Modernization of the 510(k) Pathway to Market Medical Devices

Written by Areta Kupchyk, Snehal Trivedi, Paul T. Kim

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Introduction

Congress enacted the Medical Device Amendments in 1976 establishing the regulatory framework for evaluating safety and effectiveness of medical devices. The U.S. Food and Drug Administration ("FDA" or "Agency") announced earlier this week its plan to modernize the 42-year-old 510(k) clearance pathway as part of its continuing efforts to align medical devices with innovation. Thus, the decades old framework may be facing a makeover given the rapid pace of innovation and novel complexities in emerging technologies

Current Premarket Regulation of Medical Devices

Generally, there are two popular pathways to market medical devices in the U.S.: (1) the 510(k) premarket notification and (2) the premarket approval ("PMA") pathway, depending upon a device's classification as a low-, intermediate-, or high-risk device. Low- to intermediate-risk devices are subject to premarket clearance by FDA through the 510(k) process. Devices marketed under the 510(k) process are required to demonstrate "substantial equivalence" to a "predicate" device which has previously been cleared for marketing by the Agency. High-risk devices are subject to submissions of clinical trial evidence that reasonably assures the safety and effectiveness of a medical device.

Proposed Changes to 510(k) Pathway

In Statements (Nov. 20, 2018 and Nov. 27, 2018) issued earlier this week by FDA Commissioner Scott Gottlieb (collectively, "Statement"), the Agency is proposing changes to the 510(k) pathway that would require manufacturers to compare new device applications to modern predicates as opposed to relying on older predicate devices. The Statement highlights that "nearly 20 percent of current 510(k)s are cleared based on a predicate that's more than 10 years old . . . [which] means that some devices may not be continually improving." Notably, the 510(k) modernization involves reliance on modern predicates to reflect advances in technology thus, allowing FDA to retire older predicates that "may not reflect modern performance characteristics."

To promote the use of modern or recent predicates, FDA is considering publishing information on devices and manufacturers that relied on predicates greater than 10-years old which, the Statement clarifies, "doesn't mean the products are unsafe." Accordingly, the 510(k) modernization aims to encourage companies to use newer predicates that adopt existing technological features to promote greater competition. Before publicizing older predicate devices, however, the Agency will seek public input on whether the 10-year mark is an appropriate starting point.

In an effort to further encourage the use of modern predicates, FDA aims to develop proposals to "sunset certain older predicates." Although such proposals may involve congressional input or even legislative amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA), the Agency cited the Medical Device Amendments as authority to eliminate now certain 510(k)-cleared predicates for safety reasons through its "up-classification" process. As part of up-classification, FDA reassigns a device to a "high-risk" category requiring a PMA, thus rendering ineligible certain devices as legal predicates.

FDA's announcement this week does not constitute a first-ditch effort to promote innovation in the regulatory oversight of medical devices. The Statement pointed to advancing the use of real world evidence by implementing the National Evaluation System for health Technology (NEST) to assess data related to clinical evidence and post-market benefit-risk profiles of marketed devices. In supporting the

use of real world device performance, FDA is committing to a new strategic goal of "[e]nsuring [it] is consistently first among the world's regulatory agencies to identify and act upon safety signals related to medical devices."

Looking Ahead

Moreover, the Agency intends to finalize in 2019 the guidance establishing an alternative 510(k) pathway to substantial equivalence, which would allow companies of certain "well-understood device types to rely on objective safety and performance criteria to demonstrate substantial equivalence." FDA intends to rename the alternate pathway as the "Safety and Performance Based Pathway" hoping to drive market competition and enable companies to demonstrate, in part to payors, a device's market performance capabilities for purposes of coverage decisions.

Finally, FDA expects an increased utilization of the de novo pathway as a result of the 510(k) modernization and accordingly, plans to issue a proposed rule "in the next few weeks" to establish a regulatory framework for de novo classification. The Statement acknowledged the potential need for congressional support in moving forward with many of these 510(k) policy proposals, but the Agency remains "committed to working with stakeholders to continue to modernize . . . policies."

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