

**DECEMBER 3, 2018**

For more information,
contact:

Nikki Reeves
+1 202 661 7850
nreeves@kslaw.com

Elaine T. Tseng
+1 415 318 1240
etseng@kslaw.com

Beverly H. Lorell, MD
+1 202 383 8937
blorell@kslaw.com

Quynh T. Hoang
+1 202 626 2939
qhoang@kslaw.com

Jessica Ringel
+1 202 626 9259
jringel@kslaw.com

Kate Armstrong
+1 202 626 5453
karmstrong@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500

FDA Announces “Modernization” Reforms to Medical Device Review Process

FDA Announces Intent to Modernize the Medical Device Review Process that Would Discourage Reliance on Older Devices as Predicates for the 510(k) Process

Last week FDA released two statements announcing plans and proposals aimed at modernizing the process for medical device review, particularly the 510(k) process.¹ These announcements came on the heels of another statement made the previous week, which signaled these modernization attempts and revealed plans to create a more robust network of post-market surveillance data to protect patients, particularly women, through updates and increased funding to the National Evaluation System for Health Technology (NEST).²

BACKGROUND

This series of announcements came amidst a wave of negative media attention received by the medical device industry and regulatory authorities worldwide with the release of the “Implant Files” investigations by the International Consortium of Investigative Journalists.³ Further, FDA’s Center for Devices and Radiological Health (CDRH) directly came under scrutiny after an Associated Press investigation led to the conclusion that CDRH’s “first in the world” mantra under the leadership of Center Director Jeffrey Shuren has fast-tracked the approval process for medical devices to the benefit of industry and to the detriment of patients.⁴

FDA’s pre-market oversight of medical devices—particularly the 510(k) clearance pathway for low- and moderate-risk products that can demonstrate that they are “substantially equivalent” in terms of safety and effectiveness to older “predicate” devices already on the market—has long been subject to criticism.⁵ The 510(k) pathway has been in place since



1976 when FDA began reviewing all medical devices prior to market and continues to be the pathway used for the majority of devices reviewed by FDA. One frequent criticism of this premarket pathway is that it allows new medical devices to be cleared based on substantial equivalence to an older predicate device that may lack sufficient efficacy and safety data in the first place or constitute outdated technology. These concerns have only heightened as rapid advances in technology complicate the 510(k) review process. Although FDA has required more and more data as part of this process over the years—the average length of the application has reportedly grown from around 400 pages to over 1,000 pages—the agency says that the average total time it takes to reach a decision on an application has decreased.⁶

AGENCY ACTIONS TO DISCOURAGE USE OF OLDER PREDICATES

FDA's 510(k) modernization efforts, which Commissioner Gottlieb has deemed the “most significant . . . in a generation,”⁷ are aimed at reducing industry reliance on older predicate devices—and perhaps ultimately, all predicates—to support 510(k) applications. The proposals announced this week include three potential vehicles for reaching this objective:

- Creating a “Safety and Performance Based Pathway”: This pathway is not new, but rather a rebranding of an alternative 510(k) pathway FDA proposed in guidance in April.⁸ This pathway, which FDA intends to create through an expansion of the Abbreviated 510(k) program, would allow a company to demonstrate that a device is as safe and effective as a predicate by meeting certain modernized performance criteria set by the agency, rather than a direct device-to-predicate device comparison or other existing approaches for demonstrating substantial equivalence. FDA plans to issue final guidance on this pathway by early 2019, with the goal of making it “the primary pathway for devices eligible for 510(k) review.”⁹
- Sun-setting older predicates: FDA is also considering “sun-setting”—i.e., disqualifying from use as a predicate—certain older predicates as a means of encouraging the use of newer predicates. Such an initiative would likely require legislative action, as the agency currently lacks this authority. Indeed, the agency has acknowledged that to achieve some of the proposed modernization goals it, “may need to seek additional guidance from Congress.”¹⁰
- Publishing a “shaming” list: Although FDA has said it will not do so without first asking for public comment, the agency has proposed producing a public list on its website of cleared devices that rely on predicates that are older than 10 years. The agency suggests that such a list would promote the use of newer technologies through market forces. Notably, FDA says that nearly 20% of current 510(k)s are cleared based on a predicate that is more than 10 years old.¹¹

FDA's announcement acknowledges that the plan to limit or tighten-up the use of predicates will likely drive companies toward increased use of the de novo classification process and signaled plans to issue a proposed rule that would clarify the procedures and requirements for de novo submissions in the next few weeks.¹²

The agency's overarching message seems to be that although FDA does not believe that devices that rely on older predicates are unsafe or should be removed from the market, it does believe that encouragement of newer technologies based on modern performance criteria is in the interest of the public health.¹³ Critics, however, have argued that older predicates can offer extensive performance data that helps sponsors produce new and safer devices.¹⁴

KEY TAKEAWAYS

Despite the volume of FDA's recent statements on modernization reforms to the medical device review process, there are unlikely to be immediate significant changes for most companies seeking marketing clearance through the 510(k) pathway. There are, however, a few considerations medical device firms should keep in mind. With respect to FDA's proposed alternative 510(k) pathway, it is important to note that FDA plans to establish performance criteria for “well-understood” device types—i.e., devices with an associated consensus standard—first. Furthermore, FDA is likely to rely on and collaborate with outside organizations in developing these criteria. As such, firms may wish to reach out to



organizations such as the Association for the Advancement of Medical Instrumentation (AAMI) or the American National Standards Institute (ANSI) to participate in technical groups developing these criteria or otherwise gain insight into what FDA's adopted criteria might look like.

Additionally, if FDA were to obtain congressional support and move forward with sun-setting certain older predicates, the agency would be most likely to start with technologies that have evolved rapidly over time, such as electronic technologies. Thus, if your firm plans to submit a 510(k) notification relying on a predicate that may be sun-setted, you should be aware that the predicate your device relies upon may no longer be available and it may be worth considering alternate predicates in your 510(k) planning process. Furthermore, if any of your firm's marketed 510(k) devices are subject to clearances that are more than 10 years old, it may make sense to "renew" that clearance by submitting a new 510(k) for each product (e.g. a catch-up 510(k) for changes that have been documented to the record) to preserve the ability to use those products as predicates for future product line extensions.

Ultimately, medical device companies should be on the look-out for additional agency communications—in particular, requests for public comment—as continuous engagement with FDA will be key to ensuring the future of a viable 510(k) pathway for premarket review. King and Spalding is happy to assist with FDA and potential Congressional engagement concerning these modernization efforts, or to help navigate any changes to the medical device review process.

ABOUT KING & SPALDING

Celebrating more than 130 years of service, King & Spalding is an international law firm that represents a broad array of clients, including half of the Fortune Global 100, with 1,000 lawyers in 20 offices in the United States, Europe, the Middle East and Asia. The firm has handled matters in over 160 countries on six continents and is consistently recognized for the results it obtains, uncompromising commitment to quality, and dedication to understanding the business and culture of its clients.

This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice. In some jurisdictions, this may be considered "Attorney Advertising."

ABU DHABI	CHICAGO	HOUSTON	NEW YORK	SILICON VALLEY
ATLANTA	DUBAI	LONDON	PARIS	SINGAPORE
AUSTIN	FRANKFURT	LOS ANGELES	RIYADH	TOKYO
CHARLOTTE	GENEVA	MOSCOW	SAN FRANCISCO	WASHINGTON, D.C.

¹ See U.S. FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., On How Modern Predicates Can Promote Innovation and Advance Safety and Effectiveness of Medical Devices that Use 510(k) Pathway (Nov. 27, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626838.htm>; U.S. FDA, Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on Transformative New Steps to Modernize FDA's 510(k) Program to Advance the Review of the Safety and Effectiveness of Medical Devices (Nov. 26, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626572.htm>.

² See U.S. FDA, Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D. Director of the Center for Devices and Radiological Health, on FDA's Updates to Medical Device Safety Action Plan to Enhance Post-Market Safety (Nov. 20, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626286.htm>.

³ See International Consortium of Investigative Journalists, "The Implant Files," <https://www.icij.org/investigations/implant-files/>, last accessed Dec. 1, 2018.



⁴ See Perrone, Matthew, *At FDA, a New Goal, Then a Push for Speedy Device Reviews*, ASSOCIATED PRESS (Nov. 27, 2018), <https://www.apnews.com/9f8ea03a4d324d1ba5585680d280804b>.

⁵ See Institute of Medicine of the Nat'l Academies, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 years*, THE NAT'L ACADEMIES PRESS (July 29, 2011).

⁶ See FDA's November 26, 2018 Statement, *supra* note 1.

⁷ See Scott Gottlieb, M.D., *Twitter Announcement* (Nov. 26, 2018) <https://twitter.com/SGottliebFDA/status/1067044151022227462>

⁸ See U.S. FDA, *Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria* (Draft Guidance) (Apr. 12, 2018), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM604195.pdf>.

⁹ See FDA's November 26, 2018 Statement, *supra* note 1.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *See id.*

¹⁴ *See, e.g.* Emily Field, *FDA Modernizes Medical Device Review Process*, Law 360 (Nov. 26, 2018), <https://www.law360.com/articles/1104748/fda-modernizes-medical-device-review-process>.