“SE,” Safe and Effective, Substantially Equivalent, or both?

I. INTRODUCTION

At the forefront of technological innovation is the medical device industry. Despite the rapid evolution of science and technology however, regulatory framework underlying this area is ancient and stagnant. Under the Food, Drug and Cosmetic Act (FDCA), as amended, the Food and Drug Administration (FDA) is responsible for ensuring medical devices are safe and effective. Section 510(k) of the FDCA creates a quicker and less expensive route for medical devices to reach market. ¹ Under § 510(k), a product is cleared for market distribution if it is “substantially equivalent” to another device within that type.² Section 510(k) is widely employed by medical device manufactures and is responsible for many of the medical devices currently on the market. Recently, the § 510(k) process has been spotlighted, in the wake of a recent FDA controversy involving the 510(k) clearance and then withdrawal of ReGen Menaflex, a medical device.³ The ReGen Menaflex controversy has caused prominent political figures to allege the 510(k) process’s failure to protect patients, and its failure to ensure only safe and effective medical devices reach market.⁴ Given the § 510(k) process’s important role in medical device development, it is imperative that the FDA determines § 510(k) medical devices to be both substantially equivalent and safe and effective.⁵

¹ See 21 U.S.C. § 360c(i)(2011)(detailing the substantial equivalence requirements)
² Id.
³ See generally FOOD AND DRUG ADMIN., REVIEW OF THE REGEN MENAFLEX: DEPARTURES FROM PROCESSES, PROCEDURES, AND PRACTICES LEAVE THE BASIS FOR REVIEW DECISION IN QUESTION. A PRELIMINARY REPORT (2009).
⁵ INST. OF MEDICINE, PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS (2010).
Two landmark Supreme Court cases explore the difference between medical devices cleared via § 510(k) and those approved under PMA process and delve into the role safety and efficacy determinations play for either pathway to market. In *Lohr v. Medtronic*, the Court ruled for Lona Lohr, finding that the FDA did not determine the § 510(k) medical device at issue, to be both safe and effective. The 510(k) process, the Court concluded, only focuses on the medical device’s equivalence to another device; not the device’s safety and effective. Therefore, state law product liability claims against § 510(k) devices were not preempted. Roughly eleven years later, the Supreme Court heard a similar case yet ruled instead for Medtronic. In *Riegel v. Medtronic*, the Court found that the FDA made clear safety and effectiveness findings for devices approved through the Premarket Approval Application process (PMA). Therefore, Medtronic’s medical device in *Riegel*—which was approved through PMA—was both both safe and effective; state law product liability claims were preempted by federal law.

This Article seeks to show that the FDA makes a safety and efficacy finding for medical devices cleared through the § 510(k) process. Part II provides a brief history surrounding the introduction of medical devices through the “pre-market approval process” and the “substantially equivalent standard.” In particular, Part II focuses on two landmark cases, *Medtronic, Inc. v. Lohr* and *Riegel v. Medtronic, Inc.*, and each cases role in medical device product liability suits. Part III of this Note then provides a different interpretation the arguments relied on in *Lohr*, in light of a changing statutory framework. Part III also shows that prominent players in the medical device industry agree that the FDA conducts a safety and efficacy assessment for § 510(k) devices, as well as supplies evidence of safety and effectiveness findings for medical devices.

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8 The PMA process is the most burdensome way for a medical device to reach market. The PMA process ensures medical devices are safe and effective. *See* 21 U.S.C. § 360e(c)(1)(C)(2011).
devices cleared under § 510(k). Ultimately, this note suggests that the standards established in
*Lohr* are outdated and no longer applicable because the FDA conducts a safety and efficacy
examination for 510(k) medical devices; the standard relied upon in *Riegel* should supersede that
of *Lohr*.

**II BACKGROUND**

**A. HISTORY OF MEDICAL DEVICE REGULATION**

In order to keep up with increasing technological innovation the FDCA has been
amended several times. In 1976, the Medical Device Amendments widened the FDA’s breadth
of control of medical devices by created “regulatory classes” for medical devices depending on
the medical risk the device presented. Additionally, the Medical Device Amendments introduced
the “substantial equivalence” process. In 1990, the Safe Medical Device Act and then in 2002,
the Medical Device User Fee and Modernization Act further expanded FDA’s regulatory control
over medical devices to better ensure their safety.

1. Medical Device Amendments of 1976

The original FDCA granted the FDA a limited scope of authority over medical devices.
In 1976 the Medical Device Amendments were adopted as a response to an increasing
prevalence of medical devices on the market. A key feature of the Amendments was FDA
classification of medical devices into three categories of regulatory controls: Class I, Class II and
Class III. Each device, whether classified as Class I, II, or III, is subject to general or special
controls depending on the risk the device presents. “Controls” are regulatory measures

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FOOD DRUG COSMETIC L.J. 424 (1976).
10 21 U.S.C. § 360e
11 Id.
necessary to assure the safety and effectiveness of the device.¹² Devices in Class I do not “present a potential, unreasonable risk of illness or injury”¹³ and therefore do not have to meet a safety and efficacy standard prior to distribution.¹⁴ Class I devices are regulated under “general controls”—the lowest level of control.¹⁵ A Class I device is an examination glove or elastic bandage. Class II devices present more risk than Class I devices.¹⁶ Class II devices are regulated under the general controls of Class I, but are also subject to special controls because “the general controls . . . are insufficient [by themselves] to provide reasonable assurance of the safety and effectiveness of the device . . . .”¹⁷ An example of a Class II device is infusion pump, which presents more risk and requires more safety measures than the examination glove example. with Class III devices are controlled much more extensively than either Class I or Class II. Class III devices are those subjected to “premarket approval”—a much more burdensome and time consuming process.¹⁸ Class III devices are ones which both general and special controls are insufficient to assure the safety and effectiveness of the device.¹⁹ Class III devices encompass devices like pacemakers and defibrillators. Classification of medical devices largely ensures the safety of devices by implementing proper regulatory controls.²⁰

¹² 21 U.S.C. § 360c; see also Device Classification, FOOD AND DRUG ADMIN. (Apr. 27, 2009), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm
¹³ 21 U.S.C. § 360c
¹⁴ Geller, supra note 9 at 428.
¹⁵ Id.
¹⁷ Id.
¹⁸ See id.
¹⁹ Id.
In addition to identifying classes for medical devices, the Medical Device Amendments also organized a regulatory structure allowing a post-1976 device to demonstrate substantial equivalence to a device already on the market. Substantial equivalence means the device has the same intended use as the predicate and the same technological characteristics to the predicate device.21 The device must also have the same technological characteristics as the predicate.22 If there are different technological characteristics, the device manufacturer must submit data demonstrating the device is as safe and as effective as the predicate device.23 Substantially equivalent was to be interpreted narrowly in instances “where necessary to assure safety and effectiveness,” but substantially equivalent did not refer to only devices that were “identical” to those already on the market.24 If a manufacturer could prove substantial equivalence to a device marketed prior to 1976, they could bypass the premarket notification process altogether.

2. Safe Medical Device Act of 1990

Another major reformation of the FDCA was the Safe Medical Device Act of 1990. In response to multiple mishaps in the medical device realm,25 Congress adopted the Safe Medical Device Act to expand FDA authority of medical device regulation and increase burdens on manufacturers of medical devices.26 First, the Safe Medical Device Act strengthened the definition of “substantial equivalence.” Substantial equivalence now requires the device has the same intended use as the predicate and the same technological characteristics to the predicate

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22 Id.
23 Id.
25 See Russell Mokhiber, The Dalkon Shield: A Deadly Product from A.H. Robbins, 8 CORP. CRIME AND VIOLENCE (Apr. 1987), http://multinationalmonitor.org/hyper/issues/1987/04/ahrobin.html; see also Lohr, 518 U.S. at 476 (citing the Dalkon Shield as being one of several catastrophic events leading to the Safe Medical Device Act of 1990).
device.\textsuperscript{27} The device must also have the same technological characteristics as the predicate.\textsuperscript{28} If there are different technological characteristics, the device manufacturer must submit data demonstrating the device is as safe and as effective as the predicate device.\textsuperscript{29} Particularly, the statute specifically allows the FDA to request and drug manufactures must submit clinical data when the new device has technological changes as compared to the predicate device.\textsuperscript{30} Additionally, manufacturers of medical devices must submit a summary of safety and effectiveness data to be reviewed by the Agency.\textsuperscript{31} After the Safe Medical Device Act, a device demonstrating substantial equivalence did not have to have pre-1976 device as a predicate. Any device can apply for 510(k) clearance, so long as there are proven to be substantially equivalent to a device on the market.\textsuperscript{32} After the Safe Medical Device Act, a predicate device could be “a device cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (a pre-amendment device) a device that was originally on the US market as a Class III device (PMA) and later down classified to Class II or I, or a 510(k)-exempt device.”\textsuperscript{33}

One important change promulgated by the Safe Medical Device Act and key to the analysis of this note, was the modification of pre-1976, Class III devices regulation. The original 1976 Amendments directed the FDA to conduct premarket approvals for Class III devices already on the market; in reality, few premarket approvals were actually performed for those devices. As a result, many pre-1976 devices, Class III devices never completed a premarket approval.

\textsuperscript{28} Id.
\textsuperscript{29} Id.
\textsuperscript{30} Id.
\textsuperscript{31} Flannery, supra note 26, at 149.
\textsuperscript{32} See 21 U.S.C. § 360c (“substantial equivalence” means, with respect to a device being compared to a predicate device . . .”). The language of the statute does not include a requirement that the predicate device be pre-1976.
\textsuperscript{33} COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510K, INST. OF MED. REPORT, CLEARANCE PROCESS, PUBLIC HEALTH EFFECTIVENESS OF THE FDA CLEARANCE PROCESS 1 (Theresa Wizemann ed., 2010).
approval and, were never determined to be safe and efficacious. As a further implication, devices “substantially equivalent” to pre-1976, Class III devices were purported to be substantially equivalent in all respects, including safety and efficacy of which there was no actual proof.\textsuperscript{34} After enacted, the Safe Medical Device Act required that manufactures of pre-1976, Class III devices to submit a detailed summary including adverse data relating to the safety and efficacy of the device.\textsuperscript{35} The FDA then reclassified the pre-1976 devices, conducting a premarket approval on those devices that were to remain in Class III.\textsuperscript{36} The enactment Safe Medical Device Amendment’s better ensures the safety and effectiveness of all medical devices hitting market after 1990. In doing so, the Act demonstrates the both Congress’s and the Agency’s increased focus on safety.

\textbf{3. Medical Device User Fee and Modernization Act of 2002}

In 2002, Congress enacted the Medical Device User Fee and Modernization Act (MDUFMA). The Act was intended to give the FDA resources to “better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time, and to ensure that reprocessed medical devices are as safe and effective as original devices.”\textsuperscript{37} MDUFMA has since provided the FDA with resources to better assess medical devices, ensuring their safety and

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\item[34] Flannery, supra 26, at 135.
\item[35] \textit{Id.}; see 21 U.S.C. § 360c(i).
\item[36] 21 U.S.C. § 360c(i).
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effectiveness. The enactment of MDUFMA has allowed the FDA to place more time and resources towards medical device review.

B. METHODS FOR REACHING MARKET

Currently, a medical device has three methods of reaching market. First, some class I, low risk devices such as tongue depressors do not require any approval or clearance before market. Second, a medical device may reach market via the PMA route and thirdly, a manufacturer can seek clearance via § 510(k) and a showing of substantial equivalence.

1. Braving the Premarket Approval Process

The PMA process is a regulatory review specifically evaluating the safety and effectiveness of medical devices. Before a device manufacturer can market its medical device, it must obtain FDA approval. The PMA process is the most rigorous process for a medical device to reach market. First, the manufacturer must complete the PMA application. The PMA application requires non-clinical laboratory studies and clinical investigations to be submitted to the FDA; both are time consuming and expensive. The studies must be sufficiently thorough to prove that the device is safe and effective for the intended use.

Once the application is submitted to the FDA, the device manufacturer must wait for review and approval before its device can be marketed. The time taken to respond to premarket

40 Premarket Approval, FOOD AND DRUG ADMIN. (Sept. 3, 2010), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm. PMAs are required for all Class III medical devices and some Class II devices.
41 Id.
43 Id.
approval applications is significantly longer compared to manufacturers who seek clearance through a showing of substantial equivalence. Overall, the PMA process is more expensive and take more time than clearance through § 510(k). For these reasons, manufacturers frequently attempt to gain FDA clearance under § 510(k) rather than approval through a PMA. 

2. Reaching market through a showing of Substantial Equivalence under § 510(k)

Establishing equivalence under 510(k) is significantly faster, cheaper and far less burdensome than the PMA process. In order to be classified as substantially equivalent, the device must pass through a series of checkpoints. First, the manufacturers must demonstrate that the device has the same intended use as the predicate device. If the device does not have the same intended use as its predicate, the device is “not substantially equivalent” or NSE within the meaning of § 510(k). Next the medical device must have matching technological characteristics as the predicate device. If the technological characteristics are different from those of the predicate device in such a way that may have an effect the device’s safety and efficacy, the FDA will assess whether those differences in technology raise any safety and efficacy concerns. So

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44 Statutorily, the FDA must respond to applications in 180 days after submission. See id. In practice, however, the FDA takes much longer. For example, if an amendment to the application is submitted, the 180 day clock restarts. See Peter Barton Hutt et al., Food and Drug Law: Cases and Materials 995 (Robert C. Clark et. al. eds., 3d ed. 2007) (noting that substantial equivalence “was clearly intended to embrace some inquiry into the safety and effectiveness of a new device”)(emphasis added).
45 See INST. OF MEDICINE, supra note Error! Bookmark not defined. (substantial Equivalence “allow[ed] products to go to marked quickly with the appropriate safeguards.”).
46 Goldburger, supra note Error! Bookmark not defined., at 323–24 (describing the process a device seeking clearance through 510K must pass).
47 Id. at 324.
48 Id.; see also Janice Hogan & Gwyn Simmons, Standards for Clearance of 510K Premarket Notifications in the US, RAJ DEVICES, 311–12 (Sept./Oct. 2008) http://www.hoganlovells.com/files/Publication/c6c923f0-742a-4b63-be7a-eb10fc689261/Presentation/PublicationAttachment/db563313-55cf-4519-9c8a-1417ccd17af8/RAJ.pdf. Technological characteristics may include “design, materials and energy sources.”
49 Hogan & Simmons, supra note 48.
long as no new safety and efficacy questions are raised and “accepted scientific methods [are available] for assessing the effects” of the device, the FDA will clear the device.\(^{50}\) The FDA is permitted by statute to request data from clinical trials demonstrating that the device is both as safe and as effective as the predicate device.\(^{51}\) The data also aids the FDA in its substantial equivalence determination.\(^{52}\) On the face of the statute, however, the FDA is not permitted to make an independent assessment of safety and efficacy for the § 510(k) device.\(^{53}\) The manufacturer must only show that the device is for the same intended use, has the same technological characteristics, or that the different technological characteristics do not raise safety and efficacy concerns as opposed to whether the devices is independently safe and effective.\(^{54}\)

**C. Court Analysis in *Lohr v. Medtronic, Inc.***

The device at issue in *Lohr* was a cardiac pacemaker. Medtronic produced the pacemaker and the FDA cleared it for distribution under the 510(k) process of the MDA.\(^{55}\) Due to a defect in the lead—a wire responsible for carrying electric impulses to the heart—the pacemaker failed several years later.\(^{56}\) Medtronic argued that Lohr’s defective device claim was pre-empted under the FDCA,\(^{57}\) asserting that “federally enforceable design requirement[s] . . . cannot be affected

\(^{50}\) Golderberger, *supra* note \textbf{Error! Bookmark not defined.}, at 324.

\(^{51}\) Id.

\(^{52}\) Id.

\(^{53}\) Medtronic v. Lohr, 518 U.S. 470 at 493 (determining that the 510K process does not assess safety of the device, but just the devices equivalence to its predicate).

\(^{54}\) \textit{See id.} Presently, this creates an important distinction from the PMA process. Clearance through § 510K is not determining that the device is safe and effective as it would if approved through a PMA. As currently interpreted, § 510K only assures that the device is equally as safe as its predicate device.

\(^{55}\) *Lohr*, 518 U.S. at 474.

\(^{56}\) Id.

\(^{57}\) Id. at 492. Section 360k(a) reads: “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.” 21 U.S.C. § 360 (2011).
by state-law pressures such as those imposed on manufacturers subject to product liability suits.”

The court rejected this claim and ultimately held that, because the 510(k) process does not focus on safety and efficacy, but rather equivalence, a defective device claim was not pre-empted by federal law.

1. History of Pacemaker in dispute

The pacemaker at the center of the Lohr dispute was a Model 8403 Activitrax with a Model 4011 lead. In 1980, Model 4011 leads were classified as Class III devices. Shortly thereafter, in 1982, Medtronic submitted an application to have a Model 4011 lead cleared through 510(k), claiming substantial equivalence a pre-1976 device. Approximately a month later, the FDA allowed Medtronic to “market the Model 4011 lead subject only to MDA’s Class I general controls applicable to all devices.” Medtronic continued making leads, piggy-backing on predecessors and obtaining clearance through 510(k). As summarized in a 1992 government report that reviewed multiple failures or Medtronic pacemakers, the FDA never determined Medtronic’s 4011 leads to be either safe or efficacious. Ms. Lohr was implanted with such a pacemaker in 1987.

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58 Lohr, 518 U.S. at 317.
59 Id. at 503
61 Id. at 365.
62 Id. at 366 (demonstrating that, given the timeline, neither the pre-amendment pacemaker, nor the pacemaker cleared through substantial equivalence were ever approved through PMA).
63 Id.
64 Id.
65 Id. at 367. The SMDA required pre-1976 device manufacturers to submit safety and efficacy reports for review by FDA. Before the SMDA, the safety and efficacy of many pre-1976 devices went undetermined.
2. Federal Pre-emption of State Claim under § 360k of the FDCA

Medtronic’s central defense was an assertion of federal pre-emption under § 360k(a) of the FDCA.\(^66\) Section 360k(a), prohibits states from establishing device requirements additional to or different from those required by the FDA. Section 360k(a) reads:

(a) General rule. Except as provided in subsection (b), 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 Act 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 Act.\(^67\)

This provision, as a part of the Medical Device Amendments, pre-empts state claims which establish additional requirements or different requirements relating to the safety and efficacy of devices under the FDCA.\(^68\) Medtronic asserted that Lohr’s design claim was pre-empted because the FDA, by way of clearance under 510(k), already promulgated federally enforceable design requirements for Medtronic’s pacemaker.\(^69\) Therefore, Medtronic argued, Lohr’s action for negligent design was attempting to enforce an additional and contrary requirement to an FDA established requirement.\(^70\) In rejecting Medtronic’s pre-emption argument, the court concluded that the 510(k) process did not assess safety or efficacy of the device and manufacturers entering the market under 510(k) clearance should expect “the possibility that [they] would have to defend [themselves] against state-law claims of negligent design."\(^71\) Additionally, the Court found the “general controls” that the pacemaker was subject to were not “specific requirements

\(^{68}\) 21 C.F.R § 808.1 (b) (2010).
\(^{69}\) Lohr, 518 U.S. at 486.
\(^{70}\) Id.
\(^{71}\) Lohr, 518 U.S. at 485.
applicable to a particular device under the act,” but instead were generic provisions that apply to all devices regulation under the FDCA.\textsuperscript{72}

E. HOLDING IN RIEGEL V. MEDTRONIC, INC.

The device at the center of dispute in Riegel v. Medtronic, Inc. was an Evergreen Balloon Catheter inserted into Charles Riegel in 1999.\textsuperscript{73} The catheter was a Class III device and received FDA pre-market approval in 1994.\textsuperscript{74} Contrary to what the label of the catheter instructed, Riegel’s catheter was inflated to five times the recommended pressure.\textsuperscript{75} As a result, a heart block developed and coronary bypass surgery was required.\textsuperscript{76} Riegel brought suit against Medtronic, Inc., alleging a design and label in violation New York common law.\textsuperscript{77} In contrasting with Lohr, the court found that “pre-market approval is specific to individual devices and . . . is focused on safety, not equivalence.”\textsuperscript{78} Since Riegel’s argument focused on the safety and efficacy of the catheter and the FDA already specified requirements for that same catheter, the Court concluded the New York common law imposed different and additional requirements on the device.\textsuperscript{79} The FDCA was found to pre-empt Riegel’s claim for negligent design and faulty labeling.\textsuperscript{80}

\textsuperscript{72}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, 305 (1998); see Lohr 518 U.S. at 470.
\textsuperscript{73} Riegel v. Medtronic, 552 U.S. 312 (2008).
\textsuperscript{74} Riegel, 552 U.S. at 320 (2008). The Court described the PMA process as including, among many other facets, a thorough evaluation of the safety and effectiveness of the device. The Court also noted that once a device is approved through PMA, the FDA “forbids any changes in design specifications . . . or any other attribute . . . .” Id. at 319.
\textsuperscript{75} Id. at 320
\textsuperscript{76} Id.
\textsuperscript{77} Id.
\textsuperscript{78} Id. at 323.
\textsuperscript{80} Id.
1. Prominent FDA Regulatory Decisions After Riegel

In a recent Supreme Court case, Wyeth v. Levine,81 the Court again questioned a federal pre-emption in a product liability suit. In Wyeth, the approved drug—Phenergan—presented an increased risk of gangrene if used by injection rather than intravenous drip.82 Phenergan contained an adequate warning label per FDCA requirements, yet when the plaintiff lost her arm due to gangrene, the FDCA was found not to pre-empt a state law product liability claim.83 The holding in Wyeth seems contrary to the holding in Riegel. The Court, however, noted that a drug equivalent pre-emption provision to 360k84 was non-existent. In citing Riegel, the court concluded that unless there was a “direct and positive conflict” between state law and the FDCA, state common-law suits were not pre-empted.85 In Wyeth, the Court determined, it was possible for the drug manufacturer to comply with both state and federal law. While the FDA has authority to reject the label change, the drug manufacturer, not the FDA, is responsible for maintaining their labeling. While many believe the courts holding in Wyeth to apply to medical device product liability suits as well, it is important they are distinguished. Wyeth concerned a drug, not a device and both have unique regulatory structures.

82 Id.
83 Id. at 572.
84 Section 360k pre-empts a state from supplying additional or contrary requirements for medical devices.
ANALYSIS

In Lohr, the Court conducted a statutory analysis to reach the determination that the FDCA did not pre-empt Lohr’s product liability claim. A similar statute interpretation of today’s FDCA, in conjunction with opinions of prominent medical device market players and 510(k) clearance records, reveals that the § 510(k) should pre-empt product liability claims against devices cleared under this provision.86

A. IMPLICATIONS OF THE SAFE MEDICAL DEVICE ACT OF 1990

While the Court in Lohr established that § 360k “expressly pre-empts state law,”87 they acknowledged that § 360k was not intended to pre-empt all state laws and regulations. The Court reasoned that “[a]ny understanding of the scope of a pre-emption statute must rest primarily on ‘a fair understanding of congressional purpose.’”88 Congress’ intent, of course, primarily is discerned from the language of the pre-emption statute and the “statutory framework surrounding it.”89

1. Congressional Purpose and Statutory Framework of the FDCA following the Safe Medical Device Act.

Technology experienced a rapid expansion between the Medical Device Amendments in 1976 and the Safe Medical Devices Act of 1990. The introduction of new technologies and medical devices required the FDA to modify existing practices. Consistent with the Court’s

86 At the time Lohr was decided, the 510K clearance process was different from the current process. I do not argue that Lohr was incorrectly decided, but rather, in light of the 510K clearance process conducted today, a new standard should be applied in 510K product liability suits.
87 Lohr, 518 U.S. at 484; see § 360k(a), 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301 et. seq.(2010)).
analysis in *Lohr*, a statutory interpretation of § 360k and 513(i)\(^{90}\) should start with a “fair understanding of congressional purpose” of the current regulatory scheme. The lead at issue in *Lohr* predated the Safe Medical Devices Act. If a similar situation arose today, the Court would analyze “substantial equivalence” as defined in the Safe Medical Device Act. An inference should be drawn from Congressional purpose in the passing the Safe Medical Device Act. In this instance, the purpose of Congress is clear—the Safe Medical Device Act was to further a policy promoting the safety and efficacy of medical devices, while providing a stringent regulatory frame to effectuate that purpose.\(^{91}\) After the Safe Medical Device Act, the FDA placed a greater emphasize on the safety and efficacy of medical devices in furtherance of congressional policy.

The lead at issue in *Lohr* was not cleared under the framework of the Safe Medical Device Act. At the time Medtronic’s lead was cleared for market, the FDA still allowed § 510(k) predicates to be pre-1976 devices for which there was never an independent determination of safety and efficacy. It is at least possible that Medtronic’s predicate for the lead implanted at issue in *Lohr* was never determined safe and effective. Additionally, at the time Medtronic’s lead reached market, if the FDA did not respond within ninety days to a § 510(k) request, the device was assumed cleared.\(^{92}\) If Medtronic’s lead was cleared through the 510(k) process used today—the process that has been changed by the Safe Medical Device Act—there would be a much

\(^{90}\) Section 513(i) now contains the provisions referring to substantial equivalence.

\(^{91}\) In 1997, the passage of the Food and Drug Administration Modernization Act (FDAMA) furthered Congress’s purpose of increase safety and efficacy of market distributed products. See Linda A Suydam & Milan J. Kubic, *FDA’s Implementation of FDAMA: An Interim Balance Sheet*, 56 FOOD & DRUG L.J. 131, 131 (2001) (noting the “exceptional addition” FDAMA provided FDA’s statutary authority in addition “reaffirming the agency’s vital importance for the protection of public health.”).

\(^{92}\) Merrill, *supra* note Error! Bookmark not defined., at 1830 (noting that prior to the 1990 Act, if device manufacturers had not heard from the agency within ninety days, they were assumed to be substantially equivalent to their predicate device. The Safe Medical Device Act ended that practice by requiring specific FDA clearance prior to market distribution, even if the FDA takes more than ninety days).
greater emphasis placed on the safety and effectiveness of the lead. Under a guide of the current statutory framework, the FDA would make a clear determination of the safety and efficacy of the lead prior to its clearance and prior to its implantation in any person.

The overall focus of the FDA was different in *Lohr* than it is today. When Medtronic’s lead was cleared, innovation and product development were the focus of Congress as well as the FDA. The Safe Medical Device Act’s tighter regulatory structure emphasizes a shift in that focus to risk of the device rather than the benefit of the device. A focus on the risk as opposed to the benefit coupled with the purpose behind the increased regulations for Medical Devices provides for an alternative reading of § 360k. The Safe Medical Device Act modifies § 360k particularly when considering stated requirements relating to the safety and effectiveness of the medical device. This is a result of the greater emphasis the Safe Medical Device Act places on ensuring the safety and effectiveness of all medical devices, not solely those approved through the PMA process. This particular interpretation, however, post-dates *Lohr*. Medtronic’s Model 4011 Lead never had to pass muster under this remodeled “substantial equivalence” scheme of the Safe Medical Device Act. Had the Safe Medical Device Act been in place prior to the lead’s clearance, the Safe Medical Device Act provisions would have held the Lead to a higher standard and a specific determination of safety and efficacy. Unlike the lead, however, medical devices subject to the current regulatory scheme and cleared under 510(k) are specifically determined to be safe and effective. Unlike in *Lohr*, this specific determination preempts common law product liability claims.

94 For the text of § 360k, see C.2.
95 *See generally* § 360k(a) (preempting state claims of safety and effectiveness of medical devices for which safety and efficacy has already been determined by the FDA).
B. 510(k) Assessment of Safety and Efficacy: Opinions of the FDA and Participating Market Players

In *Lohr*, the Court concluded that the “510(k) process was [not] intended to do anything other than maintain the status quo, which included the possibility that a device's manufacturer would have to defend itself against state-law negligent design claims.” At the time of *Lohr*, the FDA may have even agreed that there was no assessment of a 510(k) device’s design. In contrast, the FDA today asserts that after several “statutory and regulatory modifications, the 510(k) system has become a comprehensive premarket review process that provides reasonable assurance of safety and effectiveness and facilitate[s] innovation in the medical device industry.”96 The 510(k) is now the principal route used for medical devices to reach market.97

1. FDA asserts that they are making safety and efficacy determinations for 510(k) devices

Evidence demonstrates that the FDA is making a safety and efficacy finding for 510(k) devices. First, in August of 2010, the Center for Devices and Radiological Health (CDRH), the department in charge of overseeing medical device regulation, released a guidance document to device manufacturers detailing the current “statutory framework” of the 510(k) clearance process.98 Issued as recommendations for the future of 510(k), this guidance document makes clear that the FDA is not only currently conducting a safety and efficacy determination for

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98 *Id. at 1; see Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards, Food and Drug Admin.* (2007), available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm (bringing to attention, right away, that the 510K provision is in place to promote FDA’s public health mission by ensuring devices are safe and effective when marketed. CDRH also recognizes that past implementations of the 510K have failed in to adequately achieve this goal).
510(k) devices, but that safety and efficacy are at the crux of 510(k) clearance decisions. Second, the Office of Device Regulation, the center that evaluates medical devices, released statements bringing to date the 510(k) regulatory process. Like the guidance document, the Office of Device Regulation statements indicate that a safety and effectiveness determination is made for 510(k) devices.

The Center for Devices and Radiological Health’s guidance document engages in an in-depth analysis of the 510(k) clearance process. Areas of particular importance involve an examination of the evidence required and a “basis” of information in a device manufacturer’s 510(k) summary demonstrating substantial equivalence. For a finding of substantial equivalence, “a summary shall be [submitted] in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.” The requisite basis submitted with every 510(k) submission substantiates the FDA’s safety and effectiveness determination because the basis requires evidence demonstrating the device operates similarly to its predicate, and that the device is safe and effective. The requisite scientific evidence includes performance data—both clinical and nonclinical tests—that was used by the manufacturer. This type of information historically was only required for premarket approval devices, and was not required for Medtronic’s 4011 lead to prove substantial equivalence. Today, the FDA may request additional information prior to clearing the device for market if the information has relevance to FDA’s review; namely, FDA reviews “all available safety and effectiveness information” available for the medical device. The Center of Devices and Radiological Health’s guidance document explicitly indicates that the FDA now requires information from the device manufacturer not only pertaining to the

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100 See id. (requiring only data that shows substantial equivalence). This contrasts the PMA process where such clinical studies are required to show safety and efficacy.
101 Regulation and Guidance for Industry and FDA Staff: Recognition and Use of Consensus Standards, supra note 98, at 73.
substantial equivalence of their device, but that information determining the safety and effectiveness of the device. If the manufacturer is unable to provide this now-required data, the FDA will find that the device is not substantially equivalent and not grant the device clearance under 510(k). 102

The Office of Device Evaluation also explicitly states new devices are “not substantially equivalent” if they do not demonstrate they are at least as safe and effective, if not more so, as their predicate. 103 It logically follows that to determine whether a device is “at least as safe and effective,” it must be determined how safe and effective that device is. When it is determined a 510(k) device is “at least as safe and effective” as its predicate, that determination is a conclusion that the device is safe and effective for clearance. The Office of Device Evaluation notes: “[a]s science evolves, our regulatory approach also needs to evolve. We need to be continually assessing the regulatory framework for the review of medical devices to ensure that it is still accomplishing our fundamental mission - to promote and protect public health.” 104

Devices are increasing in complexity and the FDA’s evaluation of devices requires a “risk based and data driven evaluation” of all devices. 105 Consistent with the evolution of medical devices and statutory framework, the FDA recognizes a safety and effectiveness determination for 510(k) devices. Likewise, product liability claims should be viewed consistently, using the standard in Riegel by which state safety and effectiveness claims are preempted.

When taken together, the current scheme is unlike that in place at the time of Lohr. In Lohr, no evidence of safety and efficacy was required for the Model 4011 Lead. Medical devices

102 See id. (recommending that the FDA modify their existing practice to require all data showing substantial equivalence and the devices safety and effectiveness from device manufacturers seeking clearance through 510K.
103 Presentation from Heather S. Rosencras, supra note 97.
105 Presentation from Heather S. Rosencras supra note 103.
manufacturers now must produce such evidence demonstrating a finding of safety and
effectiveness that is then reviewed by the FDA.\textsuperscript{106} If a device is found to be both safe and
efficacious by the manufacturer and then confirmed by the FDA prior to the device’s clearance,
that specific determination of safety and efficacy does not leave open an expectation that a
device manufacturer may have to litigate a suit alleging a design that does not meet the
appropriate level of safety and effectiveness. The FDA demonstrates it is making this
determination of safety and efficacy, thereby pre-empting any sort of alternative, state-based
claim.

\textbf{2. Authoritative health institutes also believe 510(k) clearances undergo a safety and
efficacy assessment.}

The Institute of Medicine (IOM)\textsuperscript{107} is currently conducting an analysis of the 510(k)
regulatory scheme—expected to conclude in 2011—and has released several “Workshop
Reports” detailing the FDA’s 510(k) clearance process throughout their study.\textsuperscript{108} Similar to the
FDA, the IOM has found and believes a safety and effectiveness determination is conducted
prior to clearance of 510(k) medical devices. IOM pointedly asserts that the same definitions of
safe and efficacious apply to \textit{every} medical device; the difference lies in how safety and efficacy
are determined for the specific device.\textsuperscript{109} FDA’s governing statutes describe the methods FDA

\begin{footnotesize}
\textsuperscript{106} 21 C.F.R. § 807.92 (detailing all that is required for a device manufacturer to submit in their
510K summary).
\textsuperscript{107} The IOM is a highly regarded organization that provides “authoritative advice to decision
makers . . . .” Institute of Medicine, http://www.iom.edu/About-IOM.aspx (last updated Oct. 12,
2010). The FDA asked the IOM to review the 510K clearance process for medical devices. See
October Report, \textit{supra} note \textbf{Error! Bookmark not defined.}.
\textsuperscript{108} October Report, \textit{supra} note \textbf{Error! Bookmark not defined.} at 1.
\textsuperscript{109} October Report, \textit{supra} note \textbf{Error! Bookmark not defined.} (defining safety as the benefits of
the medical device outweighing the risks and defining effectiveness as device producing
significant results in a considerable portion of the intended population).
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employs to establish safety and efficacy, largely through the submission of data.\textsuperscript{110} In the PMA process, this data is used to establish the safety and effectiveness of the device; whereas in the 510(k) clearance process, this data is used to determine the proper classification of the device—Class I or Class II—that will ensure its safety and effectiveness.\textsuperscript{111} The decision to place a device in a regulatory class is a finding that the device’s safety and effectiveness will be properly maintained under the regulatory controls the class imposes. Prior to such technologically complex devices seen today, the FDA did not request data supporting the safety and effectiveness of a device prior clearance under 510(k).\textsuperscript{112} Today, the IOM finds that every 510(k) submission requires scientific data prior to classification—therefore prior to market distribution. Such data is not only ensuring the safety and efficacy of medical devices before they reach the public, but demonstrating the FDA’s focus on the safety and efficacy of 510(k) devices.\textsuperscript{113} If substantial equivalence to a predicate already on the market was truly the only concern of the FDA, such data that the IOM has found is submitted with “every 510(k) application” would not be necessary. The IOM persuasively determined that the FDA is making a finding of safety and efficacy for 510(k) devices. This finding should preempt common law product liability claim against 510(k) medical devices.

Advanced Medical Technology Association (AdvaMed) is another prominent player in the medical device industry which is deeply involved in the 510(k) regulatory process.\textsuperscript{114} In

\textsuperscript{110} Id. at 11.
\textsuperscript{111} Id. at 12–13. The accompanying scientific data demonstrates the safety and efficacy of the device, allowing the FDA to appropriately place the device under the regulatory controls that will further the safety and effectiveness of the device.
\textsuperscript{112} See supra text accompanying notes 25–30.
\textsuperscript{113} October Report, supra note Error! Bookmark not defined. at 12 (finding, in addition, that any change in the device that may affect its safety and effectiveness requires the manufacturer to submit additional data and “obtain a new clearance from the FDA”). This allows the FDA to verify that 510K devices on the market remain safe and effective for public use.
\textsuperscript{114} What We Do, ADVAMED, http://www.advamed.org/MemberPortal/.
concluding that the FDA does determine a devices safety and effectiveness prior to clearance, AdvaMed characterized 510(k) a “flexible process that builds on a knowledge base that expands over time.”\textsuperscript{115} Like the IOM, AdvaMed focuses on the data now submitted with 510(k) applications; the data that historically was not collected for 510(k) devices. Today Avamed concludes, “data on device safety and use” is always collected in 510(k) submissions.\textsuperscript{116} Ultimately, AdvaMed believes that the 510(k) process is “one of many regulatory controls the FDA has in place to ensure the safety and effectiveness of medical devices, regardless of their path to market.”\textsuperscript{117} In order to “ensure” a device’s safety and effectiveness, as AdvaMed asserts takes place, there must first come a finding of that safety and effectiveness.\textsuperscript{118} AdvaMed, as prominent a player as the IOM in the medical device realm, influentially believes 510(k) devices are found by the FDA to be safe and effective prior to market distribution and this finding weighs in favor of preemption in 510(k) medical device product liability suits and an outdated holding in \textit{Lohr}.

The California Healthcare Institute (CHI)\textsuperscript{119} also affirms FDA’s assurance of safe and effective devices through the 510(k) clearance process. In concert with the IOM and AdvaMed, the CHI relies heavily on the FDA’s increased requirements and emphasis on assuring safety as


\textsuperscript{116} \textit{Id.} at 19(emphasis added) (clarifying that “this [data] provides FDA with information on actual, clinical use of well-characterized medical devices on which to base regulatory decisions”—the regulatory decisions that will continue to assure the determined safety and efficacy of the device as demonstrated by the collected data).

\textsuperscript{117} \textit{Id.} (noting that “It is important for patients to know that devices cleared via the 510K process undergo thorough FDA review” allowing the FDA to make sure devices are safe and effective.)

\textsuperscript{118} \textit{See supra} text accompanying notes \textbf{Error! Bookmark not defined.--Error! Bookmark not defined.}. (establishing that the basis of substantial equivalence includes the safety and effectiveness of the medical device).

\textsuperscript{119} California Heath Institute is “A public policy research and advocacy organization for California’s biomedical industry.” CALIFORNIA HEALTHCARE INSTITUTE (Apr. 14, 2011), http://www.chi.org/.
opposed to promoting innovation to support their belief that 510(k) medical devices are found to be safe and effective prior to market distribution.\textsuperscript{120} As support, the CHI Institute also cites empirical data demonstrating 510(k) cleared devices, in practice, are subject to Class I recalls, recalls that present the most risk, at the same rate as premarket approved devices.\textsuperscript{121} The plain facts presented in the results of Professor Ralph Hall’s study speak to the safety ensured by the 510(k) clearance process. If 510(k) devices are recalled equally as much as premarket approved devices, then it logically follows that those devices are as safe as devices approved by PMA. If the FDA is, through its increased requirements and attention to risk rather than benefit, assuring the safety of 510(k) devices as the CHI believes, then product liability claims such as that in \textit{Lohr} should be preempted by the FDA’s prior finding of safety and efficacy.

The IOM, AvaMed and CHI are some of the most highly regarded organizations in medical device regulation. If the FDA believes and demonstrates that it is conducting a safety and effectiveness assessment for 510(k) devices and the IOM, AvaMed and CHI confirm the FDA’s belief, the 510(k) process is certainly providing only devices found safe and effective to market. The opinions of these institutes provide weigh strongly in favor of a safety and effectiveness finding.

\textbf{C. RECENT 510(K) CLEARANCES DEMONSTRATE AN ASSESSMENT OF SAFETY AND EFFICACY}

In adopting the lower courts analysis, the \textit{Lohr} Supreme Court concluded the 510(k) process was not an assessment of safety, but rather equivalence; the 510(k) process is not one that protects the public.


\textsuperscript{121} \textit{Id.}
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[T]he 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 crux of the Court’s analysis relied on the basis that the FDA never assessed the safety and efficacy of the 510(k) device; therefore, additional state regulations determining the safety and efficacy of a device were not pre-empted under § 360k. The framework of the FDCA has significantly changed since *Lohr* and there is concrete evidence of FDA safety and effectiveness assessments for 510(k) medical devices.

1. Evidence of § 510(k) devices that have been assessed for safety and efficacy prior to clearance

When a device manufacturer submits a 510(k) summary for clearance of a device, the summary must include a “basis” for the FDA to conclude substantial equivalence. As part of that “basis,” the manufacturer must include a “brief discussion of the clinical tests submitted . . . [that] include[s] . . . a discussion of the safety and effectiveness data.” Recent devices determined substantially equivalent under 510(k), coupled with their 510(k) summary demonstrate a safety and efficacy assessment performed by the Agency.

Via Biomedical, Inc.’s Stent Graft Balloon Catheter has been determined substantially equivalent and cleared for market distribution. Included in the 510(k) summary was the following:

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The Stent Graft Balloon Catheter underwent mechanical, performance, and
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123 21 C.F.R. § 807.92 (2011)
124 *Id.* Further, for a device to gain clearance, the tests must demonstrate that “the device is as safe, as effective, and performs as well as or better than the [predicate] device . . . .”
biocompatibility testing to verify that the device functions in a safe and effective manner. The results of the tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.\textsuperscript{126}

In accepting Via Biomedical’s 510(k) summary and clearing the catheter for market, the FDA acknowledged and confirmed the devices substantial equivalence for the indications determined safe and effective in the proceeding summary.\textsuperscript{127} Becton, Dickinson and Company’s (Becton) BD Flu+ Syringe was cleared for market on July 2, 2009. As part of the requisite basis the manufacturer must submit, Becton expressly indicated that “[d]esign [v]erification tests were performed based on the risk analysis performed, and the results of these tests demonstrate that the BD Flu + Syringe performed in an equivalent manner to the predicate device and is safe and effective when used as intended.\textsuperscript{128} The FDA similarly cleared the BD Flu + Syringe for its intended use—the specific use for which Becton determined. In doing so, the FDA confirmed the finding of safety and effectiveness for the BD flu + Syringe. Likewise ArthoCare’s Bone Cement Opacifier was cleared under 510(k) after the FDA confirmed that “the performance testing and device comparison demonstrated that the subject device [was] substantially equivalent to the predicate device, and is safe and effective for its intended use.\textsuperscript{129}

Other examples of 510(k) devices—Master Healthcare’s Easy Touch Insulin Syringe,\textsuperscript{130} ZOLL Circulation’s Central Venous Catheter and Thermal Regulating System\textsuperscript{131} and

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  \item \textsuperscript{126} Id. (emphasis added).
  \item \textsuperscript{127} Letter from Bram D. Zuckerman, M.D., Director of Cardiovascular Devices, to Di Caprio, President and CEO of Via Biomedical, Inc. (Oct. 15, 2009) available at http://www.accessdata.fda.gov/cdrh_docs/pdf9/K091624.pdf.
  \item \textsuperscript{129} http://www.accessdata.fda.gov/cdrh_docs/pdf4/K042947.pdf. The device was not found to be as safe as the predicate, but there was an independent assessment. The device was both substantially equivalent to the predicate as well safe and effective.
\end{itemize}
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Medtronic’s Cardiopulmonary Centrifugal Blood Pump—all included performance data specifically relating to and determining the safety and effectiveness of the device as part of the “basis” for 510(k) clearance.

D. WHAT DOES A SAFETY AND EFFICACY DETERMINATION MEAN FOR LOHR?

The aftermath of the Lohr decision allowed States to impose safety and efficacy standards on substantially equivalent medical devices cleared under 510(k). In 1996, the year Lohr was decided, State common law defective device claims were not pre-empted so long as the medical device did not go through the Premarket Approval process because the substantial equivalence process made no such determination of safety and efficacy. As the above analysis demonstrates, product liability claims asserted against 510(k) devices actually impose additional or perhaps conflicting requirements relating to the “safety and effectiveness of a medical device” cleared under 510(k). Not only does this hamper one of the central facets of the FDA mission, to foster innovation, but additional safety and efficacy requirements are pre-empted under § 360k(a) which disallows State standards “relat[ing] to the safety and effectiveness of the device.” In Lohr the Court described § 510(k) requirements as imposing only “general”

133 See supra notes 128–132 and accompanying text.
134 See § 360k(a), 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et. seq.(2010)).
135 A State is more concerned at the individual level, and therefore places greater emphasis on the safety of the device. The FDA, on the other hand, must consider the entirety of the nation and must ensure safety, yet promote innovation medical devices as well. See Brief for Petitioner at 16 Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (Nos. 95-754, 95-886).
136 § 360k(a), 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et. seq.(2010)); see also 21 C.F.R. § 808.1(d) (2010) (stressing that state requirements relating to safety and efficacy are pre-empted when the FDA “has established specific counterpart regulations or there are other specific requirements applicable to a particular device.”). The assessment of safety and efficacy
requirements on cleared medical devices. The Court found such requirements to be exceedingly
general to constitute duties with respect to the device, therefore they did not pre-empt a state’s
more specific requirements for the 510(k) device.\textsuperscript{137} If the FDA is conducting an individual
safety and efficacy assessment for each 510(k) device, the requirements promulgated for the
device are certainly not “general” as \textit{Lohr} concluded in 1996, but have now risen to a specific
requirements; more akin to those found in the PMA process.

\textit{As Riegel} accurately describes the PMA process as a federal safety review, thereby pre-
empting State claims relating to the safety or effectiveness of the medical device.\textsuperscript{138} The FDA is
now conducting a safety and efficacy review for 510(k) devices as well and as such, state claims
imposing additional safety standards should similarly be pre-empted. Arguably, if Medtronic’s
Model 4011 Lead was cleared under today’s statutory regime, the Court in \textit{Lohr} may reach a
different result.

\textbf{CONCLUSION}

The most recent FDA controversy involving the 510(k) clearance and then withdrawal of
RenGen Menaflex has brought 510(k) into the limelight. In a preliminary report of the RenGen
Menaflew review FDA avowed: “[o]ur review identified multiple sources of disagreement and
confusion about 510(k) standards and practices.”\textsuperscript{139} While all agree that a 510(k) cleared device
is “substantially equivalent” to a predicate, “substantial equivalence” is a flexible phraseology

\textsuperscript{137} \textit{Lohr}, 518 U.S. at 499–501.
\textsuperscript{138} \textit{Riegel}, 552 U.S at 499–500 (concluding that Riegel’s defective device claims were pre-
empted by \S\ 360k(a) because the State’s requirements held Medtronic’s balloon catheter to a
different safety standard than the requirements placed by the FDA).
\textsuperscript{139} \textit{FOOD AND DRUG ADMIN., REVIEW OF THE REGEN MENAFLEX: DEPARTURES FROM
PROCESSES, PROCEDURES, AND PRACTICES LEAVE THE BASIS FOR A REVIEW DECISION IN
capable of different meanings. Unlike prior “substantial equivalence” clearances, today’s substantial equivalence includes a finding that the device is both safe and efficacious. Not only does congressional purpose and statutory framework surrounding § 513(i) and the FDA as well as other persuasive authorities show that a safety and efficacy determination is present in 510(k) clearances, but there are express findings of safety and effectiveness documented with the device’s clearance letter. The standard applied in Lohr principally relied on the fact that the safety and effectiveness of the implanted lead were not accounted for prior to the device’s clearance. This finding is now outdated and no longer applicable. The Court’s finding in Riegel—in which a negligent design claim brought under state law was preempted due to the FDA’s prior determination of safety and effectiveness for the PMA device—should apply to 510(k) devices as well.