Defending Substantial Equivalence: An Argument for the Continuing Validity of the 510(k) Premarket Notification Process

James M. Flaherty, Jr.
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I. INTRODUCTION

The United States Food and Drug Administration’s (FDA’s) Center for Devices and Radiological Health (CDRH) strives to both protect and promote the public health by attempting to assure safe and effective medical devices reach the market, and hence patients, in a timely fashion. FDA’s dual goal of protection and promotion of public health is reflected in its branding slogan—Protecting and Promoting Your Health.1 This dual purpose is reinforced through FDA’s Mission Statement, which states:

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.2

The dualism behind device regulation originates from the Cooper Committee, which was a medical device study group formed in 1969 and led by Dr. Theodore Cooper, then Director of the National Heart and Lung Institute. The recommendations included in the Cooper Committee’s report, issued in September 1970, ultimately formed the basis of the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA).3 With respect to premarket review of medical devices, the Cooper Committee focused on the goals of “avoiding hazards and promoting the development of medical devices.”4 In an effort to balance these competing demands, “FDA’s job … is to strike the appropriate balance between regulatory scrutiny and permissiveness in weighing the risks and benefits of a new medical device.”5

As suggested by the Cooper Committee, one tool FDA has at its disposal to effectuate this dual goal—protection and promotion of health—is regulation of new

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4 Id. at 320.
5 Id. at 321.
medical devices prior to market introduction through the FDCA and its implementing regulations. In 1976, Congress granted this premarket regulatory authority to FDA by passing the MDA. Prior to the enactment of this legislation, FDA did not have the power to review new medical devices for safety and effectiveness before market introduction unless it could justify regulating the device as a drug.

The most widely used market introduction regulatory pathway since the enactment of the MDA has been the premarket notification process outlined in section 510(k) of the FDCA, which is utilized for premarket regulation of mid-risk medical devices. The theory behind the 510(k) premarket notification process is the concept of substantial equivalence. In short, for certain types of devices, if the new device can be proven to be substantially equivalent to a legally-marketed device, then the 510(k) premarket notification process can be utilized as opposed to the more rigorous premarket approval (PMA) process. It has been reported that for the period of 1976 through 1990, more than 98 percent of devices subject to FDA premarket regulation utilized the 510(k) premarket notification process. In 2005, FDA approved 32 PMAs but cleared 3,148 510(k)s, meaning that 98.99 percent of medical devices that obtained marketing “approval” that year did so through 510(k) clearance as opposed to PMA approval.

Medical device manufacturers have embraced the 510(k) premarket notification process since its inception. Courts and commentators, however, have not always demonstrated the same level of ardor for the 510(k) process. This lack of enthu-

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6 See generally FDCA §§ 510(k), 515; 21 U.S.C. §§ 360(k), 360e (outlining primary methods and requirements of federal regulation of new medical devices prior to market introduction); 21 C.F.R. §§ 807.81-100, pt. 814 (implementing FDCA market introduction requirements via regulation).


9 Peter Barton Hutt, Richard A. Merrill, & Lewis A. Grossman, FOOD AND DRUG LAW 991 (3d ed. 2007).

10 FDCA §§ 510(k), 513(f); 21 U.S.C. §§ 360(k), 360c(f) (identifying premarket notification process and associated substantial equivalence mechanism); see also Jonathan S. Kahan, Premarket Approval versus Premarket Notification: Different Routes to the Same Market, 39 FOOD DRUG COSM. L.J. 510, 514-15 (1984) (describing 510(k) premarket notification process utilizing substantial equivalence mechanism); Adler, supra note 8, at 513-14 (explaining interrelationship between premarket notification and substantial equivalence).

11 FDCA §§ 510(k); 513(f), 21 U.S.C. §§ 360(k), 360c(f) (identifying process by which substantially equivalent devices may enter market via premarket notification); see also Kahan, supra note 10, at 515 (noting substantially equivalent devices not considered new and therefore not automatically classified as Class III); Adler, supra note 8, at 513-14 (noting free marketing of substantially equivalent devices available using premarket notification procedures).

12 Id. at 992. Notably, at least in the context of FDA law and regulation, a 510(k) clearance is not an approval. Indeed, a device will be misbranded if the word “approved” is used to describe it if only a 510(k) clearance has been obtained. See 21 C.F.R. § 807.97.

13 Adler, supra note 8, at 516 (identifying attraction of “substantial equivalence” mechanism to manufacturers). This attraction is due to the relatively limited amount of information normally required to support a 510(k) premarket notification as well as the speed with which a 510(k) is typically processed and “cleared” by the FDA. Id.; see also Kahan, supra note 10, at 514 (characterizing the 510(k) process as simple, fast, and relatively cheap). Moreover, “[t]he 510(k) process generally is less expensive than the PMA process in terms of both time and money … .” Goldberger, supra note 3, at 317-18.

14 See, e.g., Medtronic, Inc. v. Lohr, 518 U.S. 470, 492-93 (1996) (characterizing as “exaggerated” importance placed on 510(k) process and substantial equivalence by manufacturer); Lohr v. Medtronic, Inc., 56 F.3d 1335, 1348 (11th Cir. 1995) (noting 510(k) process concerned with equivalence, not safety, thereby not adequately assessing safety and effectiveness); Adler, supra note 8, at 516 (arguing little protection afforded to public by substantial equivalence determination); see also infra notes 169 - 173 and accompanying text.
siasm is usually related to a belief that 510(k) premarket notification is not suitably robust to assure a reasonable level of safety and effectiveness for devices utilizing the process. For example, even the United States Supreme Court has stated, in favorably quoting a lower court, that “‘the 510(k) process is focused on equivalence, not safety.’ As a result, ‘substantial equivalence determinations provide little protection to the public.’”17 This focus on equivalence as opposed to “pure” safety, it has been noted, “results usually in less FDA scrutiny of the new device.”18

In September 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which the President signed into law on September 27, 2007.19 Included within the FDAAA as Title II of the Act was the Medical Device User Fee Amendments of 2007 (MDUFA II).20 In addition to reauthorizing the medical device user fee program established by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA),21 MDUFA II included a provision that required the Government Accountability Office (GAO) to conduct a study of the 510(k) premarket notification process.22 Specifically, Section 225 of MDUFA II requires the GAO to investigate whether a new device is as safe and effective as a classified (i.e., marketed) device, and also requires that the study consider the evaluation of the intended uses and technologies of such devices, including the effectiveness of comparative assessment of certain technical characteristics.23 This provision of MDUFA II further requires that the GAO submit a report to Congress on the results of the study.24 The GAO report, originally scheduled for release within one year of the enactment of FDAAA, is now expected to be issued by the end of 2008.

In view of the Congressional mandate that the 510(k) premarket notification process be reviewed and in anticipation of the GAO report’s expected release later this year, this article argues in favor of the continuing validity of the 510(k) premarket notification process as an appropriate vehicle for regulating the market introduction of mid-level risk medical devices. First, this article summarizes the history of medical device regulation, focusing specifically on the history of the 510(k) premarket notification process. Second, this article briefly analyzes the relationship between the 510(k) process and medical device preemption jurisprudence. Third, the article examines the treatment and characterization of the 510(k) process by courts, commentators and critics, using such treatment and characterization as a lens to examine how the 510(k) process is viewed by individuals and institutions whose daily activities do not involve 510(k)s. Finally, this article provides reasons why the 510(k) process plays an important role in regulating medium-risk devices and explains why the GAO report should support the continuing validity of the 510(k) process.

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16 Lohr, 56 F.3d at 1348 (questioning whether 510(k) clearance incorporates finding of safety and effectiveness).
18 Goldberger, supra note 3, at 318.
20 Id. at §§ 201-230.
22 FDAAA, supra note 19, at § 225.
23 Id.
24 Id.
II. STATUTORY AND REGULATORY BACKGROUND

A. History of Medical Device Regulation

Over one hundred years ago, Congress enacted the first federal statute specific to the regulation of foods and drugs, the Food and Drugs Act of 1906. Although the 1906 Act did not specifically apply to devices, it did cover drugs, thereby asserting regulatory authority over therapeutic products and laying the groundwork for eventual regulation of devices. The 1906 Act also led to the formation of the federal agency that ultimately evolved into FDA.

Subsequently, the enactment of the FDCA in 1938 expanded governmental regulation of foods and drugs and widened the scope of regulation to include medical devices and cosmetics. Although the FDCA expanded governmental control over drugs to include premarket review of safety data, this premarket review was not extended to devices. The FDCA did, however, grant the government postmarket oversight of devices by providing for governmental enforcement actions against adulteration and misbranding of devices.

The first significant amendment to the FDCA was the Drug Amendments of 1962. Although primarily related to the regulation of drugs, the 1962 Amendments did have some effect on the regulation of devices in that FDA used its authority to regulate some devices as if they were drugs. For example, the 1962 Amendments allowed FDA to regulate both sutures and contact lenses under a broad definition of “drugs,” a definition ultimately accepted by the U.S. Supreme Court in United States v. An Article of Drug … Bacto-Unidisk, 394 U.S. 784 (1969). The majority of medical devices, however, remained unregulated by FDA with respect to premarket regulation.

Responding to a need for increased device-specific federal regulatory oversight, Congress enacted the second amendment of significance to the FDCA—the MDA—in 1976. Through the MDA, Congress created a new system for regulating medical devices focusing on the development, market introduction, and post-launch marketing
of devices. Two key features of the new system were (i) the classification scheme for medical devices and (ii) the authority granted to FDA to review medical devices prior to market introduction. Specifically, the MDA established a comprehensive device classification scheme aimed at grouping devices according to the risks posed, with each group receiving the appropriate degree of regulation based on that risk—i.e., increasing levels of regulatory oversight for increasing levels of risk posed. The MDA also laid the foundation for the 510(k) and PMA processes.

Since the MDA, medical device regulation has been altered and enhanced by the Safe Medical Devices Act of 1990 (SMDA), the Medical Device Amendments of 1992 (MDA of 1992), the Food and Drug Modernization Act of 1997 (FDAMA), MDUFMA and the FDAAA. Each of these legislative actions was intended to augment the basic structure of the MDA as opposed to altering the MDA regulatory scheme in any fundamental fashion. However, both the SMDA and FDAMA included significant enhancements and added clarity to the 510(k) premarket notification process and the concept of substantial equivalence, as will be discussed in detail below.

B. Device Classification

The device classification scheme outlined in the MDA is a risk-based system with the greatest amount of regulatory oversight given to those devices that pose

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37 Hutt, et al., supra note 9, at 980. The new system created by the MDA included six key features. Id. First, the MDA revised and broadened the definition of “devices” to capture both those products previously regulated as drugs and other devices not previously captured within prior definitions of devices. Id. Second, the MDA required FDA to classify all devices according to the relative assurance of safety and effectiveness associated with the device. Id. Third, the MDA provided for a comprehensive system of market introduction regulation for devices independent from, but related to, the classification scheme. Id. at 980-81. Fourth, the MDA distinguished two classes of preamendment devices subject to special requirements—Class II devices were required to comply with special controls per Section 514 and Class III devices were subject to a safety and effectiveness evaluation and approval process. Id. at 980. Fifth, the MDA provided that all devices be subject to “general controls” including, but not limited to, misbranding and adulteration provisions and good manufacturing practices (GMPs). Id. Sixth, the MDA established special rules relevant to specific types of devices such as custom devices. Id.


39 Goldberger, supra note 3, at 317-18 (noting concept behind classification scheme); Gibbs, supra note 26, at 2 (same).

40 Gibbs, supra note 26, at 2 (providing statutory history of 510(k) and PMA processes).


44 MDUFMA, supra note 21.

45 FDAAA, supra note 19.

46 See supra notes 41 - 45; see also generally Goldberger, supra note 3, at 325-29 (tracing changes in medical devices regulation from SMDA to FDAMA); Gibbs, supra note 26, at 2 (summarizing structural changes of medical device regulation in MDA of 1992); Littlefield & Hadas, supra note 43 (summarizing various medical devices provisions included in FDAMA).
the greatest risk to patients.47 In other words, the classification scheme assigns “dif-
ferent amounts of regulation for different amounts of risk.”48 Medical devices fall
into one of three broad categories: Class I, Class II or Class III.49 Class I devices
pose the least risk to patients, Class III devices pose the greatest risk, while Class II
products, not surprisingly, fall somewhere in between in terms of risk.50 The three
classes of devices have been described as follows:

Class I devices are noncritical products, whose safety and effectiveness
can be maintained through the general control provisions of the Medical
Device Amendments, and the adulteration and misbranding sections of
the FDCA. Class II devices entail a higher degree of risk, and so Congress
required that performance standards be established for these products. The
most "risk-laden" devices are placed into Class III. Class III devices must
undergo premarket approval by FDA.51

When initially classifying devices, the FDCA requires that the least restrictive
classification must first be considered, and only when the device in question cannot
meet the definition of a less restrictive class can more restrictive classifications be
considered.52 In this fashion, the FDCA seeks to winnow out lower risk devices
through the classification process, resulting in mid-risk devices being subject to
the 510(k) premarket notification process and only those devices with the highest
risk profile being subject to the PMA process. Furthermore, the classifications are
designed to be mutually exclusive such that any given device may only be subject to
the requirements of one classification.53 Despite this mutual exclusivity, however,
the definitions of classes are “closely interrelated.”54

Generally, Class I devices are not subject to any premarket review process, while
Class II devices are subject to the 510(k) premarket notification process, and Class
III products are subject to the PMA process.55 The primary exception to this gen-
eral premarket review format is the situation involving pre-amendment Class III

47 Sayler & Thomas, supra note 38, at 186 (commenting on risk-based medical device classification
system).
48 Kahan, supra note 10, at 511.
49 FDCA § 513(a)(1); 21 U.S.C. § 360c(a)(1) (identifying and defining three classes of devices); see also Hutt, et al., supra note 9, at 984-86 (describing initial classification procedures employed by FDA).
50 Sayler & Thomas, supra note 38, at 186 (characterizing three classifications and associated
levels of risk). Examples of Class I devices include manual surgical instruments for general use
such as scissors and forceps. 21 C.F.R. § 878.4800 (classifying manual surgical instruments for general use
as Class I, exempt from premarket notification). An example of a Class II device is a silk suture. Id. §
878.5030 (classifying silk sutures as Class II devices). An example of a Class III device is a permanent
cardiovascular pacemaker electrode. Id. § 870.3680(b) (classifying permanent cardiovascular pacemaker
electrodes as Class III devices). Interestingly, temporary cardiovascular pacemaker electrodes are Class II
devices and, consequently, are classified less restrictively than permanent pacemakers. Id. § 870.3680(a).
One legal commentator, noting this distinction, has recorded the history of and reasoning for this
duality of classification for cardiovascular pacemaker electrodes. Richard S. Morey, Characterization
of Medical Devices—Another View, 35 FOOD DRUG COSM. L.J. 594, 599-600 (1980).
51 Kahan, supra note 10, at 511.
52 FDCA § 513(a)(1); 21 U.S.C. § 360c(a)(1) (describing classification process as requiring con-
sideration of least restrictive class first); see also Morey, supra note 50, at 595 (interpreting § 513(a) as
requiring consideration of less restrictive classifications before more restrictive classifications).
53 Morey, supra note 50, at 595.
54 Id.
55 Sayler & Thomas, supra note 38, at 186 (describing device classifications and associated premar-
tek review processes); see also Classify Your Medical Device, http://www.fda.gov/cdrh/devadvice/313.
html (providing information and guidance on device classification for interested parties).
This exemption, in part, allows some Class III devices to enter the market via the 510(k) process. The system allowing Class III devices to utilize the 510(k) process instead of the PMA process is only available to manufacturers until such time as FDA “calls for” PMAs for the devices at issue.

C. Evolution of the 510(k) Premarket Notification Process

The MDA provided that devices on the market prior to the enactment of the MDA could remain on the market under a “grandfathered” status until such time as FDA classified and regulated them. In order to avoid giving devices that were on the market prior to the MDA an unfair advantage, Congress also established the 510(k) premarket notification process. This process allowed manufacturers to freely market devices that were established to be “substantially equivalent” to a “grandfathered” pre-amendment device.

The concept of substantial equivalence is at the core of the 510(k) premarket notification process. The legislative history of the MDA indicates that Congress envisioned that substantial equivalence should be assessed based on safety and effectiveness, physical characteristics, and intended use:

The term “substantially equivalent” is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The Committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between “new” and marketed devices in materials, design, or energy source, for example, would have a bearing on the adequacy of information as to a new device’s safety and effectiveness, and such devices should be automatically classified into Class III. On the other hand, copies of devices marketed prior to enactment or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme.

In June 1986, to address the fact that there was no statutory or regulatory definition of the term “substantially equivalent,” FDA published a guidance document.

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56 21 C.F.R. § 814.1(c)(1) (exempting certain Class III devices from PMA process). As used herein, the term “preamendment” refers to prior to the enactment of the MDA, i.e., prior to May 28, 1976.
57 See Lohr, 518 U.S. at 478-79 (describing process by which Class III devices may utilize 510(k) process).
58 Id.
60 Id.
61 Id.
62 See supra note 10 and accompanying text.
63 Hutt, et al., supra note 9, at 994-95 (quoting H.R. REP. No. 853, 94th Cong., 2d Sess. 36-37 (1976)).
64 “Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency’s interpretation of or policy on a regulatory issue. Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.” 21 C.F.R. § 10.115.
entitled “Guidance on the CDRH Premarket Notification Review Program.” According to this guidance document, the initial focus of a substantial equivalence determination is the intended use of the device at issue. In order for a device to be found substantially equivalent to a predicate device, the new device must have the same intended use as the predicate.

Once it is established that the new device and predicate device share the same intended use, the focus of the substantial equivalence determination turns to the technological characteristics of the new and predicate devices. The new device may be found substantially equivalent to the predicate device so long as it has the same technological characteristics as the predicate or it can be established that any technological differences do not negatively impact the safety and effectiveness of the new device.

In 1990, Congress passed the SMDA, which adopted FDA’s treatment of substantial equivalence determinations, as expressed in the 1986 guidance document. Most importantly, the SMDA amended § 513(i) of the FDCA to provide a statutory definition of “substantial equivalence,” which essentially codified the FDA definition set forth in the 1986 guidance document. Section 513(i), as amended, reads in pertinent part:

Substantial equivalence
(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(i) of this title, the term “substantially equivalent” or “substantial equivalence” means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and

(II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term “different technological characteristics” means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

66 Id.; see also Hutt, et al., supra note 9, at 995-96; Goldberger, supra note 3, at 324.
67 Id.
68 Id.
69 Id.
70 SMDA, supra note 41.
(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.\footnote{21 U.S.C. § 360c(ii); see also Goldberger, supra note 3, at 326.}

Thereafter, FDA utilized the new statutory definition of substantial equivalence to revise the existing medical device regulations to incorporate a regulatory definition of substantial equivalence. The relevant portion of 21 C.F.R. § 807.100 reads as follows:

(b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:

(1) The device has the same intended use as the predicate device; and

(2) The device:

(i) Has the same technological characteristics as the predicate device; or

(ii)(A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device;

(B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device; and

(C) Does not raise different questions of safety and effectiveness than the predicate device.\footnote{21 C.F.R. § 807.100(b); see also Hutt, et al., supra note 9, at 996.}

As a result of the changes to medical device regulation introduced by the SMDA, FDA published a short, two-page guidance document summarizing the changes.\footnote{SMDA Changes—Premarket Notification; Regulatory Requirements for Medical Devices (510k) Manual Insert, April 17, 1992, http://www.fda.gov/cdrh/ode/655.pdf.} FDA used this guidance document to again provide a summary of the concept of substantial equivalence:

Substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.\footnote{Id. at 2.}

Other important changes made by the SMDA included (i) allowing manufacturers to use any marketed device as a predicate device as opposed to only pre-amendment
devices, and (ii) enhancing and clarifying the regulation of Class II devices through the use of performance standards and “special controls.”

In 1997, Congress again made significant changes to medical device regulation in the context of FDAMA. Most significantly, FDAMA amended § 510 of the FDCA to exempt most Class I devices and many Class II devices from 510(k) premarket notification. With respect to Class I devices, FDAMA provided that those devices would be exempted from 510(k) premarket notification unless the device “is intended for a use which is of substantial importance in preventing impairment of human health, or … presents a potential unreasonable risk of illness or injury.” As to Class II devices, FDAMA provided that those devices could be exempted from 510(k) premarket notification if FDA “determines that such report is not necessary to assure the safety and effectiveness of the device.” “Under the current system, manufacturers of less risky devices routinely determine substantial equivalence for themselves.”

FDAMA also included some changes and clarifications to the concept of substantial equivalence. For example, pursuant to FDAMA, the substantial equivalence determination must focus on the objective intended use of the new device as identified in the labeling and not on possible uses of the device at issue. Also, FDAMA clarified that preclinical or clinical data could be requested as part of the substantial equivalence determination, but such information was required to be the “least burdensome” information necessary to determine substantial equivalence. “Information not related directly to substantial equivalence, such as information about the absolute safety and effectiveness of a device, may not be requested.” Further, FDAMA instructed FDA to “consider the extent to which reliance on postmarket controls may expedite” the 510(k) premarket notification process.

Additionally, FDAMA amended § 513(f) of the FDCA to add the Evaluation of Automatic Class III provision, which is also known as “de novo” or “risk-based” classification. Soon thereafter, FDA published a guidance document concerning this provision entitled “New Section 513(f)(2)—Evaluation of Automatic Class III Designation.” As explained in the guidance document, this new provision “is intended to apply to low risk products that have been classified as class III because they were found not substantially equivalent (NSE) to any identifiable predicate device.” Specifically, § 513(f) provides a mechanism to reclassify devices that are automatically classified as Class III when no device exists that could serve as the predicate to establish substantial equivalence, but the risk profile of the device does not warrant a Class III designation.

75 SMDA, supra note 41; see also Goldberger, supra note 3, at 326-27.
76 FDAMA, supra note 43.
77 Id. § 206(a); see also Hutt, et al., supra note 9, at 996; Goldberger, supra note 3, at 328.
78 Id.
79 Id.
80 Hutt, et al., supra note 9, at 996.
81 FDAMA, supra note 43, §§ 205(b), 206(c); see also Goldberger, supra note 3, at 328.
82 FDAMA, supra note 43, §§ 205(b), 206(c); see also Goldberger, supra note 3, at 328.
83 Goldberger, supra note 3, at 328.
84 FDAMA, supra note 43, § 205(b); see § id. at 328.
85 FDAMA, supra note 43, § 207.
87 Id.
Finally, and of particular importance to this article, FDAMA codified FDA's mission statement to focus on the protection and promotion of public health. In specific to promotion, the codified mission statement provides that FDA shall "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner . . .". In other words, "Congress made clear that [FDA's] mission is not limited to protection of public health by preventing distribution of unsafe products, but also requires timely review and approval of beneficial new products."

Soon after the enactment of FDAMA, FDA released a new guidance document entitled “The New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.” The goal of this guidance was to streamline the 510(k) premarket notification process by introducing two new types of 510(k)s in addition to the traditional 510(k). The guidance document describes the “New 510(k) Paradigm” as follows:

To streamline the evaluation of premarket notifications for the reserved Class I devices, Class II devices subject to premarket notification, and pre-amendment[] Class III devices for which FDA has not yet called for PMAs, the Agency has developed “The New 510(k) Paradigm.” Attachment 1 outlines the New Paradigm, which presents device manufacturers with two new optional approaches for obtaining marketing clearance for devices subject to 510(k) requirements. While the New Paradigm maintains the traditional method of demonstrating substantial equivalence under section 510(k) of the Act, it also presents the “Special 510(k): Device Modification” option, which utilizes certain aspects of the Quality System Regulation, and the “Abbreviated 510(k)” option, which relies on the use of guidance documents, special controls, and recognized standards to facilitate 510(k) review. Use of either alternative, however, does not affect FDA's ability to obtain any information authorized by the statute or regulations.

Because these new types of 510(k)s are intended to make the substantial equivalence determination process more efficient and provide an incentive to manufacturers to use the new options, the guidance states that FDA intends to expedite the processing of 510(k)s utilizing these options, specifically within 30 days of receipt for Special 510(k)s and an undefined “expedited review” for Abbreviated 510(k)s.

Additionally, in order to legally market a device pursuant to a 510(k) clearance, the manufacturer must ensure that any changes made to the device subsequent to the clearance do not impact the existing 510(k) clearance. Pursuant to 21 C.F.R. § 807.81(a)(3), a new premarket notification is required when:

The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture or intended use. The following constitute significant changes
or modifications that require a premarket notification: (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source or manufacturing process; or (ii) A major change or modification in the intended use of the device.94

In short, a new 510(k) clearance is required if the change or modification to the device “could significantly affect the safety or effectiveness of the device,” or if there is a “major change or modification in the intended use of the device.”95

In 1997, FDA published a guidance document entitled “Deciding When to Submit a 510(k) for a Change to an Existing Device” to explain how these regulations should be interpreted.96 Included within that guidance document are a series of flowcharts that are useful tools to help apply the requirements of 21 C.F.R. § 807.81(a)(3) from a practical perspective.97 The basic premise of the flowcharts, and the guidance document generally, is that changes that could potentially affect the safety or effectiveness of a device require a new 510(k) submission whereas changes that are not likely to affect safety or effectiveness do not.

The 510(k) premarket notification process can be further understood through a comparison of it with the PMA process.98 The statutory requirements of a PMA are as follows:

Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

94 21 C.F.R. § 807.81(a)(3).
95 Id.
97 Id. at 28-32.
(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such sample is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.99

As is clear from the above requirements, the PMA process, because of its association with the highest-risk medical devices, is arduous and time consuming.100 As opposed to the “substantial equivalence” standard utilized in the 510(k) process, the basis for PMA approval is proof of the safety and effectiveness of the subject medical device.101 In contrast, the 510(k) process, because of its association with less risky devices and reliance on “substantial equivalence,” is not as rigorous and time consuming.102 It is because of the relative ease of the 510(k) process in comparison to the PMA process that the 510(k) process has been characterized as manufacturer-friendly.103

One commentator argues that this attraction to manufacturers is based on 1) the quick processing speed for 510(k) premarket notifications, 2) the relatively small amount information required to support 510(k)s, and 3) the infrequency of negative FDA responses associated with 510(k)s.104 Another commentator has noted that the 510(k) process has become the “option of choice” for manufacturers to bring new devices to market because of the associated speed, minimal cost and simple nature.105 Still another commentator has addressed the manufacturer-friendly nature of the 510(k) process by noting that “the preparation of 510(k)s is normally far less difficult and less costly for firms than PMA applications,” and “the FDA finds substantial equivalence in the vast majority of 510(k) determinations made each year.”106

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100 See Lohr, 518 U.S. at 479 (noting typical PMA requires 1,200 hours of FDA review).
102 See Lohr, 518 U.S. at 479 (noting typical 510(k) FDA review duration is twenty hours).
103 Adler, supra note 8, at 516 (noting “attraction” of 510(k) process to manufacturers); see also supra note 14 and accompanying text.
104 Id. With respect to the first point, between the years 2000 and 2004, the annual average time between 510(k) premarket notification submission and clearance ranged from 96 days (2001 and 2003) to 102 days (2000), whereas for PMAs the annual average time from submission to approval ranged from 359 days (2003) to 436 days (2004). Hutt, et al., supra note 9, at 994 n.1. Regarding the second point, the information differential for PMAs versus 510(k)s is clear from the requirements comparison set forth above. As to the third point, it has been reported that during the five-year period from 2000 to 2004, FDA refused to provide clearance for only 1.8 percent of 510(k) premarket notifications (369 rejections for 20,652 510(k)s received), while FDA determined that 12.1 percent of PMAs received during that same time period were “not approvable” (41 “not approvable” findings for 338 PMAs received). Id. The historical infrequency of negative 510(k) responses is further supported by the statements of an FDA official during a 1980 speech noting that over 10,000 510(k)s were processed by FDA between 1976 and 1980 with only two percent not being found substantially equivalent. James R. Veale, Characterization of Medical Devices, 35 FOOD DRUG COSM. L.J. 588, 592 (1980).
105 Kahan, supra note 10, at 514.
The 510(k) process, however, is not as quick and simple as many courts and commentators suggest. In addition to the requirements set for in 21 C.F.R. § 807.87, FDA has stated the following with respect to the data requirements for 510(k)s:

The requirements of section 510(k) of the act are intended not only to notify FDA that a device is about to be marketed but primarily to enable FDA to determine whether the device is SE [substantially equivalent] to one already in commercial distribution. To fulfill this responsibility, the Center requires that a 510(k) include descriptive data needed to understand a new device’s intended use, physical composition, method of operation, specifications, performance claims, etc. Similar information about the device to which the new device is being compared may also be required. In addition, under certain circumstances, the Center requires performance testing information, i.e., data from bench, animal, or clinical tests, in order to determine that a device performs according to its description.107

Notably, this FDA guidance was published in 1986, so these more thorough data requirements have been in place for more than 20 years.

Due to FDA’s significant reliance on the 510(k) process, in many cases the standard of review has gone beyond mere substantial equivalence to what can be viewed as a pseudo safety and effectiveness review.108 It has been noted that FDA requires significant information from manufacturers to establish substantial equivalence, with clinical data requested in some circumstances.109 For example, it was reported in 2003 that between five percent and fifteen percent of the 4000-5000 510(k)s submitted annually required clinical data to support the substantial equivalence claim.110 This expansion of the 510(k) premarket notification process far beyond a simple premarket notification has led at least two commentators to equate some 510(k)s with “mini PMA[s].”111 As expressed by one of these commentators:

A mini-PMA is a 510(k) application that is processed under the 510(k) paradigm but includes clinical data demonstrating safety and effectiveness. Although in theory the clinical data in a mini-PMA should be directed only “to answer the comparative question whether new device B is substantially as safe and effective as pre-enactment device A,” in practice FDA was likely to demand data showing safety and effectiveness in absolute terms—the vary same type of data included in a PMA.112

107 Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), June 30, 1986, http://www.fda.gov/cdrh/k863.html. The information necessary to support a 510(k) submission has also been generally described as follows: “The manufacturer [has] to report … the device name, its classification (unless the FDA [has] yet to classify the device), all action taken to comply with applicable performance standards, proposed labeling, engineering drawings, a statement indicating that the device is similar to comparable products (with data to support the statement), supporting data showing the effects of any modifications on safety and effectiveness, and any additional information requested by the FDA to make a finding of substantial equivalence. A device is substantially equivalent to a previously marketed device if it has the same intended use and technical characteristics as the original or, if it has different technical characteristics, the data submitted contains information, including clinical data if requested by the FDA, that demonstrates that the device is as safe and effective as the original and does not raise different questions regarding safety and effectiveness.” Bivans, supra note 58, at 1092.

108 Morey, supra note 50, at 598 (noting expansive use of 510(k) process by FDA).

109 Id.; Goldberger, supra note 3, at 324.


111 Alan H. Kaplan, Through the Maze of 510(k)s, 39 FOOD DRUG COSM. L.J. 160, 162 (1984) (chronicling transformation of the 510(k) process from “simple premarket notification system” to “mini PMA”); Goldberger, supra note 3, at 324.

112 Goldberger, supra note 3, at 324.
In this way, the 510(k) process has evolved over time into the flexible and practical premarket pathway it is today. For those devices that require 510(k) premarket notification but are on the lower end of the risk spectrum, FDA requires a relatively simple and straightforward showing of substantial equivalence between the new device and the predicate devices. For 510(k) devices on the higher end of the risk spectrum, however, FDA holds the manufacturer to a much higher standard of review, although still within the framework of a substantial equivalence determination. For example, FDA may take a closer look at the actual safety and effectiveness of the new device in the context of its substantial equivalence review to confirm that the new device is as safe and effective as the predicate device. This closer look may include requirements for more comprehensive bench data, animal testing, and in some cases clinical trials. Accordingly, devices on the higher end of the 510(k) risk spectrum are subject to a quasi safety and effectiveness review similar to a “mini-PMA.”

III. JUDICIAL BACKGROUND

A. Medical Device Preemption and Its Relationship to the 510(k) Premarket Notification Process

Within the scope of the FDCA, as amended by the MDA, Congress explicitly stated that federal medical device law and regulation would take precedence over, or preempt, inconsistent state medical device law and regulation. FDA’s regulations implementing Section 521(a) shed additional light on the issue of medical device preemption:

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

Prior to 1996, virtually every court to consider the issue had held that the FDCA preempts state law tort claims based on injury caused by medical devices. This view was based, in part, on the U.S. Supreme Court’s 1992 decision in Cipollone v.

See supra notes 111 - 112 and accompanying text.

FDCA § 521(a); 21 U.S.C. 360k(a). Section 521(a) states: 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 and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. § 808.1(d).

Suzanne Darrow Kleinhaus, Medtronic v. Lohr: For Want of a Word, the Patient Was Almost Lost – Fixing the Mischief Caused in Cipollone by Dividing the Preemption Stream, 53 FOOD DRUG L.J. 297, 297 (1998) (stating vast majority of courts have held, either expressly or implicitly, state tort law preempted by MDA); Sayler & Thomas, supra note 38, at 185 (noting broad preemption of state tort law by FDCA found by majority of courts considering issue).
Liggett Group, Inc.\textsuperscript{117} The Supreme Court’s subsequent holding in Medtronic, Inc. v. Lohr,\textsuperscript{118} however, significantly changed this view in allowing the tort claim at issue to proceed by refusing to recognize preemption based on the 510(k) premarket notification process.\textsuperscript{119} Specifically, the Supreme Court in Lohr held that, given the specific facts of the case,\textsuperscript{120} compliance with the requirements of the FDCA did not preempt state law tort claims.\textsuperscript{121} Because the device in Lohr utilized the 510(k) process, and the Court did not comment on the FDCA’s preemption provision beyond the specific device at issue in the case, the scope of the preemptive effect of other medical device regulatory “requirements” under the FDCA, including the requirements associated with the PMA process, remained unresolved following Lohr.\textsuperscript{122}

In 2001, the Supreme Court considered the issue of whether state law fraud-on-the-FDA tort claims are preempted by the FDCA in Buckman Company v. Plaintiffs’ Legal Committee.\textsuperscript{123} The Supreme Court decided that such claims are preempted because state tort claims conflict with “the federal statutory scheme [which] amply empowers FDA to punish and deter fraud against the agency.”\textsuperscript{124} While it could have done so, the Supreme Court did not use the Buckman decision to clarify the medical device preemption issues left unresolved by Lohr. Although the Supreme Court in Buckman expressly stated that Lohr “does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim,” it left unresolved the issues of whether the PMA process specifically, or any process under the FDCA, would involve “requirements” under § 521(a) sufficient to support preemption.\textsuperscript{125}

\begin{itemize}
  \item \textsuperscript{117} 505 U.S. 504 (1992) (holding federal statute preempted specific state requirements relating to health and smoking and some common law claims).
  \item \textsuperscript{118} 518 U.S. 470 (1996).
  \item \textsuperscript{119} Id. at 490; see also Kleinhaus, supra note 116, at 297 (noting Supreme Court in Lohr tried to “fix” Cipollone, thereby surprising many courts); Sayler & Thomas, supra note 38, at 185 (noting survival of state tort common law claim from preemption in factual context of Lohr).
  \item \textsuperscript{120} In Lohr, a pacemaker lead was cleared to market using the 510(k) process. Lohr, 518 U.S. at 480. As part of its decision, the Supreme Court announced and utilized a two-prong test for determining preemption under the FDCA, as amended by the MDA, and held that the 510(k) process did not meet its two-prong test. Id. This two-prong test has been summarized by the U.S. Court of Appeals for the Tenth Circuit, in applying the Supreme Court’s Lohr decision, as follows: Based on the MDA’s statutory language and the FDA’s regulation, the Court developed a two-prong inquiry to determine the preemptive scope of the MDA. First, a federal requirement must be “applicable to the device” in question. In other words, a federal requirement will preempt state law only if “specific” to a “particular device.” Second, a state requirement must be “with respect to” a medical device and must be “different from, or in addition to” a federal requirement. Accordingly, “state regulations of ‘general applicability’ are not preempted except where they have ‘the effect of establishing a substantive requirement of a specific device.’” Oja v. Howmedica, Inc., 111 F.3d 782, 788 (10th Cir. 1997).
  \item \textsuperscript{121} Lohr, 518 U.S. at 490.
  \item \textsuperscript{122} Sayler & Thomas, supra note 38, at 208 (commenting Court did not explain how Lohr holding applies to PMA devices generally); see also Kleinhaus, supra note 116, at 320 (characterizing lack of comment by Supreme Court on preemptive effect of PMA process as open issue).
  \item \textsuperscript{123} 531 U.S. 341 (2001). In Buckman, plaintiffs who claimed injuries resulting from bone screws implanted in the pedicles of their spines argued that a consulting company (Buckman) who assisted a bone screw manufacturer in obtaining marketing clearance from FDA made fraudulent representations to FDA during the regulatory premarket review process. Id. at 343.
  \item \textsuperscript{124} Id. at 348.
  \item \textsuperscript{125} Id. at 352-53.
\end{itemize}
Earlier this year, in *Riegel v. Medtronic, Inc.*, the Supreme Court clarified the uncertainty surrounding the preemptive effect of the PMA process. Distinguishing *Lohr*, the Supreme Court in *Riegel* held that the PMA process does impose the requisite “requirements” under § 521(a) such that PMA approval could block state law tort claims due to preemption. The Supreme Court explained its reasoning by noting that “[w]hile § 510(k) is ‘focused on equivalence, not safety,’ … premarket approval is focused on safety, not equivalence. While devices that enter the market through § 510(k) have ‘never been formally reviewed under the MDA for safety or efficacy,’ … FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness, § 360e(d).”

**B. Judicial Characterization of the 510(k) Premarket Notification Process**

Since 1996, the lack of preemptive effect for 510(k) devices has been well established based on the Supreme Court’s *Lohr* decision. Now, following the recent decision by the Supreme Court in *Riegel*, the preemptive effect of PMA process is equally well established. In reaching its decisions in *Lohr* and *Riegel*, the Supreme Court had the opportunity to compare and characterize the 510(k) and PMA processes, and other courts considering the issue of medical device preemption have similarly taken the opportunity to characterize the 510(k) process in connection with their preemption determinations.

1. **The U.S. Supreme Court**

As part of its decision in *Lohr*, the Supreme Court had to consider the nature of the 510(k) process because the device at issue had utilized that process. The Supreme Court’s characterization of the 510(k) process and its substantial

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129 Id. at 1007, 1011.
126 128 S. Ct. 1007, 1011.
127 Id. at 1007 (quoting *Lohr*, 518 U.S. at 493) (emphasis in original). Based on the uncertainty surrounding the preemptive effect of PMA approval prior to the Supreme Court recently clarifying the issue in *Riegel*, court decisions on this issue following *Lohr* but prior to *Riegel* were inconsistent. While some courts interpreted the *Lohr* decision as holding that the medical device regulatory process never reaches the level of having preemptive effect, other courts placed greater emphasis on the PMA versus 510(k) distinction, thereby finding preemptive effect based on the requirements of the PMA process. For example, in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), the U.S. Court of Appeals for the Eleventh Circuit held that FDA’s approval of a medical device under the PMA process did not result in preemptive effect. *Id.* at 1382. The U.S. Court of Appeals for the Tenth Circuit reached a similar conclusion in *Oja v. Howmedica, Inc.*, holding that the two-prong “requirements” test elucidated in *Lohr* was not met by the PMA process and therefore the PMA process had no preemptive effect. 111 F.3d at 789. Conversely, the U.S. Court of Appeals for the Seventh Circuit, in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), found that the specific state common law claims at issue were preempted by PMA process. *Id.* at 913-915. Further, in *Papke v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. 1997), the U.S. Court of Appeals for the Ninth Circuit held that preemption determinations of state tort claims are device and disease specific. *Id.* at 742.
130 *Lohr*, 518 U.S. at 494 (interpreting “requirements” associated with 510(k) substantial equivalence as insufficient to support preemptive effect).
131 *Riegel*, 128 S. Ct. at 1007 (interpreting “requirements” associated with PMA approval as supporting preemptive effect).
132 *Lohr*, 518 U.S. at 480 (noting Medtronic had utilized 510(k) process in placing pacemaker lead device on market).
equivalence standard focused on its limits in comparison to the more rigorous PMA process. The Supreme Court supported this view, in part, by noting that the typical PMA involves 1,200 hours of FDA review whereas the typical 510(k) review time is twenty hours. Indeed, the Supreme Court stated that the 510(k) process, through its utilization of substantial equivalence and its reliance on devices already on the market, is not intended to do anything more than maintain the status quo. Moreover, the Supreme Court further denigrated the 510(k) process in its opinion in stating:

The company’s defense exaggerates the importance of the § 510(k) process and FDA letter to the company regarding the pacemaker’s substantial equivalence to a grand-fathered device. As the court below noted, ‘the 510(k) process is focused on equivalence, not safety.’ As a result, ‘substantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.’ The design of the Model 4011, as with the design of pre-1976 and other “substantially equivalent” devices, has never been formally reviewed under the MDA for safety or efficacy.

Although the Supreme Court again addressed preemption under the FDCA in the Buckman case, which involved bone screws cleared for commercial marketing under the 510(k) process, the decision as to whether state law fraud-on-the-FDA tort claims are preempted by the FDCA did not ultimately turn on the 510(k) versus PMA distinction. Nevertheless, the Supreme Court did compare and contrast the 510(k) and PMA processes in the context of its decision in Buckman, and took a slightly more favorable view of the 510(k) process. For example, the Supreme Court stated that the 510(k) premarket notification process “sets forth a comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device.” Further, in contrasting the 510(k) process to the PMA process, the Buckman Court noted the following:

Admittedly, the § 510(k) process lacks the PMA review’s rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device. Nevertheless, to achieve its limited purpose, the § 510(k) process imposes upon applicants a variety of requirements that are designed to enable FDA to make its statutorily required judgment as to whether the device qualifies under this exception.

In Riegel, however, the Supreme Court seemingly returned to its more negative view of the 510(k) process, perhaps because its decision relied heavily on the precedent set in Lohr. Contrast the PMA process at issue in Riegel with the

133 Id. at 478-79 (stating 510(k) process is “by no means comparable” to PMA process).
134 Id. at 479.
135 Id. at 494.
136 Id. at 492-93 (citations omitted).
137 Buckman, 531 U.S. at 346, 348.
138 Id. at 348-50.
139 Id. at 348.
140 Id. at 348-49.
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510(k) process at issue in *Lohr*, the Supreme Court noted that premarket approval “imposes ‘requirements’ under the MDA as we interpreted in *Lohr*. … And it is in no sense an exemption from federal safety review—it is federal safety review. Thus, the attributes that *Lohr* found lacking in § 510(k) review are present here.”

2. Federal Appellate and District Courts

Other federal courts, especially those applying the *Lohr* decision, have similarly characterized the 510(k) process as limited in its ability to properly assure a reasonable level of safety and effectiveness for devices cleared for marketing under the process. For example, numerous courts have cited the limited, twenty-hour 510(k) review time identified in *Lohr*, implying that twenty hours is insufficient to assure a reasonable level of safety and effectiveness. Similarly, the U.S. Court of Appeals for the Sixth Circuit has stated that the 510(k) process allows companies to market devices “without inquiry and without submitting much information.” Further, the U.S. District Court for the Northern District of Ohio has labeled the 510(k) premarket notification process as quick, cheap, less intrusive, and not focused on safety and effectiveness.

Indeed, the U.S. Court of Appeals for the Eleventh Circuit has gone so far as to question whether the 510(k) process may even perpetuate the marketing of unsafe and ineffective devices via the utilization of the substantial equivalence standard. Specifically, the Eleventh Circuit in *Goodlin* expressed a belief that FDA considers substantial equivalence “regardless of how unsafe or ineffective” the predicate device may be. The *Goodlin* Court further characterized the 510(k) process as “limited in scope” and also negatively referenced the twenty-hour average review time noted in the Supreme Court *Lohr* opinion and discussed above.

In addition, many other courts have downplayed the significance and appropriateness of the 510(k) premarket notification process as a means for FDA to grant marketing permission, frequently characterizing the process as “limited.” Other courts have used similar minimizing language to discredit the 510(k) premarket notification process. Still other courts have been quick to term the 510(k) pre-

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141 Riegel, 128 S. Ct. at 1007.
143 Martin v. Teleconetrans Pacing Sys., Inc., 105 F.3d 1090, 1095 (6th Cir. 1997).
145 Goodlin, 167 F.3d at 1369.
146 *Id.* But see infra notes 175-176 and accompanying text.
147 *Id.*
148 For example, the U.S. Court of Appeals for the Fifth Circuit has labeled the 510(k) process a “limited form of review” as opposed to the “rigorous” PMA process. Reeves v. Acromed Corp., 105 F.3d 442, 445 (5th Cir. 1997). The U.S. District Court for the Northern District of Texas used similar language in characterizing the FDA 510(k) review as “limited” and intended solely to establish substantial equivalence. Dyer v. Danek Med., Inc., 115 F. Supp. 2d 732, 736 (N.D. Tex. 2000). Further, citing the Supreme Court’s decision in *Lohr*, the U.S. District Court for the District of New Jersey identified the 510(k) process as a “limited form of review.” Hawkins v. Leslie’s Poolmart, 965 F. Supp. 566, 571 (D.N.J. 1997).
149 For example, the Seventh Circuit in *Mitchell* noted that Justice O’Connor stated in *Lohr* that the 510(k) process “merely” determines substantial equivalence. Mitchell, 126 F.3d at 908. The U.S. District Court for the Middle District of Florida held that the 510(k) premarket notification process “requires only” a demonstration of substantial equivalence to a predicate device. Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1355 (M.D. Fla. 1999). Similarly, the U.S. District Court for the Southern District of New York held that the 510(k) process requires submission of “limited information” and is not comparable to PMA process. Richman v. W.L. Gore & Assoc., 988 F. Supp. 753, 756 (S.D.N.Y. 1997).
market notification process as “expedited,” thereby implicitly downplaying the importance of the process.150 Interestingly, device manufacturers themselves may choose to downplay the 510(k) process under certain circumstances.151

At other times, courts appear to simply misunderstand the fundamentals of the 510(k) premarket notification process. For example, the U.S. Court of Appeals for the Third Circuit cited the statutory definition of substantial equivalence in a decision and then further stated that “[t]his substantial equivalence determination therefore requires the manufacturer to provide information to FDA in order to ensure that ‘the device is safe, effective and performs as well as or better than the [predicate] device …’. 21 C.F.R. § 807.95; see 21 U.S.C. § 360c(i)(3)(A); 21 C.F.R. § 807.92.”152 As written, this statement seems to apply to the concept of 510(k) substantial equivalence generally, but a close review of the regulation being quoted indicates that the cited regulation only applies to 510(k) submissions “in which a determination of substantial equivalence is also based on an assessment of performance data,” including nonclinical and clinical test results.153 Such loose characterizations of the 510(k) process, even if implying a more rigorous standard of review than is generally applied to the process, can lead to significant confusion and misunderstanding.

Similarly, the U.S. District Court for the District of Delaware has commented upon the 510(k) process in a case involving patent infringement and validity.154 In connection with its decision, the Delaware District Court stated that “[a] 510(k) submission to FDA is a ‘submittal[] of engineering and clinical information which [is] provided to FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market.’”155

The Delaware District Court is clearly incorrect in broadly stating that 510(k)s involve the submission of “engineering and clinical information” to permit FDA “to assess the safety and effectiveness of a new product.”156 Perhaps the use of broad characterizations and imprecise language with respect to the 510(k) process may be at the core of some courts’ seemingly overall negative perception of the 510(k) process.

150 For example, the U.S. Court of Appeals for the Seventh Circuit utilized the term “expedited” to characterize the 510(k) process within a discussion of Supreme Court’s Lohr decision. Chambers v. Osteonics Corp., 109 F.3d 1243, 1246 (7th Cir. 1997). In a similar fashion, the U.S. District Court for the Southern District of Iowa, while discussing the Supreme Court’s Lohr decision, identified the 510(k) process as an “expedited review.” Carey v. Shiley, Inc., 32 F. Supp. 2d 1093, 1104 (S.D. Iowa 1998). The U.S. Court of Appeals for the Ninth Circuit described a similar situation with a bit more flourish in characterizing the 510(k) process as an “escape” from the onerous PMA requirements. United States v. Bowen, 172 F.3d 682, 687 (9th Cir. 1999). Additionally, in an opinion issued prior to the Supreme Court’s Lohr decision, the U.S. Court of Appeals for the Eighth Circuit stated that “the 510(k) process results in no more than permission to market … [and] the FDA can grant such permission without an express determination of compliance.” Nat’l Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 995 (8th Cir. 1994).

151 For example, the opinion of the U.S. Court of Appeals for the Sixth Circuit in In re Sofamor Danek Group, Inc. reports that the defendant device manufacturer described the 510(k) process as a “relatively simple method” in a prospectus issued when the company went public. 123 F.3d 394, 397 (6th Cir. 1997).


153 21 C.F.R. § 807.92.


155 Id. at 667 n.12 (quoting Sunrise Med. HHG, Inc. v. AirSep Corp., 95 F. Supp. 2d 348, 405 (W.D. Pa. 2000)).

156 Id.
Not all courts, however, view the 510(k) process in a negative fashion. For example, in English v. Mentor Corp., supra, the Third Circuit found the 510(k) process to be “rigorous” enough to encompass safety and effectiveness “requirements” sufficient to support preemption. 157 It must be noted, however, that this decision preceded the Supreme Court’s holding in Lohr, which held the 510(k) process and related “requirements” insufficient to support preemption. 158 But even after Lohr, some courts continue to lend support to the 510(k) process despite the Supreme Court’s expressed negative view of the process, although these courts have been in the minority. For example, the U.S. District Court for the District of Columbia recognized that the SMDA toughened the 510(k) requirements to include safety and effectiveness information among other additional information. 159

C. Characterization of the 510(k) Premarket Notification Process in Published Literature and Elsewhere

Discrediting of the 510(k) process can also be found, and frequently more forcefully argued, in the writings of legal commentators. For example, one commentator has characterized the 510(k) premarket notification process as a “simple notification provision.” 160 Another commentator has published an article questioning the level of public health protection provided by 510(k) process. 161 In fact, the Supreme Court quoted from this article in characterizing the 510(k) process in the Lohr opinion. 162

Yet another commentator, Professor Robert Leflar, has further proffered that the 510(k) substantial equivalence review process, in addition to potentially being ineffective at assuring a reasonable level of safety and effectiveness, may also contain procedural problems that make it an unsuitable premarket regulatory pathway. 163 Professor Leflar expands upon these perceived problems in noting three specific procedural issues associated with the 510(k) process:

First, substantial equivalence review is conducted entirely as an internal agency process, without public participation. FDA does not convene advisory committees to discuss substantial equivalence determinations; there is no public record of any debate over the matter. Second, unlike premarket approvals or denials, substantial equivalence determinations are not accompanied by summaries of safety and effectiveness data. No FDA-approved information about the products’ performance typically is released, so would-be buyers may have little reliable basis for their purchasing decisions. Since the agency provides no reasons for its determinations, neither Congress nor the public has a means of assessing the propriety of the agency’s actions. Finally, there is no practical method for a member of the public or a competitor to mount an administrative

157 English, 67 F.3d at 482.
158 Lohr, 518 U.S. at 494.
160 Kaplan, supra note 111, at 161.
161 Adler, supra note 8, at 516.
162 See supra note 136 and accompanying text and quotation.
or judicial challenge to a substantial equivalence determination, despite the fact that such a determination constitutes de facto permission for marketing.164

Many commentators, however, do endorse a continuing role for the 510(k) process within FDA's premarket regulatory approval scheme. For example, one commentator has noted the increased importance and validity of the 510(k) process as 510(k)s and PMAs become “progressively blurred.”165 Similarly, Mr. Kahan, who in the past has been somewhat dismissive of the 510(k) process,166 has acknowledged that FDA is able to request evidence concerning a subject device's safety and effectiveness as part of the 510(k) premarket notification review.167 Additionally, Professor Leflar has noted the importance of the 510(k) process because an FDA finding of substantial equivalence constitutes a "green light for marketing."168

Nevertheless, consumer advocacy groups such as Public Citizen and the National Research Center for Women and Families (NRC) recently have been vocal in their criticism of the 510(k) process, which they argue “lets sometimes complex products on the market after proving substantial equivalence to a predicate device without having to undergo comprehensive clinical evaluation for safety and effectiveness.”169 For example, NRC President Diana Zuckerman has stated that “the definition of substantial equivalence no longer has any scientific meaning,”170 and what is “most worrisome about the 510(k) process is whether products that are made out of a new material or using a new technology can realistically be considered safe without clinical trials or a thorough review.171 Similarly, Public Citizen’s Peter Lurie argues “[t]he tragedy here is not that effective devices are being withheld from people or would be, [t]he tragedy currently is that devices with no meaningful evidence of effectiveness that would never be approved, were they drugs, instead can be approved when they’re devices.”172 In short, Mr. Lurie believes “[t]he 510(k) process is a loophole that’s swallowed the law.”173

164 Id. at 33. It should be noted, however, that Congress remedied the second procedural problem identified above by implementing a safety and effectiveness summary requirement for 510(k)s in the SMDA. Gibbs, supra note 26, at 2. According to the FDA's guidance document explaining the SMDA's changes to the 510(k) premarket notification process, “[t]he safety and effectiveness information in the 510(k) summary ... refers to that information upon which an equivalence determination is based. Depending on the device, this 510(k) summary could be descriptive information about the new and the legally marketed device, and in addition for some devices, about performance or clinical evaluation.” SMDA Changes—Premarket Notification; Regulatory Requirements for Medical Devices (510k) Manual Insert, supra note 73, at 1.

165 HAZARDOUS TO OUR HEALTH?: FDA REGULATION OF HEALTH CARE PRODUCTS 63 (Robert Higgs ed., The Independent Institute (1995)).
166 See supra note 105 and accompanying text.
167 Kahan, supra note 10, at 521.
168 Leflar, supra note 163, at 28.
172 Mezo, supra note 169, at 6-7.
173 Mezo, supra note 171, at 7.
IV Analysis

A. The Appropriate and Essential Role of the 510(k) Premarket Notification Process

Court decisions discrediting the 510(k) process have often misinterpreted and misunderstood the process by failing to give proper credit to the leveraging of predicate device clinical history offered by the substantial equivalence process.\(^{174}\) By utilizing a substantial equivalence standard, the 510(k) process compares and equates a new device to a successful device already on the market and in clinical use. The successful history of the predicate device serves to establish a reasonable assurance of safety and effectiveness for the new device. Under the postmarket regulations and controls of the FDCA and its implementing regulations, an unsafe and/or ineffective predicate device would not remain on the market and thus would not be available as a predicate for later devices.\(^{175}\) Due to the presence of postmarket regulation and controls, the Eleventh Circuit’s concern—as expressed in the Goodlin decision—that FDA considers substantial equivalence “regardless of how unsafe or ineffective” the predicate device may be is unfounded.\(^{176}\)

Commentators and critics have similarly failed to recognize the critical role clinical history plays in establishing the safety and effectiveness of devices utilizing the 510(k) process.\(^{177}\) One commentator has stated:

To compare the procedures, a PMA application requires testing results that are reviewed by a panel of experts for safety and effectiveness. A Premarket Notification, on the other hand, only requires data to support the assertion that the subject device is as safe and effective as a device marketed prior to May 1976—a device that itself has never been reviewed or approved by FDA.\(^{178}\)

What this commentator fails to take into account in this statement is the fact that predicate devices to which 510(k) devices claim substantial equivalence have been successfully marketed and used for a period of time, thereby establishing their safety and effectiveness to a reasonable degree through a successful clinical history. By establishing substantial equivalence to a marketed product, manufacturers are leveraging the successful clinical history of the predicate product to establish the reasonable assurance of safety and effectiveness for the medical device to be marketed, a process appropriate for the mid-level risk devices eligible for the 510(k) process.

In addition, because of the risk-based nature of the classification system and premarket regulatory scheme employed by FDA, lower risk devices should have a less onerous path to market to both encourage manufacturers to develop lower risk devices and speed these types of devices to market to promote public health.\(^{179}\)

Increasing levels of risk warrant increasing levels of regulatory oversight, hence the

\(^{174}\) See supra notes 59-61 and accompanying text.

\(^{175}\) 21 U.S.C. § 360c(i)(2) (“A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.”).

\(^{176}\) Id.

\(^{177}\) See, e.g., Bivans, supra note 58, at 1093-94.

\(^{178}\) Id.

\(^{179}\) See supra notes 47-48 and accompanying text.
classification scheme and associated premarket review procedures implemented by the MDA. Lower risk devices should have lessened regulatory burdens in order for these products to reach patients more quickly and promote public health. As risk increases, so too must regulatory oversight so that the benefit of promoting public health is properly weighed against the risk of the device posed to the patient.

The Supreme Court recognized the criticality of this risk-based approach to premarket regulation in its Buckman opinion. Addressing the fact that certain Class III devices may be eligible for the 510(k) process due to a lesser risk profile as compared to Class III devices that must receive PMA approval, the Supreme Court stated that:

This flexibility [in oversight options available to FDA] is a critical component of the statutory and regulatory framework under which FDA pursues difficult (and often competing) objectives. For example, with respect to Class III devices, FDA simultaneously maintains the exhaustive PMA and the more limited § 510(k) processes in order to ensure both that medical devices are reasonably safe and effective and that, if the device qualifies under the § 510(k) exception, it is on the market within a relatively short period of time.\(^\text{180}\)

Later in its decision, addressing off-label usage concerns in the context of fraud-on-the-FDA claims, the Supreme Court noted that if fraud-on-the-FDA claims were not preempted, companies would be pressured to submit a “deluge of information” to FDA as part of the 510(k) process to protect themselves from state law tort claims.\(^\text{181}\) “As a result, the comparatively speedy § 510(k) process could encounter delays, which would, in turn, impede competition among predicate devices and delay healthcare professionals’ ability to prescribe appropriate off-label uses.”\(^\text{182}\)

Moreover, all devices are subject to the broad statutory provisions against adulteration and misbranding.\(^\text{183}\) According to the regulations implementing these statutory provisions, a device will be considered adulterated if it violates any applicable regulations set forth in 21 C.F.R. Parts 800-895, and particularly those regulations pertaining to manufacturing requirements. Similarly, a device will be considered misbranded if it violates any applicable regulations set forth in 21 C.F.R. Parts 800-895, and particularly those regulations pertaining to labeling requirements. Furthermore, devices cleared for marketing via the 510(k) process are also subject to additional requirements intended to promote safety and effectiveness.\(^\text{184}\) In addition to any specific requirements or limitations identified within a particular 510(k) clearance letter, there are certain “general controls” that manufacturers must comply with in order to legally market a device pursuant to a 510(k) clearance as well as various “special controls” for certain types of devices.\(^\text{185}\)

For example, all medical device manufacturers, regardless of the classification of the devices that they manufacture, must follow applicable portions of the Quality

\(^{180}\) Buckman, 531 U.S. at 350-51.

\(^{181}\) Id. at 351.

\(^{182}\) Id.

\(^{183}\) 21 U.S.C. §§ 351 (adulteration), 352 (misbranding).

\(^{184}\) See generally Leflar, supra note 163, at 22-27 (providing description of controls for non-Class III devices).

\(^{185}\) 21 C.F.R. § 860.3(c)(2).
System Regulation (QSR), which is set forth in 21 C.F.R. Part 820. The QSR details the premarket and postmarket requirements that manufacturers must comply with in the design, manufacture and distribution of devices. Further, all medical device manufacturers must abide by the medical device establishment registration and device listing requirements, as set forth in 21 C.F.R. Part 807, Subparts A-B. Under these requirements, manufacturers must register their facilities with FDA using a form known as a “Form FDA-2891” and “list” the devices they intend to design, manufacture and market on “Form FDA-2892.” Furthermore, medical device manufacturers must comply with labeling regulations (21 C.F.R. Part 801) and various postmarket requirements. The postmarket requirements include procedures for medical device reporting (MDR) due to adverse events (21 C.F.R. Part 803), reports of corrections and removals (21 C.F.R. Part 806), and recalls (21 C.F.R. Part 810). These regulations pertain to the reporting requirements associated with defective devices and complaints as well as any market corrections and/or removals resulting therefrom, including FDA-ordered recalls.

B. The GAO Should Endorse the 510(k) Process in its Report to Congress as an Appropriate Premarket Vehicle for Medium-Risk Devices

As previously noted, § 225 of Title II (MDUFA II) of the FDAAA requires the Government Accountability Office (GAO) to conduct a study of the 510(k) premarket notification process. Specifically, § 225 states:

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186 Id. at pt. 820 (outlining current good manufacturing requirements applicable, at least in part, to all device manufacturers).
187 Id.
188 Id. at pt. 807 (describing requirements and procedures for registering medical device manufacturing establishments and listing devices).
190 See, e.g., 21 C.F.R. pt. 801 (outlining medical device labeling requirements and provisions); pt. 803 (medical device reporting due to adverse events); pt. 806 (medical device market corrections and removals); pt. 810 (medical device recall authority procedures).
191 Id. at pt. 803 (summarizing medical device reporting requirements related to deaths and serious injuries associated with devices); pt. 806 (detailing requirements for reporting medical device market corrections and removals); pt. 810 (describing FDA medical device recall authority and associated recall procedures).
192 Although beyond the scope of this article, a related argument in favor of the 510(k) premarket notification process finds support in social utility theory. See generally Jeremy Bentham, An Introduction to the Principles of Morals and Legislation (1789) (outlining utilitarianism and related social utility theory). Under this theory, as developed by Jeremy Bentham and later expanded upon by John Stuart Mill, actions should be based on consequences resulting in the greatest good for society at large, not for the individual actor. Id.; see also John Stuart Mill, Utilitarianism (1863). Mill argued that “the happiness which forms the utilitarian standard of what is right in conduct, is not the agent’s own happiness, but that of all concerned.” Id. at ch. 2. Thus, by applying social utility theory to risk-based medical device regulation, one concludes that the 510(k) process plays an appropriate role insofar as the benefit to the public through promotion of public health via faster access to medical devices outweighs the risk to the few individuals who may be harmed under such a system. It follows that lower risk devices warrant reduced regulatory oversight because the potential for harm is lessened, thereby justifying faster speed to market through fewer regulatory restrictions. Using the language of Bentham and Mill, happiness (i.e., protection and promotion of health) of the public as a whole can be maximized while pain (i.e., adverse events and regulatory delays) is minimized under the 510(k) scheme because of the relative risks and benefits involved.
SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the appropriate use of the process under section 510(k) of the Federal Food, Drug, and Cosmetic Act as part of the device classification process to determine whether a new device is as safe and effective as a classified device.

(b) CONSIDERATION.—In determining the effectiveness of the premarket notification and classification authority under section 510(k) and subsections (f) and (i) of section 513 of the Federal Food, Drug, and Cosmetic Act, the study under subsection (a) shall consider the Secretary of Health and Human Services’s evaluation of the respective intended uses and technologies of such devices, including the effectiveness of such Secretary’s comparative assessment of technological characteristics such as device materials, principles of operations, and power sources.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.193

For the reasons set forth above, the GAO should conclude that the 510(k) premarket notification process plays an important role in the medical device regulatory system, and that role should be endorsed and continued. The flexible and practical nature of the 510(k) process strikes the proper balance between “the appropriate level of regulatory scrutiny with the potential dangers of a particular medical device,” which is critical to the proper functioning of FDA in view of its limited resources.194 Through its substantial equivalence determination, the 510(k) process provides a reasonable assurance of safety and effectiveness, thereby achieving its goal. FDA’s implementation and use of various tools in the 510(k) process, such as the “New 510(k) Paradigm” and other guidance documents, also serves to advance the goals of the 510(k) process specifically and the medical device premarket regulatory system generally. The GAO should recognize this crucial role of the 510(k) process and report to Congress accordingly.

V. CONCLUSION

Federal regulation of medical devices must strive to balance promoting and protecting public health. The risk-based classification system and associated premarket review scheme established by the Medical Device Amendments of 1976 provide a statutory framework to build such a system. This overall regulatory structure has been largely successful.

The 510(k) premarket notification process, both as outlined in the MDA and even more so as currently utilized by FDA, is an appropriate regulatory mechanism for medium-risk devices. Although not as rigorous a review as found in a PMA, the 510(k) process, through its use of the substantial equivalence standard and pseudo safety and effectiveness review for higher risk devices, succeeds in achieving a useful balance between protecting public health through premarket review and

193 FDAAA, supra note 19, § 225.
194 Goldberger, supra note 3, at 317.
promoting public health by providing access to medium-level risk devices more quickly. Despite the criticisms of some courts and commentators, the 510(k) process works for its intended purpose, as explained throughout this article and in a recent “white paper” on the subject released by the Advanced Medical Technology Association (AdvaMed). According to one AdvaMed representative, “[c]ritics have often mischaracterized the 510(k) process as just a quick and easy, sort of rubber-stamp mechanism for companies to market their product. This is far from the actual process.”

In an editorial published in *The New England Journal of Medicine* prior to the Supreme Court’s decision in *Riegel*, a group of physicians argued that the Supreme Court should conclude that the PMA process does not have preemptive effect because such a decision would “protect patients.” In making their argument, the physicians questioned whether a contrary conclusion “[w]ould … benefit patients by making more lifesaving medical devices available, or would there be adverse effects on the overall safety of devices?” This query, although acknowledging the trade-offs that form the core of medical device regulation and recognizing the tension between protection and promotion of public health, cannot be answered in such a binary, “either/or” fashion. As explained throughout this article, the foundation of the medical device regulatory scheme is the risk-based classification and regulation system, which is intended to balance the protection and promotion of public health. The 510(k) premarket notification process plays a crucial role in this balance, and the GAO should recognize this role and endorse the 510(k) process in its report to Congress.

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198 Id.