "substantially similar" loophole); Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2247 (1996) (asserting that "not all, or even most, Class III devices on the market today have received premarket approval").

89. See 21 U.S.C.A. § 360e(b)(1)(A)-(B) (West Supp. 1997); 21 C.F.R. § 814.2(a) (1996) (stating that although loopholes exist, the ultimate purpose of the PMA process is to provide an efficient and thorough review of devices).

90. See supra notes 45-46 and accompanying text (delineating the policies underlying the MDA).


92. See id.; 21 C.F.R. § 814.1(c)(1).

93. See Medtronic, 116 S. Ct. at 2247 n.3. The MDA calls for initiation of the PMA process for several Class III devices, such as implantable pacemaker pulse generators and lead adapters. See id.

94. See id.
2. Substantial Equivalence

The second exception to premarket approval is known as the "substantial equivalence" exception. Under this exception, devices that are shown to be substantially equivalent to devices which are already legally marketed under the MDA may be marketed without going through the premarket approval process. Interestingly, the MDA also allows the marketing and sale of devices that prove to be substantially equivalent to a grandfathered device without subjecting them to the premarket approval process or requiring any other showing of safety and effectiveness. The MDA included this exception to the PMA process to prevent manufacturers' grandfathered devices from obtaining an instant monopoly and to ensure that improvements and changes to existing devices are easily introduced into the market. Medical device manufacturers have used this exception extensively. In fact, most Class III devices introduced since 1976 have been approved by the MDA through determination of "substantial equivalence."

In order to market a product as "substantially equivalent," a manufacturer must undergo a process known as premarket notification, or section 510(k) notification, ninety days before the device is marketed. Then the FDA must clear the device for marketing. This requires only a showing that the product is, in fact, substantially similar to a device that is being marketed legally under the MDA, including a grandfathered device. Under the "substantial equivalence" exception through the section 510(k) notification process, no substantive inquiry is made with respect to the safety or effectiveness of a device before it is allowed to be marketed.

The implication of the "substantial equivalence" and grandfather exceptions is that many Class III devices, the most life-sustaining and possibly

96. See 21 U.S.C. § 360c(b)(1)(B); 21 C.F.R. § 814(c)(1); see also Medtronic, 116 S. Ct. at 2247 (concluding that approximately 92% of the Class III devices introduced since 1957 were admitted as "substantial equivalents" without any PMA review).
98. See 21 U.S.C. § 360e(b)(1)(B); see also Medtronic, 116 S. Ct. at 2247 (noting that the "substantial equivalence" exception to the PMA was allowed to prevent an instant monopoly on pre-1976 devices, and to facilitate improvements to existing devices for quick introduction into the market).
99. See Medtronic, 116 S. Ct. at 2247. The allure of this exception is the drop in reviewing time from 1200 hours for normal PMA approval to 20 hours for the "substantial equivalent" exception. See id.
100. See id.
102. See 21 C.F.R. § 807.100 (detailing the FDA clearance process).
103. See id. § 807.92(a) (3).
104. See Kahan, supra note 82, at 515.
life-threatening of all medical devices in use today, have never been tested by the FDA for safety or effectiveness. In fact, when notifying a manufacturer that its device may be marketed under the "substantial equivalence" exception, the FDA actually includes a notice informing the manufacturer that it does not verify that the device is safe or effective and that the manufacturer may not represent FDA approval of the safety or effectiveness of the device in question. The "general controls" applicable to Class I devices are still applicable, however, to a Class III device that is marketed as a "substantial equivalent.

This exception stretches to the breaking point the MDA policy of protecting the public from harm by ensuring the safety and effectiveness of a medical device. Under this exception, life-supporting devices which can easily cause serious injury or death upon malfunction may legally be sold to the public without any testing or other assurances of their safety or effectiveness.

3. Investigational Device Exemption

The third exception to premarket approval is known as the Investigational Device Exemption (IDE). This exception allows a manufacturer to conduct clinical testing of devices on humans without being subject to the PMA process. These devices, however, remain subject to the PMA process before they can be marketed to the public. The IDE provides this limited exception to premarket approval so that manufacturers have the opportunity to prove the safety and effectiveness of their devices. An example of a device that has been tested on humans prior to premarket

105. See id. at 521-22.
106. See Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2248 (1996) ("The [FDA] emphasized, however, that this determination should not be construed as an endorsement of the pacemaker lead's safety."); see also Jacobs v. E.I. du Pont de Nemours & Co., 67 F.3d 1219, 1225 (6th Cir. 1995) (quoting the letter approving marketing of a medical device, including language to that effect that the letter does not constitute approval by the FDA of the device or its labeling); Lamonntagne v. E.I. du Pont de Nemours & Co., 41 F.3d 846, 852 (2nd Cir. 1994) (quoting the letter approving marketing an implant as substantially equivalent).
107. See Mendes v. Medtronic, Inc., 18 F.3d 13, 14 (1st Cir. 1994) (noting that "[a]ll classes of devices are subject to 'general controls', including labeling requirements and good manufacturing practices").
110. See 21 U.S.C.A. § 360g(1); see also 21 C.F.R. § 813.3 (1996) (defining an investigational device as one used in a study that involves humans and where the purpose of the study is to determine whether the device is safe and effective).
approval under this exception is an intraocular lens. This device consists of a plastic lens that is implanted into the eye to correct damage done during cataract removal surgery.

The exceptions to the PMA process allow devices to be marketed to the public without any FDA determination of the safety or effectiveness of the devices. This situation is especially problematic when a device is marketed as "substantially equivalent" to a grandfathered device. Under these circumstances, neither the grandfathered device nor the device marketed under the "substantially equivalent" exception has ever been FDA-tested for safety and effectiveness. Thus, manufacturers in the United States sell life-sustaining and possibly life-threatening medical devices that have never been proven safe or effective.

The next section of this Note presents an additional layer of complexity to this problem. In addition to marketing medical devices that have never been proven safe or effective, manufacturers also have argued successfully that the MDA preempted state tort claims with respect to those devices. Thus, medical device manufacturers were able to market devices that had never been proven safe or effective while using preemption to avoid tort liability.

D. The Preemption Provision

The MDA specifically addresses preemption of state and local regulations with respect to medical devices. Section 360k states, in pertinent part:

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.

This section of the MDA also allows for an exemption from preemption. It provides, in part:

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 require-

111. See Slater v. Optical Radiation Corp., 961 F.2d 1330, 1331-32 (7th Cir. 1992) (noting that an intraocular lens that was implanted in the plaintiff's eye was part of a clinical trial under the investigational device exemption).

112. See id.


114. Id. § 360k(a)(1)-(2).

115. See id. § 360k(b).
ment 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.\textsuperscript{116}

This section provides that an exemption from preemption is available under certain conditions. First, exemption is available when the requirement in question is more stringent than an already existing requirement under the MDA.\textsuperscript{117} Second, exemption is available when the requirement is necessitated by compelling local conditions. Finally, an exemption is also available when compliance with the requirement would not cause the device to violate the MDA.\textsuperscript{118}

The MDA's preemption provision is an example of an express preemption provision, whereby Congress plainly stated its intent to preempt state law through statutory language.\textsuperscript{119} Courts have inconsistently interpreted the requirement that no state law be enacted that is "different from, or in addition to" any of the provisions of the MDA.\textsuperscript{120} As the following Part shows, courts generally agree that the MDA expresses Congress' intent to preempt state law. However, courts have disagreed as to the extent to which the MDA preempts state law.\textsuperscript{121} The following Part discusses the federal courts of appeals decisions that have addressed this issue.\textsuperscript{122}

IV. MDA PREEMPTION OF STATE-LAW CLAIMS

Typically, the preemption issue arises when a plaintiff brings state tort claims against a medical device manufacturer, and the manufacturer argues that section 360k(a) of the MDA preempts such claims.\textsuperscript{123} Courts

\begin{itemize}
  \item[116.] Id.
  \item[117.] See id.
  \item[118.] See id.
  \item[119.] See supra Part II.A (discussing express preemption).
  \item[120.] See infra Part IV (discussing inconsistent judicial interpretations).
  \item[121.] See infra Part IV (discussing federal appellate preemption cases).
  \item[122.] For the sake of brevity, this Note discusses only federal courts of appeals decisions dealing with MDA preemption of state law.
have been divided on the issue of whether the preemptive provision of the MDA precludes state tort actions for damages against manufacturers of devices sold under the MDA.\textsuperscript{124} This Part discusses these decisions according to the manner in which the FDA approved the device. Most cases in which devices were marketed through the full PMA process have held that the MDA preempts state tort actions.\textsuperscript{125} Similarly, courts have found state tort law to be preempted in cases in which the particular devices were marketed under the IDE exception to the PMA process.\textsuperscript{126} However, courts were much less likely to find the state tort claims preempted in cases where the “substantial equivalence” exception to the PMA process was used.\textsuperscript{127} The reasons for this distinction are apparent when one considers the Medtronic decision.\textsuperscript{128}

When deciding whether the MDA preempts state tort claims, courts initially must consider whether state tort law imposes “requirements” for purposes of MDA preemption.\textsuperscript{129} Courts must then determine whether the MDA imposes any applicable requirements upon the device in question. Third, a determination must be made as to whether the specific state tort theories asserted are “different from or in addition to” the requirements imposed under the MDA.\textsuperscript{130} The following section will show that courts generally have agreed on the first issue by holding that state tort law can impose “requirements” for purposes of MDA preemption. The remaining sections in this Part will address the second and third questions and will show that courts generally have answered both questions in the affirmative with respect to devices shown to be safe and effective under the MDA. However, the answers change when courts have considered devices that are marketed under section 510(k).

\textsuperscript{124} See infra Part IV.A-D.
\textsuperscript{125} See infra Part IV.B (discussing five cases in which the MDA preempted most state tort claims).
\textsuperscript{126} See infra Part IV.C (discussing three cases in which the plaintiffs' state tort claims were preempted by the MDA).
\textsuperscript{127} See infra Part IV.D (discussing six cases in which plaintiffs' state tort claims received mixed treatment by the courts).
\textsuperscript{128} See infra Part V.C (discussing the Medtronic Court's resolution of the extent to which the MDA preempts state tort claims).
\textsuperscript{129} See Feldt, 61 F.3d at 439.
\textsuperscript{130} See id.
A. State Tort Theories Impose Requirements

Courts generally have agreed that state tort theories can impose requirements under section 360k(a). There are two common bases for this determination. One basis is the Supreme Court's interpretation of the term "requirement" in *Cipollone v. Liggett Group, Inc.* In *Cipollone*, the Court held that the term "requirement," as contained in the preemption clause of the Public Health Cigarette Smoking Act of 1969, was not limited in application to positive enactments by legislatures and agencies. The *Cipollone* court held that state tort theories constitute requirements. A second basis courts have used is the FDA's interpretation of section 360k(a). According to the FDA, state tort law can impose requirements for purposes of MDA preemption under section 360k(a).

Although courts which have considered the issue found that state tort claims are requirements, these courts stopped short of holding that section 360k(a) of the MDA preempts all state tort suits. Courts have reasoned that section 360k(a) preempts only those requirements that are "different from, or in addition to" requirements imposed under the MDA.

To find preemption under section 360k(a), courts must make two additional findings. First, the court must determine that a requirement exists with respect to the device in question. If no requirement exists, no preemption issue arises. Second, the court must determine that the

131. See supra note 123 (listing cases in which the courts were in agreement on the issue).
133. See id.
134. See id.; see also Michael v. Shiley, Inc., 46 F.3d 1316, 1322 (3rd Cir.) (citing *Cipollone* as supporting the proposition that the term "requirement" includes state tort law), cert. denied, 116 S. Ct. 67 (1995); Stamps v. Collagen Corp., 984 F.2d 1416, 1420 (5th Cir. 1993).
136. See 21 C.F.R. § 808.1(b) (1996); see also infra Part IV.E (discussing the FDA's interpretation).
137. See supra note 123.
138. See, e.g., King v. Collagen Corp., 983 F.2d 1130, 1134 (1st Cir. 1993).
139. See id.
140. See id. In *King*, the court held that preemption under section 360k(a) does not apply when the FDA has not issued regulations or other requirements specific to the particular device. See id. An FDA interpretation of section 360k(a) also supports this assertion. See 21 C.F.R. § 808.1(d) (1996). This interpretation states:

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 re-
state tort law actually imposes a requirement that is different from, or additional to, the requirement imposed by the MDA.141 If there is no requirement different from, or in addition to, one promulgated by the FDA, preemption under the MDA is not invoked.142

Thus, courts generally have agreed that state tort actions could impose requirements under the MDA.143 Courts did not agree, however, whether Class III devices marketed through section 510(k) premarket notification had any requirements applicable to them and, if so, whether state tort theories imposed requirements different from MDA requirements.144 With respect to these questions, courts have arrived at different conclusions and based their decisions upon different rationales.145 As the next two sections show, a common thread between these decisions is whether the device in question has been approved for marketing through the full PMA process or through section 510(k) notification.

B. Cases in Which a Device Was Marketed After PMA Approval

In a number of cases, courts considered the MDA preemption issue with respect to devices that had been marketed after passing through the full PMA process. For each case that discussed below, the court's decision with respect to two questions will be explained: (1) Are there any requirements applicable to the device in question under the MDA?; and (2) If so, are the state tort claims in the case at hand different from or in addition to the requirements imposed under the MDA?146 The cases in which the courts answered both questions in the affirmative will be presented first, followed by the cases in which the courts answered one of the questions in the negative. As the analysis will show, in most cases in which a device was marketed after a full PMA approval process, courts have answered both questions in the affirmative.

\[\text{Id.}\]

141. See King, 983 F.2d at 1134.
143. See supra note 123.
144. See infra Part IV.B.
145. Compare Michael v. Shiley, Inc., 46 F.3d 1316, 1328-29 (3rd Cir. 1995) (deciding that to preempt state fraud claims would require a court to scrutinize the FDA), with Talbott v. C.R. Bard, Inc., 63 F.3d 25, 28 (1st Cir. 1995) (declining to declare MDA preemption when a manufacturer fraudulently obtained approval from the FDA because the legislative history did not contain language which supported this exemption).
146. See supra Part IV.A. Because most courts agree that state tort theories can impose requirements, the first of the three questions described in Part IV.A will not be addressed in each of the following case summaries.
In *Stamps v. Collagen Corp.*, the plaintiff was injured after receiving injections of an antiwrinkle product. The product had been approved for marketing by the FDA through the PMA process as a Class III device. The PMA process itself was held to be the requirement applicable to the product under the MDA. The court then held that state tort law related to the safety or effectiveness of the product. Based on this analysis, and without discussing the individual claims at length, the court concluded that the state tort claims were preempted by section 360k(a).

In *Talbott v. C.R. Bard, Inc.*, a woman was killed when a heart catheter failed to deflate while inserted in one of her coronary arteries. The heart catheter was a Class III device approved for marketing through the PMA process. The plaintiffs claimed an exception to MDA preemption should apply because the manufacturer had fraudulently obtained approval for the device from the FDA. The court, however, declined the invitation to create such an exception.

In *Michael v. Shiley, Inc.*, the plaintiff claimed injuries arising out of the removal of a defective heart valve. The valve had been approved for marketing by the FDA through the PMA process as a Class III device.

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147. 984 F.2d 1416, 1419 (5th Cir. 1993).
148. *See id.* at 1421.
149. *See id.* at 1422.
150. *See id.* at 1421-23. The theories of inadequate labeling and failure to warn were easily found to be preempted. *See id.* at 1422. Interestingly, Stamps posed the theory that the MDA preempts state law only to the extent that the state requires a process similar to PMA. *See id.* at 1423. The court found this to be a close question and noted that a device that had been marketed as a "substantial equivalent" did not trigger preemption. *Id.* (citing *Larsen v. Pacesetter Sys.*, 837 P.2d 1273, 1282 (Haw. 1992)). The court distinguished *Stamps* from *Larsen* as follows:

*Larsen* is distinguishable from the instant case in that it involved a device that passed through a less stringent Class III review process by virtue of its being 'substantially equivalent' to devices already allowed to be on the market. . . . The instant devices are not 'substantially equivalent' to marketable devices; rather, they have been subjected to the full rigor of the PMA process.

*Id.* at n.6.
151. *Id.* at 1423.
152. 63 F.3d 25, 26-27 (1st Cir. 1995).
155. *See id.* The court based its decision on a lack of language supporting such an exception in either the statute itself or its legislative history. *Id.* at 27-30.
157. *Id.* at 1320-21. Interestingly, the product in question in *Michael*, the Shiley valve, was approved early in the development of the PMA process. It was approved for marketing without a recorded vote and despite some deficiencies that would not currently be acceptable. *See id.* at 1320. The Shiley valve was ap-
The court found that there were some irregularities in the approval of this specific device and that no device-specific regulations existed with respect to the valve. However, the court found that the valve was still subject to requirements under the MDA, thereby invoking preemption. The court then examined the plaintiff's individual claims to determine whether they were preempted. The court held that the breach of implied warranties claim and the fraud on the FDA claim were preempted, but the express warranty claim based on the valve's label and the fraud based on the manufacturer's advertisements were not preempted.

In Mitchell v. Collagen Corp., an individual was injured after receiving injections of an antiwrinkle product. The product was marketed after FDA approval as a Class III device following the PMA process. The court held that the PMA process itself constituted a "specific requirement" with respect to the product in question, thereby invoking preemption. The court went on to analyze the individual claims to determine whether any of them were different from, or additional to, any of the PMA requirements. Based on its analysis, the court found the claims of strict liability, negligence, fraud, and breach of implied warranty to be preempted.

Apparently one of the first mechanical devices approved under the MDA. See id. at 1323.

158. Id. at 1324-25.
159. Id. The court listed the following as requirements under the MDA that applied to the valve: the PMA process, labeling requirements, "good manufacturing practices" (GMP) that are required of all medical device manufacturers, and the FDA's power to force notification of a previously unknown risk. Id. at 1324.
160. Id. at 1324-36.
161. Id. at 1324-25. The court concluded that the terms of an implied warranty would be determined by looking at the state law in Pennsylvania, which could significantly differ from MDA requirements. See id. at 1325.
162. Michael, 46 F.3d at 1328-29. The court observed that to allow such a claim would require the courts to scrutinize intensively the workings of the FDA. Id. at 1329. The court stated that if the FDA was misled, "it is for the FDA to remedy that situation using the authority Congress gave it in the MDA." Id.
163. Id. at 1325-28. The court held that, because the obligations arose directly from language approved by the FDA, the liability that results is not different from, or additional to, the FDA regulation. Id. at 1328.
164. Id. at 1329-31. The court held that because Congress did not express a wish to insulate medical device manufacturers from liability arising from fraud, the theory is not preempted by the MDA. Id. at 1331.
165. 67 F.3d 1268, 1272 (7th Cir. 1995).
166. Id.
167. Id. at 1279. The court noted that the FDA had not promulgated any regulations that exclusively applied to the device in question. However, the court determined that the term "specific requirements" means specificity with respect to the nature of the requirements, not in their applicability to an individual device. Id. at 1279 (quoting Lohr v. Medtronic, Inc., 56 F.3d 1335, 1345-46 (11th Cir. 1995)).
168. Id. at 1280-86.
169. Id. at 1280. The court found these claims to be preempted because...
However, the claim of breach of an express warranty was deemed to have survived preemption.\textsuperscript{172}

In \textit{King v. Collagen Corp.}, the plaintiff brought suit after being injected with processed cow tissue, otherwise known as collagen, regulated as a medical device under the MDA.\textsuperscript{173} The issue was a Class III device approved for marketing through the PMA process.\textsuperscript{174} The court approached the preemption issue by looking at each claim individually and analyzing whether each presented a regulation different from, or additional to, any in place under the MDA.\textsuperscript{175} An analysis of each of the following claims was conducted: strict liability, breach of warranty, negligence, product misbranding, misrepresentation and failure to warn, and fraud.\textsuperscript{176}

All of the plaintiff's claims were found to be preempted because they could constitute regulations different from or additional to those found in the MDA.\textsuperscript{177}

In \textit{Kennedy v. Collagen Corp.}, the plaintiff was injected with a collagen implant and subsequently developed systemic lupus erythematosus.\textsuperscript{178} In making its decision, the court rejected the analysis used in preceding cases.\textsuperscript{179} Rather, the court reviewed certain FDA interpretations of the ap-

\textsuperscript{172} They certainly would add requirements that would be different from or additional to the requirements set forth in the MDA. \textit{Id.} at 1280-81. In addition, the court indicated in dicta that the mislabeling, misbranding, and adulteration claims were not preempted, and it upheld the lower court's granting of summary judgment against Collagen Corporation on these claims. \textit{Id.} at 1281-82.

\textsuperscript{173} \textit{Id.} at 1283. The court based its judgment on the notion that to allow such a claim to proceed would require courts to make detailed inquiries into the PMA process, essentially performing the same function with which the FDA is entrusted. \textit{Id.} at 1283 (citing Michael v. Shiley, Inc., 46 F.3d 1316, 1329 (3rd Cir.), cert. denied, 116 S. Ct. 67 (1995)).

\textsuperscript{174} \textit{Mitchell}, 67 F.3d at 1284. The court found this claim preempted to the extent that it alleged a breach of an implied warranty with respect to the design, manufacturing, or labeling of the product, because the product was subject to such requirements under the MDA. \textit{Id.} at 1284 (citing Michael, 46 F.3d at 1325).

\textsuperscript{175} \textit{Mitchell}, 67 F.3d at 1285. The court relied on other cases which held that express warranty claims were not preempted by the MDA. \textit{See id.} (discussing American Airlines, Inc. v. Wolens, 513 U.S. 219, 222, 228-29 (1995); Michael, 46 F.2d at 1325).

\textsuperscript{176} \textit{Id.} at 1130, 1131 (1st Cir. 1993).

\textsuperscript{177} \textit{Id.} at 1131-32. The court discussed the submissions required in the PMA process and listed the information submitted to the FDA in this case. \textit{See id.} This included proposed labeling, extensive safety testing data, descriptions of manufacturing methods and materials, and certain revisions after the initial submissions. \textit{Id.} at 1131.

\textsuperscript{178} \textit{Id.} at 1135-36.

\textsuperscript{179} \textit{Id.} at 1135.

\textsuperscript{177} \textit{Id.} at 1458. The court claimed that courts previously addressing this
The court concluded that the PMA process does not qualify as a "specific requirement applicable to a particular device" and that Congress did not intend to foreclose relief for those injured by a device regulated by the MDA and approved through the PMA process.

In most cases discussed above, the courts held that the MDA preempted the state tort claims. With the exception of claims for express warranty, fraud on the basis of advertising, and the entire Kennedy decision, courts have found that regulations existing under the MDA with respect to Class III devices introduced after a PMA process preempted state tort claims. As discussed in the following section, similar results have been reached with respect to devices approved for use under the IDE exception.

C. Cases in Which a Device Was Marketed Under the Investigational Device Exemption

This section discusses cases in which courts have considered whether the MDA preempts state tort suits with respect to a device marketed under the IDE exception to the PMA process. As the analysis shows, courts consistently found that state tort claims were preempted when the device in question was being marketed pursuant to the IDE exception to the PMA process.

In Becker v. Optical Radiation Corp., the plaintiff was injured when a defective experimental lens was implanted in her eye. The product was being used without undergoing the PMA process pursuant to the IDE exception. The issue had failed to address the following issues adequately: the meaning of the term "general applicability" as it is used in the MDA; the question of whether Class III devices as a group may be a "particular device" as that term is used by the FDA; and the meaning of certain regulations promulgated by the FDA. Id. at 1458-59.

180. Id. at 1459. The court determined that 21 C.F.R. § 808.1(d)(1) stood for the proposition that the MDA does not preempt laws of general applicability. Id. The court then found that state tort law is law of general applicability because it merely imposes an indirect effect on manufacturers and, therefore, such laws are not preempted under the MDA. Id.

181. Id. The fact that the PMA process involves some specific requirements was distinguished from the notion the PMA process is itself acting as a specific requirement. Id.

182. Id. This line of reasoning - claiming Congress would have been required to use more specific language to end the possibility of a consumer having any remedy against a medical device manufacturer - appears again in the Medtronic court of appeals' decision. See Lohr v. Medtronic, Inc., 56 F.3d 1335, 1345-46 (11th Cir. 1995). The Kennedy court also noted that the approval of medical devices was not intended to free manufacturers from ordinary market burdens such as state tort suits. Kennedy, 67 F.3d at 1459. The court noted, "Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers." Id. at 1460.

183. 66 F.3d 18, 19 (2d Cir. 1995).
ception. The court found that the IDE exemption to the general requirements applies only when the manufacturer has obtained the informed consent of the patient. The court then analyzed the preemption question under the assumption that the IDE exemption did not apply to the lens in question and, in the alternative, under the assumption that it did apply to the lens. The court found that if the lens were not exempt from normal MDA requirements through the IDE exemption, the lens would have to undergo the PMA process, which constitutes a device-specific requirement. The court then held that the tort claims of defective design, defective manufacture, failure to warn, and failure to test impermissibly would add requirements different from those imposed by the MDA. Next, the court considered whether the claims being asserted would be barred by MDA preemption if the lens were exempt from the normal MDA requirements by means of the IDE exemption. The court held that the state tort claims being asserted in this case would impose requirements different from "the MDA scheme" and therefore were preempted.

In Martin v. Telectronics Pacing Systems, Inc., the plaintiff was injured when she received a defective pacemaker that had been approved for use under the IDE exception to the PMA process. The court found that the IDE exception imposed several device-specific requirements with respect to the pacemaker. The court held that all of the plaintiff's state tort claims would impose additional requirements different from those imposed by the MDA.

184. Id. at 20. The court cited 21 C.F.R. § 813.5, which the court says "arguably" states that a shipment of the lenses in question is not exempt unless the informed consent of the patient has been obtained. Id.

185. Id.

186. Id.

187. Id. The court cited several cases in support of the proposition that tort claims impose requirements different from those imposed by the MDA. Id. (citing Reeves v. Acromed Corp., 44 F.3d 300 (5th Cir.), cert. denied, 115 S.Ct 2251 (1995); Martello v. Ciba Vision Corp., 44 F.3d 1167, 1168-69 (8th Cir. 1994), cert. denied, 115 S. Ct. 2614 (1995); Stamps v. Collagen Corp., 984 F.2d 1416, 1420-25 (5th Cir. 1993); and King v. Collagen Corp., 983 F.2d 1130, 1135-36 (1st Cir. 1993)).

188. Becker, 66 F.3d at 21.

189. Id. The court noted that there were detailed procedures in place for determining whether the lenses in question were safe and effective under the MDA. The court cited several cases in support of the proposition that state tort theories would impose impermissible additional requirements on intraocular lenses. See id. (citing Gile v. Optical Radiation Corp., 22 F.3d 540, 542-44 (3rd Cir. 1994); Duncan v. Iolab Corp., 12 F.3d 194, 195 (11th Cir. 1994); Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333-34 (7th Cir.), cert. denied, 113 S. Ct. 927 (1992)).


191. Martin, 70 F.3d at 42. The court cited the following provisions as examples of device-specific regulations imposed through use of the IDE exemption:
claims were preempted by section 360k(a) of the MDA in that they would impose requirements different from those imposed under the MDA's device-specific regulations. 192

In *Gile v. Optical Radiation Corp.*, the plaintiff was blinded in one eye when she had an experimental replacement lens removed. 193 The lens had been approved for use under the IDE exception to the PMA process. 194 The court first determined that state tort claims can constitute requirements for purposes of MDA preemption. 195 The court went on to address whether any of the specific tort claims asserted in the case at hand were preempted. 196 The court found that the IDE exemption does impose device-specific regulations and that the tort theories being asserted in this case would impermissibly impose requirements different from those imposed by the MDA. 197 The court found all of the plaintiff's state tort claims preempted by section 360k(a) of the MDA. 198

In each of the above cases involving an IDE device, the courts strictly applied section 360k(a) preemption. This was due, in large part, to the public policy favoring experimentation and the development of new devices. The next section will show that section 360k(a) has not been applied as strictly with respect to devices approved for marketing under section 510(k) notification.

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21 C.F.R. § 812.5, which mandates investigational device labeling; 21 C.F.R. § 812.7, which prevents the promotion of IDE devices and prohibits representations that the device is safe or effective for the purposes for which it is being tested; and 21 C.F.R. § 812.25(f), which requires that all labeling with respect to IDE devices be submitted to the FDA for approval. *Id.*

192. *Id.* at 41. The plaintiffs also made a novel Seventh Amendment argument that the government cannot preempt a state tort action if it provides no other analogous tort remedy. *Id.* at 42. The court, however, did not find this argument persuasive. *Id.*

193. 22 F.3d 540, 541 (3rd Cir. 1994).

194. *Id.* at 542.

195. *Id.* at 543. The court based this determination on *Cipollone*, in which the Supreme Court held that state tort theories can be requirements for purposes of an express preemption provision where the provision itself does not specifically mention state tort law. *Id.*

196. *Id.* Claims of lack of informed consent and adulterated products were asserted in this case. *Id.*

197. *See id.* at 544-45. The plaintiff raised an interesting argument to the effect that public policy favors allowing remedies to the injured victims of experimental treatment. *Id.* at 545. The court found that there is a countervailing public policy favoring encouragement of discovery and development of new products. *Id.* at 546.

198. *Id.* at 545.
D. Cases in Which a Device Was Marketed Under Section 510(k) Notification

The reasoning that consistently has been applied to cases involving the preemption of state tort claims under the MDA has not been applied consistently to cases involving devices approved for marketing under section 510(k) notification. In this section, six cases are discussed. Four of the cases employ the reasoning found in the decisions finding state tort claims preempted by the MDA. However, two of the decisions depart from the rationale of decisions involving devices approved for marketing under theories other than section 510(k) notification. The reasoning in these decisions laid the foundation for the Supreme Court’s decision in Medtronic. The decisions finding preemption are discussed first, followed by an explanation of the two decisions in which courts refused to find state tort claims preempted with respect to section 510(k) devices.

1. Cases Finding State Tort Theories Preempted

In English v. Mentor Corp., the plaintiff was injured when his inflatable penile implant malfunctioned. The implant had been approved for marketing by the FDA through the section 510(k) notification exception to the PMA process, also known as the substantial equivalence exception. The court held that the section 510(k) process and the “general controls” that apply to section 510(k) products create requirements sufficient to create preemption. The court concluded that all of the plaintiff’s state tort claims were preempted by section 360k(a).

199. 67 F.3d 477, 478 (3rd Cir. 1995).
200. Id. at 480. The court noted that the FDA views the section 510(k) notification procedure as an intermediate step to obtaining full premarket approval and that the FDA eventually will require the product to endure a full PMA process. Id.
201. Id. at 481-82. The plaintiffs specifically had argued that MDA preemption did not apply when the product in question was approved under section 510(k). Id. at 482-83. The court found the following to be examples of requirements specifically applicable to the device under section 510(k): the notification must include proposed labels, labeling, and advertisements sufficient to describe the device; its intended use; photos or engineering drawings of the device; a statement that the device is similar to and/or different from other products; any other information requested by the FDA; and “general controls” which include labeling requirements and good manufacturing practices. Id. at 481.
202. Id. at 483. The court reversed summary judgment on the breach of express warranty claim and remanded for consideration of that claim. Id. at 484. The plaintiff had also brought claims of strict product liability, negligence, and breach of implied warranty. Id. at 483.
In *Mendes v. Medtronic*, the plaintiff brought suit after his pacemaker failed. The pacemaker was approved for marketing as a substantial equivalent under the section 510(k) exception to the PMA process. The court found that the general controls imposed on the device with respect to labeling and good manufacturing practices constituted requirements for purposes of section 360k(a). The court considered the causes of action individually and found each of the following tort theories preempted: negligent failure to warn, implied warranty, and negligent manufacture.

The plaintiff in *Griffin v. Medtronic, Inc.*, brought suit after she was injured by an allegedly defective pacemaker which was approved for marketing and use by the FDA under the 510(k) premarket notification procedure. The court found that all of the state tort claims were preempted by section 360k. In addition, the court remanded the case for the district court to determine whether the claim was based on voluntary promises made by Medtronic, in which case it would not be preempted.

In *Duvall v. Bristol-Myers-Squibb Co.*, an individual was injured by the failure of a penile implant that had been approved for marketing and use by the FDA through section 510(k). The plaintiff argued that section 360k did not preempt his state-law claims since there were no requirements applicable to the defendant’s device from which the state requirements could differ. The court rejected this argument, finding that a variety of requirements were imposed by the section 510(k) process. The

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203. 18 F.3d 13, 15 (1st Cir. 1994).
204. See id. The court noted that the device had been sold since 1981 without premarket approval. Id.
205. Id. at 18-19. The court held that labeling rules found in 21 C.F.R. §§ 801.1, 801.15, and 801.109 and the good manufacturing practices found in 21 C.F.R. §§ 801.1 to 820.198 constitute requirements for purposes of 360k(a) preemption. Id.
206. Id. at 18-20.
207. 82 F.3d 79, 81-82 (4th Cir. 1996), cert. granted and judgment vacated by 117 S. Ct. 939 (1997).
208. Id. The court found the following claims to be preempted: negligent design and manufacture, breach of implied warranty for fitness for a particular purpose, strict liability for defective manufacture, and intentional misrepresentation. Id. The court also held that the 510(k) process, in and of itself, constitutes a “requirement” for purposes of section 360k(a). Id. at 82.
209. Id. The court held that if the express warranty claim were found on remand to be based on FDA-mandated rules with respect to advertising, labeling, and packaging, then it would be preempted by section 360k(a). Id. at 83.
210. 65 F.3d 392, 395-96 (4th Cir. 1995). In this case, the FDA required the manufacturer to provide additional information with respect to “sterilization techniques, testing protocols, design of specific components of the device, package inserts, indicated uses and fluid requirements.” Id.
211. Id. at 396.
212. Id. at 399. The court found the following to constitute requirements under section 360k(a): good manufacturing practices, the 510(k) notification process itself, and labeling requirements. Id.
court then held that all state tort claims were preempted, with the possible exception of the express warranty claim. 215

2. Cases Finding State Tort Theories Not Preempted

In *Jacobs v. E.I. du Pont de Nemours & Co.*, the plaintiff brought suit after being injured by an allegedly defective temporomandibular joint interpositional implant. 214 This device was distributed after a section 510(k) premarket notification procedure. 215 The court declined to determine the entire scope of preemption under the MDA, focusing instead on the plaintiff's individual claims. 216 The court noted that there were no specific counterpart regulations or any specific requirements with respect to the device in question, because the defendant had been a supplier of raw materials, an entity not regulated by the MDA. 217 Further, the court found that there were no specific requirements or any specific counterpart regulations applicable to the device. 218 Based on these determinations, the court found that the plaintiff's state tort claims were not preempted. 219

In *Feldt v. Mentor Corp.*, the plaintiff alleged injury after the failure of an implanted pump-activated inflatable penile prosthesis. 220 The device was marketed as a substantial equivalent under section 510(k). 221 The court held that there were specific requirements applicable to the device in question, 222 including regulations with respect to labeling and warnings. 223 Based on its analysis, the court went on to discuss whether any

213. *Id.* at 401. The basis for this decision was the notion that an express warranty claim is based upon voluntary promises that are made by the warrantor instead of upon duties imposed under state law and, therefore, promises are not preempted by section 360k(a). *Id.*

214. 67 F.3d 1219, 1222 (6th Cir. 1995). The offending implant was coated with the defendant's Teflon product as substitute cartilage. The temporomandibular joint is more commonly known as the jaw joint. *Id.*

215. *Id.* at 1225 n.13. The letter authorizing the marketing of the device as a substantial equivalent through section 510(k) is reprinted in the opinion. *Id.* The end of the letter states, "This letter should not be construed as approval of your device or its labeling." *Id.*

216. *Id.* at 1234.

217. *Id.* at 1236.

218. *Id.* (discussing Anguiano v. E.I. du Pont de Nemours & Co., 44 F.3d 806 (9th Cir. 1995); Lamontagne v. E.I. du Pont de Nemours & Co., 834 F. Supp. 576 (D. Conn. 1993), aff'd, 41 F.3d 846 (2d Cir. 1994)).

219. *Id.*

220. 61 F.3d 431, 432 (5th Cir. 1995).

221. *Id.* at 434.

222. *Id.* at 435-36. "Preemption does not depend on the route the product takes to the market, but on whether there are any specific federal requirements applicable to the device." *Id.* (citing Reeves v. Acromed Corp., 44 F.3d 300, 305 (5th Cir. 1995)).

223. *Id.* at 436. The plaintiff apparently conceded that federal regulations preempted his failure-to-warn claim. *See id.*
other specific requirements affected the device. The court held that the plaintiff's breach of warranty with respect to design and defective design claims were not preempted because no FDA regulations applied with respect to design.

Four of the cases discussed in the preceding section concluded that section 360k of the MDA preempted state tort claims against manufacturers of devices approved through the section 510(k) notification process. However, the Jacobs and Feldt courts held that the PMA process, in and of itself, does not create "requirements" sufficient to invoke section 360k preemption. On this basis, those courts ruled that the MDA did not preempt the state tort claims in question.

E. FDA Interpretation

The FDA has also interpreted the meaning of section 360k(a) of the MDA, stating:

Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that... no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

The FDA interpretation continues:

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

224. Id. at 436-38 (noting that the existence of some federal requirements did not necessarily mean all claims were preempted).
225. Id. at 438. The court noted that the defendant had not cited, and the court was unable to find, any specific FDA regulations that were applicable to the design of the device in question. Id. at 437.
226. See Exemptions From Federal Preemption of State & Local Medical Device Requirements, 21 C.F.R. § 808 (1996). This chapter is a means by which certain regulations can be exempted from the preemption of section 360k(a). See id. § 808.1(a). Interestingly, FDA regulations state that Minnesota Statutes sections 145.43 and 145.44 were denied an exemption by the FDA and are, therefore, preempted by section 521(a) of the MDA. See id. § 808.73.
227. Id. § 808.1(b).
addition to, the specific Food and Drug Administration requirements.\textsuperscript{228}

The FDA's interpretation goes on to describe other state and local requirements that affect medical devices, but that are not preempted by section 360k(a).\textsuperscript{229} It states, in pertinent part:

Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices... or to unfair trade practices in which the requirements are not limited to devices.

\ldots

\ldots Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.\textsuperscript{230}

Courts have interpreted this language in different manners.\textsuperscript{231}

F. Conclusion

There had been considerable disagreement among the various federal circuit courts of appeals with respect to whether there are any preemptive effects resulting from the MDA, specifically sections 360k(a) and 510(k).\textsuperscript{232} Courts were allowing express warranty claims to survive in cases involving Class III PMA devices\textsuperscript{233} and were split on the extent of preemption with respect to Class III substantially equivalent devices.\textsuperscript{234} Although not detailed here, federal district courts were in as much conflict on the issue of preemption of state-law claims by section 360k(a) of the MDA as the federal circuit courts.\textsuperscript{235} Even the FDA's interpretation of the provi-

\textsuperscript{228} Id. § 808.1(d).
\textsuperscript{229} Id. § 808.1(d)(1)-(9).
\textsuperscript{230} Id. § 808.1(d) (1), (d)(6) (ii).
\textsuperscript{231} See supra Parts IV.A-C (discussing several cases in which this language is interpreted).
\textsuperscript{232} See supra Part IV.A-D (discussing relevant cases); see also 21 U.S.C. §§ 360k(a), 510(k) (1994).
\textsuperscript{233} See supra Part IV.B (discussing cases in which devices were marketed after PMA approval).
\textsuperscript{234} See supra Part IV.D (discussing cases in which devices were marketed under section 510(k) notification).
\textsuperscript{235} See, e.g., Moss v. Outboard Marine Corp., 915 F. Supp. 183 (E.D. Cal. 1996) (holding that an express preemption provision contained in the Federal Boat Safety Act preempts common-law actions in addition to positive state enactments); Blanchard v. Collagen Corp., 909 F. Supp. 427, 437 (E.D. La. 1995) (concluding that state common-law claims are preempted by section 360k(a) of the
sion in question had been cited for different propositions. The Supreme Court granted certiorari in *Medtronic v. Lohr* to resolve the conflict.

V. THE *MEDTRONIC* DECISION

In *Medtronic v. Lohr*, the United States Supreme Court considered whether the doctrine of federal preemption bars a state tort suit against the manufacturer of a medical device that was sold under the regulatory guise of the Medical Device Amendments of 1976 (MDA). The Supreme Court granted certiorari in this case to reconcile a disagreement among the federal courts of appeals over the extent to which the MDA preempts state common-law claims. In doing so, the Supreme Court


239. *See Medtronic*, 116 S. Ct. at 2250; *see also supra* Part IV.A-D (discussing


See supra Part IV.E.

236. *See supra* Part IV.E.


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 any 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.


239. *See Medtronic*, 116 S. Ct. at 2250; *see also supra* Part IV.A-D (discussing
squared MDA preemption of state-law claims with the policy rationale underlying the MDA, by preventing manufacturers from introducing untested medical devices while being shielded from tort suits. 240

A. Factual Background

The Medtronic case involved a malfunctioning cardiac pacemaker. 241 Medtronic designed and manufactured various models of "pacemaker leads." These "leads" are the wires that extend out of the pacemaker and come into direct physical contact with the heart. The leads transfer the pacemaker's electric signal to the heart muscle, stimulating it so that it beats at a regularized rate. 242 Model 4011 pacemaker leads were used in the pacemaker implanted in the plaintiff Lora Lohr. 243 The Lohrs alleged that three years later after the pacemaker was implanted, it failed, resulting in a "complete heart block" requiring emergency surgery. 244 The Lohrs' physician attributed the failure of the pacemaker to the pacemaker leads. 245

B. Procedural Background

The Lohrs filed an action in Florida state court under the theories of negligence and strict liability. 246 Medtronic successfully moved to have the case removed to federal district court where it filed a motion for summary judgment. 247 In its motion, Medtronic argued that the Lohrs' claims were barred by the express preemption provision of the MDA. 248 The district court denied the motion. 249

the lack of uniformity among federal circuit courts of appeals). 240. See Medtronic, 116 S. Ct. at 2245 (stating, in the first words of the opinion, that "Congress enacted the Medical Device Amendments of 1976, in the words of the statute's preamble, 'to provide for the safety and effectiveness of medical devices intended for human use'"). 241. Id. at 2248. 242. Id. 243. Id. 244. Id. 245. Id. 246. Medtronic, 116 S. Ct. at 2248. The negligence claim included an alleged breach of the 'duty to use reasonable care in the design, manufacture, assembly and sale of the subject pacemaker' in several respects, including the use of defective materials in the lead and a failure to warn . . . . The strict liability count alleged that the device was in defective condition and unreasonably dangerous to foreseeable users at the time of its sale. Id. The Lohrs' complaint also included a third count alleging breach of warranty; the count was dismissed by the Florida state court for failure to state a claim. Id. 247. Id. 248. Id. 249. Id. at 2249.
Soon after the Medtronic district court decision, the United States Court of Appeals for the Eleventh Circuit decided Duncan v. Iolab. In Duncan, the court held that the preemption provision of the MDA required preemption of some common-law claims brought against a medical device manufacturer. In light of the Duncan decision, the district court reversed its earlier decision and dismissed the Lohrs' complaint in its entirety. The Eleventh Circuit affirmed in part and reversed in part, holding that the Lohrs' negligent design claims were not preempted by the MDA but that the negligent manufacturing and failure to warn claims were preempted by certain FDA regulations. Finally, the Eleventh Circuit held that the Lohrs' strict liability claims were not preempted with respect to their unreasonably dangerous design claims, but that preemption did prevent the Lohrs from going forward with their negligent manufacturing and failure to warn claims. The Supreme Court granted Medtronic's petition for certiorari on January 19, 1996.

C. The Supreme Court's Analysis

The Supreme Court considered three central issues in Medtronic. The threshold issue was whether all tort claims were preempted by the MDA. Medtronic argued that the entire complaint should be dismissed on this basis. Second, the Supreme Court considered the Lohrs' claims individually, analyzing whether section 360k(a) preempted the individual state tort claims brought by the Lohrs. The individual claims included a defective design claim, an identity of requirements claim, a manufacturing claim, and a labeling claim. Finally, the Court considered whether the

250. 12 F.3d 194 (11th Cir. 1994).
251. Id. at 195.
252. Medtronic, 116 S. Ct. at 2249.
253. Lohr v. Medtronic, Inc., 56 F.3d 1335, 1352 (11th Cir. 1995) (noting that common-law actions are requirements imposed by the state for purposes of the MDA's preemption provision, that preemption could not be avoided by claiming that the negligence in question flowed from a violation of federal standards, that the term "requirements" in the MDA's preemption provision was unclear, and that in view of the FDA regulations with respect to the meaning of "requirements," the specific device in question would have to be regulated to fit the definition).
254. Id. at 1344-45; see also Medtronic, 116 S. Ct. at 2249 (noting that the court of appeals based its decision on the FDA's general "good manufacturing practices" and labeling regulations).
255. Medtronic, 56 F.3d at 1351-52.
257. Medtronic, 116 S. Ct. at 2240-55.
258. Id. at 2245.
259. Id. at 2251.
260. Id. at 2254.
261. Id. at 2254-56.
presence of a damages remedy amounted to an additional or different requirement for purposes of section 360k(a) preemption.\footnote{262}

1. Preemption of the Negligent Design Claim

Medtronic argued the Lohrs' negligent design claim was preempted by section 360k(a).\footnote{263} Medtronic argued that any common-law action would constitute a "requirement" that would, in effect, be "different from, or in addition to" the general federal standards found in the MDA and, therefore, would be preempted.\footnote{264} The Court disagreed with Medtronic, concluding that such a reading of the statute would be implausible.\footnote{265} In its analysis, the Court noted that the MDA does not give an express private right of action for violation of its regulations and that an implied private right of action had not even been suggested.\footnote{266} Based on these observations, the Court noted that if Medtronic were correct and all common-law claims were preempted by the MDA, private plaintiffs would have no recourse against manufacturers of devices falling under this statute.\footnote{267}

Such a result contradicts the first policy underlying the MDA — to protect the public from harm by ensuring the safety and effectiveness of medical devices.\footnote{268} The court noted that to allow a product to be marketed and sold without any safety assurances, while holding that individuals harmed by such products have no recourse, would contradict this policy.\footnote{269} The Court explicitly stated that Congress's purpose in enacting the MDA was to provide more stringent regulation of these devices and their manufacturers rather than freeing them entirely from potential liability.\footnote{270} Looking to the language of the statute, the Court concluded that "it would take language much plainer than the text of [section] 360k to convince us that Congress intended that result."\footnote{271} Examining section 360k(a)'s language, the Court noted that the preemption provision in question uses the word "requirement."\footnote{272} The Court observed that Congress easily could have used the word "remedy" instead of "requirement" and that such language would have clearly made the preemption provision of the MDA applicable to state common-law claims.\footnote{273}

\footnote{262. \textit{Medtronic, Inc. v. Lohr}, 116 S. Ct. at 2255.}
\footnote{263. \textit{Medtronic, Inc. v. Lohr}, 116 S. Ct. at 2251.}
\footnote{264. \textit{Id.}}
\footnote{265. \textit{Id.}}
\footnote{266. \textit{Id.}}
\footnote{267. \textit{Id.}}
\footnote{268. \textit{Id.} at 2245.}
\footnote{269. \textit{Medtronic, Inc. v. Lohr}, 116 S. Ct. at 2251.}
\footnote{270. \textit{Id.} at 2245.}
\footnote{271. \textit{Id.} The result implies a scenario in which no recourse exists for parties injured by devices covered by the MDA. \textit{See id.}}
\footnote{272. \textit{Id.}}
\footnote{273. \textit{Id.}}
The Court then distinguished this case from *Cipollone v. Liggett Group, Inc.*, in which the Supreme Court held that a statute preempting state "requirements" could also preempt common-law damages claims. Initially, the Court posited that the preemption statute in *Cipollone* did not have ramifications as broad as those advocated for the MDA by Medtronic. The Court explained that the preemption in *Cipollone* was quite narrow and that giving the result in that case its widest possible interpretation would result in preemption under only limited circumstances. The Court's analysis relied heavily on the fact that under *Cipollone*, it was still possible to bring some common-law claims, thereby insuring that individuals have some legal recourse available. In contrast, Medtronic's position would preclude all such claims and leave plaintiffs without legal redress. In addition, the Court looked at the issue from a federalism viewpoint and held that to adopt Medtronic's position would be a "serious intrusion into state sovereignty." The Court held that to give such effect to language as ambiguous as that in the preemption provision of the MDA would be unacceptable.

Continuing its attack on the position advocated by Medtronic, the Court distinguished the two statutes in question. The Court compared the language of section 360k to the language of the preemptive statute at issue in *Cipollone*, and it concluded that Congress was concerned with "specific, conflicting State statutes and regulations rather than the general duties enforced by common-[law]-law actions" when it enacted section 360k.

In support of its decision to reject Medtronic's position, the Court directed its attention to the basic purpose of section 360k. The Court explained that the legislative history of the MDA reflected a desire to curb federal and state regulatory burdens, not preexisting common-law du-

275. See Medtronic, 116 S. Ct. at 2252.
276. Id.
277. Id. (noting that *Cipollone* would result in preemption of state common-law damages claims only when the requirements are based on health and smoking and, of those actions, only those that involve the promotion or advertising of cigarettes that are labeled in conformity with the provisions of the federal statute in question).
278. Id.
279. Id. at 2251.
280. Id. at 2252.
281. Medtronic, 116 S. Ct. at 2252.
282. Id.
283. Id. (noting that section 360k refers to "requirements" frequently and consistently throughout its text, that this word is linked with language suggesting that Congress intended preemption of specific positive law, and that within the act itself, the FDA is given authority to exempt "requirements" from preemption and while having made exemptions has never done so with respect to any common-law duty).
284. Id. at 2252-53.
Further, the Court noted that any concern that Congress had for protecting the medical device manufacturing industry was reflected in the enactment of fewer substantive provisions within the Act itself and not by means of section 360k(a). The Court also stated that the "primary issue motivating the MDA's enactment" was the safety of consumers using the products that are covered by the MDA. In other words, the Court decided that Medtronic's interpretation of the MDA undercut the policy underlying the Act— to protect the public from harm by ensuring the safety and effectiveness of medical devices.

Finally, the Court relied upon legislative history to support the conclusion that section 360k(a) was not intended to preempt most, and certainly not all, suits brought under general common-law theories. The Court concluded that due to the lack of language indicating such a result, combined with the somewhat imprecise language of section 360k(a), "at least some common[-]-law claims against medical device manufacturers may be maintained after the enactment of the MDA."

An important policy consideration underlies this portion of the Court's decision. The underlying policy of the MDA is to protect the public from harm by ensuring the safety and effectiveness of medical devices. In this case, the device in question had never been tested by the FDA for safety and effectiveness because it was marketed under the "substantial equivalence" exception to premarket approval. Because this device had not been proven safe or effective, the only safety-related constraint upon the manufacturer was the threat of a tort suit. If that piece of the regulatory puzzle is removed, then nothing remains to protect the public from harm and, at that point, the MDA's purpose is undermined.

285. Id. at 2253 (citing 122 Cong. Rec. 5850 (Mar. 9, 1976)).
286. Id.
287. Medtronic, 116 S. Ct. at 2253. Interestingly, the Court did not cite to any MDA provision, any legislative history, or anything else to support this proposition.
288. See supra note 45 and accompanying text.
289. See Medtronic, 116 S. Ct. at 2253 (noting that there is no language in the hearings, the committee reports, or the debates suggesting that the legislation in question should have the broad sweeping preemptive effect advocated by Medtronic).
290. See id. (noting the absence of language to support Medtronic's position not only in the Act and its legislative history, but also in a number of reviews of the legislation by other authors).
291. See supra note 45 and accompanying text.
292. Medtronic, 116 S. Ct. at 2254; see also supra Part III.C.2 (discussing the "substantial equivalence" exception).
293. Medtronic, 116 S. Ct. at 2254.
294. Id. at 2251 (explaining that "Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry").
2. Individual State Tort Claims

Next, Medtronic argued that even if all common-law claims were not preempted by section 360k(a), the Lohrs' claims in this case were preempted individually. In analyzing this argument, the Court addressed the Lohrs' claims individually to determine whether they imposed any requirements different from or additional to any already in place. Each of these claims is discussed in turn.

a. Premarket Approval and the Defective Design Claim

First, Medtronic argued that a suit under a state common-law theory of defective design is preempted by the FDA's determination that the pacemaker leads in question are "substantially equivalent" to pacemaker leads sold previously. Substantial equivalence, or section 510(k) approval, is a determination made by the FDA pursuant to the MDA and allows medical device manufacturers to market their products without proving the safety and effectiveness of the device through the PMA process.

Medtronic argued that a state common-law suit alleging defective design would be preempted by the FDA's determination that the pacemaker leads were "substantially equivalent" under section 510(k) and that such a determination amounts to a specific and federally enforceable design requirement. The Court, however, rejected this argument on the basis that the section 510(k) process is not aimed at a determination of safety and effectiveness, but rather is aimed at "substantial equivalence," thereby providing little protection to the public with respect to the safety and effectiveness of the product. In support of this position, the Court noted that the letter from the FDA to Medtronic contained a disclaimer specifically precluding Medtronic from representing to the public that the FDA approved of the safety or effectiveness of their pacemaker leads.

The Court adopted the position that due to the nature of the section 510(k) process, the FDA had not issued any "requirements" with respect to the pacemaker leads at issue and, therefore, section 360k was not invoked. An opposite holding would allow manufacturers to be absolved...
from any tort liability under circumstances in which they are faced with no other source of liability. Such a result would fly in the face of the MDA's policy.303

b. Identity of Requirement Claims

The Lohrs argued that even if the premarket notification process imposed "requirements" with respect to the manufacturing and labeling of the pacemaker and even if state-law claims imposed a "requirement" under the MDA, the state "requirement" would not be preempted unless it were "different from, or in addition to" the federal requirement.304 Specifically, the Lohrs argued that they could sue in state court based on Medtronic's violation of FDA regulations.305 The Court held that state requirements that are parallel to, or narrower than, the FDA regulations are not "different from, or in addition to" the federal requirements within the meaning of the statute and, therefore are not preempted.306

Again, the Court distinguished this case from Cipollone on the basis of statutory differences.307 Specifically, the Court found that the statute considered in Cipollone had a preemptive effect, whereas the structure of the MDA requires the FDA to promulgate a "requirement" in order to preempt specific state laws.308 The Court also noted that because the FDA is given the authority to implement the provisions of the MDA in this fashion, it is "uniquely qualified" to determine what, if anything, should be preempted by the MDA.309 Further, the Court noted that the regulations promulgated by the FDA supported the Lohrs' arguments, in that no common-law claims had been declared to be preempted.310

c. Manufacturing and Labeling Claims

The Lohrs also argued that Medtronic's preemption defense should be rejected outright with respect to their manufacturing and labeling

out that the FDA included a disclaimer with the letter approving marketing of the pacemaker leads, stating that the FDA did not approve of the safety or effectiveness of the device. Further, the Court pointed out that section 510(k) was intended to maintain the status quo with respect to devices on the market before the MDA was enacted and their substantial equivalents. This status quo included the possibility of defending a tort suit. Id. at 2255.

303. See supra notes 45-47 and accompanying text.
304. Medtronic, 116 S. Ct. at 2255.
305. Id.
306. Id.
307. Id.
308. Id. (explaining that "[u]nlike the statute construed in Cipollone, for instance, preemption under the MDA does not arise directly as a result of the enactment of the statute").
309. Id.
310. Medtronic, 116 S. Ct. at 2256.
As explained earlier, certain regulations apply to both the manufacturing and labeling of medical devices. These regulations are enforceable by the FDA and require such devices to be labeled with information on use of the product, relevant hazards, side effects, and precautions. Similarly, manufacturers must comply with "Good Manufacturing Practices," or GMPs. These requirements apply to Class I, Class II, and Class III devices whether they have been approved through the PMA process or one of its exceptions.

The Lohrs argued that section 360k(a) mandates preemption only where there is a conflict between a specific state regulation and a federal regulation specifically applicable to the same device. The Lohrs posited that the general nature of the manufacturing and labeling regulations precludes those regulations from meeting the standard of specific applicability to a given device. On this basis, the Lohrs argued that section 360k(a) preemption was not invoked and their claim was not preempted.

The Court agreed with the Lohrs on this issue, citing FDA regulations and exemptions to section 360k(a) preemption granted by the FDA to support this conclusion. The Court noted that none of the existing exemptions was applicable to a state law of general applicability, only to "excruciatingly specific" state requirements. Further, neither the existing requirements as described above, nor the state common-law claims asserted by the Lohrs, were specific enough or directed at a specific device and, therefore, section 360k(a) preemption was not invoked.

d. Common-Law Duties Can Never Be "Requirements"

Finally, the Lohrs argued that common-law duties can never be "requirements" for purposes of section 360k(a) and, therefore, this statute can never preempt common-law actions. The Court specifically declined to address this issue for two reasons. First, the issue was merely hypothetical in this case, because the Court already had found that none of the

311. Id.
312. See supra Part III.A.
313. Medtronic, 116 S. Ct. at 2258.
314. Id.
315. See supra Part III.A.
316. Medtronic, 116 S. Ct. at 2256.
317. Id.
318. Id.
319. Id. at 2257.
320. Id.
321. Id. at 2258.
322. Medtronic, 116 S. Ct. at 2258.
323. Id. at 2259.
Lohrs' claims was preempted. Second, in view of the decision's emphasis on device specificity, very few, if any, common-law duties could be preempted by section 360k(a). In the Court's analysis, such a determination would have to be made on the facts of the case and the interpretation of the statute given by the Court.

e. Concurrences and Dissents

Given the lack of uniformity at the appellate level on this issue, it is not surprising that the United States Supreme Court was not unanimous in the Medtronic decision. In fact, the court was distinctly split on central issues. Justice Breyer wrote a concurring opinion. Justices O'Connor, Brennan, Scalia, and Thomas concurred in part and dissented in part. The dissent focused on the manner in which the majority opinion distinguished this case from Cipollone. The dissent did not agree that the two statutes were distinguishable, and thus argued that the outcome in both cases should be the same. In other words, the dissenting Justices felt that the Lohrs' claims should be preempted. The dissenting Justices also was critical of the majority's deference to FDA regulations, noting, "Where the language of the statute is clear, resort to the agency's interpretation is improper." The dissent then argued that the language of section 360k clearly required preemption in this case. Finally, the dissent concluded that a section 360k(a) "requirement" does include state common-law claims.

D. Analysis of the Medtronic Decision

The Medtronic decision was a policy-based decision. The MDA has two major policies underlying its existence: to promote the development of new medical devices and to protect consumers by ensuring the safety and effectiveness of medical devices. The Supreme Court relied heavily on the second policy rationale.

324. Id.
325. Id. (stating 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'").
326. Id.
327. Id. at 2259-62 (Breyer, J., concurring).
328. Medtronic, 116 S. Ct. at 2262-64 (O'Connor, J., dissenting).
329. Id. at 2262-63.
330. Id.
331. Id. at 2263.
332. Id. at 2263-64.
333. Id. at 2253.
334. See supra notes 45-46 and accompanying text.
335. See Medtronic, 116 S. Ct. at 2253.
The Court easily could have found, as many other courts previously had concluded, that there were requirements in place with respect to Class III devices approved for marketing through section 510(k). GMPs and labeling requirements are two examples of regulations applicable to Class III section 510(k) devices that other courts have found to constitute "requirements" for purposes of section 360k(a). Instead, the Court relied heavily upon the fact that if state tort actions are preempted with respect to section 510(k) devices, consumers who are injured by those devices will have no legal recourse against the manufacturers.

VI. IMPLICATIONS

To determine the implications of Medtronic, it is vital to discuss cases that have interpreted the Medtronic decision. By analyzing those cases, the future implications of the Medtronic decision for medical device manufacturers become more clear.

A. Cases Decided Post-Medtronic

Since the Court rendered Medtronic, several federal courts of appeals have had the opportunity to interpret the decision. Each case is discussed below with two goals in mind. The first goal is to explain the holding of the court and the court's interpretation of the Medtronic decision. The second goal is to address whether the court's interpretation is correct in light of Medtronic.

Three groups of cases are discussed. First, this Note discusses cases in which the devices were marketed pursuant to section 510(k) approval. Second, cases involving a device tested pursuant to the IDE exception from premarket approval will be discussed. Finally, this Note examines cases in which Medtronic was used as the basis for a decision but in which neither of the above types of medical devices was involved.

1. Cases Considering Devices Marketed Under Section 510(k)

In Reeves v. Acromed Corp., the Fifth Circuit Court of Appeals held that the MDA did not preempt the plaintiff's unreasonably dangerous per se claim under state law. The court cited Medtronic for the proposition that section 510(k) notification does not amount to a specific, federally enforceable design requirement and, therefore, does not preempt state tort claims. The Fifth Circuit also noted that Medtronic holds that plaintiffs

336. See id.
337. See id. at 2257.
338. 103 F.3d 442, 447 (5th Cir. 1997).
339. Id. at 446. As the Fifth Circuit noted, Medtronic stressed section 510(k) provides little protection to the public because the section 510(k) process focuses
may sue under state rules that duplicate the FDA regulations without involving section 360k(a) preemption, because such rules are not different from or additional to any regulations.\textsuperscript{540}

In \textit{Duvall v. Bristol-Myers-Squibb Co.}, the Fourth Circuit Court of Appeals interpreted \textit{Medtronic} to mean that state common-law causes of action may constitute requirements for purposes of the MDA.\textsuperscript{341} The court, however, indicated that such requirements would be preempted only if they conflict with a specific regulation promulgated by the FDA applicable to the particular device at hand, or with some other device-specific requirement imposed by the MDA.\textsuperscript{342} The court concluded, "[S]tate-law claims pertaining to medical devices subject only to the general controls imposed by the section 510(k) notification process, GMPs, or labeling requirements are not preempted."\textsuperscript{343} Interestingly, the \textit{Duvall} court extended the holding of \textit{Medtronic} to include claims for breach of implied warranty.\textsuperscript{344}

In both \textit{Reeves} and \textit{Duvall}, the respective courts held that the substantial equivalence, or section 510(k), approval process does not create the type of device-specific regulations required to invoke preemption under section 360k(a).\textsuperscript{345} Both courts cited the \textit{Medtronic} decision for that propo-
sition and, on that basis, concluded that state tort remedies would not be preempted with respect to a section 510(k) device. This is clearly a correct interpretation of the Medtronic decision, in that the key holding of the decision is that state tort theories are not preempted by section 360k(a) with respect to devices that are approved for marketing under section 510(k). Both of these decisions correctly apply and adhere to Medtronic.

2. Cases Considering Devices Being Tested Pursuant to the Investigational Device Exemption

Martin v. Teletronics Pacing Systems, Inc. distinguished between cases involving devices approved for marketing by showing the devices were substantially equivalent to preexisting devices, and those marketed under the IDE exception to the PMA process. In Martin, the device at issue was approved for use under the IDE exemption to the PMA process. In Martin, the court analogized the process of receiving approval for an IDE device to the PMA process. The court noted that like the PMA process, the IDE process subjects the device in question to a set of complex and comprehensive regulations, setting forth detailed procedures for determining whether it is safe and effective. On the basis of the difference between the IDE and section 510(k) processes, the court held that the Medtronic analysis does not apply to IDE devices. Under the regulations applicable to IDE devices, the court found the plaintiffs' claims were preempted.

In Sanders v. Optical Radiation Corp., the plaintiff brought an action against the manufacturer of an IDE device alleging negligence per se. The Fourth Circuit held that under Medtronic the negligence per se claim

346. Reeves, 103 F.3d at 445; Duvall, 103 F.3d at 329.
347. See supra Part V.C-D (discussing the Medtronic decision).
348. 105 F.3d 1090, 1095-96 (6th Cir. 1997).
349. Id. at 1097-98. The Martin plaintiffs argued that the pacemaker was approved under the section 510(k) process rather than under the IDE exception to the PMA process. The pacemaker contained a combination of parts, some of which had been approved through the section 510(k) process and others through the IDE process. The court treated the device as a whole and classified the device as an IDE device. Id. at 1098.
350. Id. at 1095.
351. Id. The court cited several sources for the proposition that IDE devices are subject to a determination of safety and effectiveness. Id. (citing 21 U.S.C. § 360j(g)(3) (1994); 21 C.F.R. §§ 812.20, .25, .27 (1996)).
352. Id. at 1097.
353. Id. at 1098-1101. The court addressed the plaintiffs' manufacturing defect, design defect, inadequate warning, and nonconformance to express representations claims, as well as their claim that the supplier was individually liable. Id.
was not preempted. The court based its conclusion on the fact that a negligence per se action merely incorporates the FDA's standards and, therefore, it cannot involve a requirement that is "different from, or in addition to" those standards. The court remanded the plaintiff's other claims to the district court for a careful determination of whether each alleged something other than noncompliance with federal standards.

In Chambers v. Osteonics Corp., the Seventh Circuit held that a claim of negligence with respect to an IDE device can survive MDA preemption under Medtronic. The court held that such a suit would not add any requirements different from or additional to those required by the MDA, because the nucleus of the claim was that the FDA's required procedures were not followed. The court did, however, find that claims of strict liability and breach of implied warranty of merchantability were preempted under Medtronic, because they imposed greater requirements on the device manufacturer than did the FDA regulations.

The decisions in these three cases are not in harmony. In both Sanders and Chambers, the respective courts held that tort theories relying upon the FDA regulations are not preempted by section 360k(a). However, in Martin, the court held that the IDE process itself is analogous to the PMA process and, therefore, all tort theories are preempted by section 360k(a). Under Medtronic, a court analyzing preemption should ask two questions: (1) whether there are specific regulations in place with respect to the medical device, and (2) if so, whether the claims being asserted are different from or additional to those requirements. The answers to those questions are not provided by the Medtronic decision for any devices other than section 510(k) devices.

355. Id. at *2.
356. Id. at *1.
357. Id. at *2 (stating that Medtronic "suggests a case-specific assessment of the claims and of any applicable federal requirements").
358. No. 96-1742, 1997 WL 155113, at *6-*7 (7th Cir. Apr. 3, 1997).
359. Id. at *6. The court held that a suit seeking damages for noncompliance with FDA regulations does not impose requirements different from or in addition to those imposed by the FDA. Id.
360. Id. at *4. The court found that under either strict liability or breach of implied warranty of merchantability, the manufacturer could be found liable while meeting the FDA regulations and that this constituted the imposition of an impermissibly different requirement. Id.
361. Id. at *6-*7; Sanders v. Optical Radiation Corp., No. 95-1967, 1996 WL 423124, at *3-*4 (9th Cir. July 30, 1996).
363. Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2254-56 (1996); see also supra Part V.C-D (discussing the Medtronic decision).
3. **Cases Applying Medtronic in Other Contexts**

In *Papike v. Tambrands Inc.*, the Ninth Circuit cited *Medtronic* for the proposition that a specific FDA requirement applicable to a particular device triggers MDA preemption.\(^{364}\) In this case, the court found that specific regulations for labeling the product existed.\(^{365}\) The plaintiff argued that general duties owed to consumers were not preempted because the tort theories were not specifically developed with respect to the device in question.\(^{366}\) Comparing the state tort theory in question to the FDA’s labeling requirements, the court determined that allowing the tort theory to go forward would impose a requirement different from the FDA requirements.\(^{367}\) Therefore, the court held that section 360k(a) preempted the plaintiff’s claim.\(^{368}\)

In *Committee of Dental Amalgam Manufacturers & Distributors v. Stratton*, the Ninth Circuit considered whether the MDA preempted the California Safe Drinking Water and Toxic Enforcement Act (Proposition 65).\(^{369}\) The court of appeals applied the reasoning from *Medtronic*, which held that a state or local requirement is preempted by the MDA only if there are specific counterpart requirements or regulations in existence that are applicable to a particular device.\(^{370}\) The court noted that Proposition 65 had general applicability and was not enacted as a device-specific requirement.\(^{371}\) The court also noted that Proposition 65 imposed warning requirements on all products and services that pose a public health risk.\(^{372}\) On this basis, the Ninth Circuit held that the MDA did not preempt Proposition 65.\(^{373}\)

In *Papike* and *Stratton*, the courts applied the *Medtronic* analysis to situations not involving section 510(k) devices.\(^{374}\) Under *Medtronic*, courts conduct a two-part analysis: First, are there any device-specific regulations in place with respect to the device in question, and second, are the theo-

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\(^{364}\) 107 F.3d 737, 742 (9th Cir. 1997).
\(^{365}\) *Id.* (citing 21 C.F.R. § 808.1(d)(6)(ii) (1996) as the specific requirement for tampon labeling).
\(^{366}\) *Id.* at 741. The plaintiff argued that a state tort rule of general applicability does not constitute a state requirement that is made “with respect to” a specific medical device. *Id.*
\(^{367}\) *Id.* at 742. The court noted that *Medtronic* does not preclude general state requirements, such as state tort theories, from ever being preempted. *Id.*
\(^{368}\) *Id.*
\(^{370}\) See *id.* at 812.
\(^{371}\) *Id.* at 813.
\(^{372}\) *Id.* The court stressed that California had not adopted any specific regulations or requirements with respect to dental amalgam. *Id.*
\(^{373}\) *Id.* at 813-14.
\(^{374}\) *Papike* v. *Tambrands*, Inc., 107 F.3d 737, 742 (9th Cir. 1997); *Stratton*, 92 F.3d at 807.
ries being advanced additional to or different from those regulations? 375
This part of the *Medtronic* analysis likely will be used when analyzing any
claim of preemption under the MDA and is the proper analysis. However,
the *Medtronic* decision does not shed light on what the answers to either of
these questions should be with respect to any devices other than those ap-
proved for marketing under section 510(k).

B. Implications

Based upon *Medtronic* and subsequent cases interpreting it, the impli-
cations of *Medtronic* are clear in most respects. In this section, the general
implications for the analysis of MDA preemption issues under *Medtronic*
will be discussed. A discussion of the implications of the *Medtronic*
decision in the context of PMA-approved devices, IDE-approved devices, and
section 510(k)-approved devices will follow.

1. General Implications for the Analysis of MDA Preemption Issues

Under *Medtronic*, courts are to analyze whether section 360k(a) pre-
emption is invoked with respect to a medical device by answering two
questions. First, the court is to determine whether there are any specific
regulations in place with respect to the device in question. 376 Second, the
court is to look at the state tort theory being advanced and compare it to
the requirements applicable to that device. 377 If the tort theory in ques-
tion does not pose requirements different from or additional to any re-
quirements already existing with respect to the device, then the claim will
not be preempted by section 360k(a). 378 On the other hand, if the tort
theory does impose requirements different from or additional to those
applicable to the device, the claims will be preempted by section
360k(a). 379

2. Implications for PMA-Approved Devices

The *Medtronic* decision did not specifically address devices approved
through the PMA process. As such, the decision does not shed any light
on what the correct answers are to the two questions used to analyze MDA
preemption issues with respect to devices approved for marketing through
the PMA process. However, under the analysis presented in *Medtronic*
and other cases, it is quite clear that the PMA process is sufficient to establish a
"requirement" with respect to such a device for section 360k(a) purposes.

376. See id. at 2254.
377. See id. at 2254-56.
378. See id. at 2257.
379. See id.
In fact, these requirements are so detailed that it is unlikely that any state tort claim would survive section 360k(a) preemption.

3. Implications for IDE-Approved Devices

The implications of Medtronic on the preemption of state tort claims with respect to IDE-approved medical devices are unclear. It is clear that the same two questions as explained above are to be asked in the analysis of the preemption question when considering preemption of an IDE device. However, Medtronic gives no guidance as to what the correct answers to those questions are with respect to these devices. As has been discussed previously, this lack of guidance has led to inconsistent decisions, and it could prompt Supreme Court consideration of the issue.

4. Implications for Section 510(k) Premarket Notification Devices

The Medtronic decision clearly answers the question of whether the section 510(k) process creates requirements for purposes of section 360k(a) preemption: The answer is a resounding "no." Because there are no regulations in place with respect to these devices, there is nothing for state tort theories to be different from or additional to. This means that manufacturers of section 510(k) devices will no longer be able to argue successfully that state tort claims are preempted by section 360k(a). This conclusion is supported by the holdings in Reeves and Duvall.381

VII. CONCLUSION

The Medical Device Amendments of 1976 granted the FDA authority over medical device regulation. The MDA contains an express preemption provision preempting any state law that is "different from, or in addition to" any provision of the MDA. This provision was the subject of years of inconsistent interpretations by the courts. Some of that ambiguity has been resolved by the Supreme Court decision in Medtronic v. Lohr.

In Medtronic, the Court delineated a two-step approach to analyzing preemption issues. First, are any device-specific requirements in place? Second, if so, do the tort theories being asserted have requirements which are "different from, or in addition to" those imposed under the MDA? If tort theories do impose different or additional requirements on the medical device, then they are preempted.

Medtronic holds that the answer to the first question with respect to devices approved for marketing under section 510(k) is "no." In other words, the section 510(k) process does not impose requirements upon a

380. See id. at 2254.
381. See supra Part VI.A.1.
device for purposes of preemption under the MDA. Therefore, there are no requirements in place for state tort theories to be different from or additional to, and preemption is not invoked when a device manufacturer is being sued under tort theories for a device that was approved for marketing under section 510(k) of the MDA. Post-Medtronic cases have correctly adhered to the principles outlined in Medtronic. Although Medtronic clearly resolves the preemption issue with respect to section 510(k) premarket notification devices, a clear answer does not exist with respect to preemption of claims involving PMA- and IDE-approved devices.

William Stute