FDA’s Plans to Fundamentally Modernize the 510(k) Process

Alert
11.29.2018
By Tricia Kaufman and Joel Schwartz

FDA’s “510(k)” process, by which a medical device manufacturer can bring a product to market based on the premise that the proposed device is the substantially equivalent to a already legally marketed “predicate device”, has been viewed as a streamlined pathway to market when compared to more rigorous evidentiary requirements of premarket approval. Critics, however, have cited patient safety issues allegedly caused by the “lower” standards needed for 510(k) clearance.

This week FDA announced its plans to modernize the 510(k) regulatory pathway as part of its Medical Device Safety Action Plan by: (1) “encouraging product developers” to use more modern devices as predicates under the current 510(k) pathway; and (2) developing and eventually moving the majority of 510 (k)s to an expanded Abbreviated 510(k) Program, for which FDA published draft guidance last April. FDA intends to finalize the guidance document in early 2019. This expanded program, dubbed by FDA as the ”Safety and Performance Pathway,” would require manufacturers to demonstrate that a product meets objective, modern, performance-based criteria that reflect current technological principles. As stated in the agency’s announcement, these changes are a continuation of FDA’s efforts to “develop innovative and forward-leaning regulatory policy” while it keeps pace with the “unparalleled period of invention in medical devices.”

With respect to the current 510(k) pathway, FDA aims to propel reliance on more modern predicate devices by potentially sunsetting older, i.e., more than 10 years old, predicates so that they are no longer available for substantial equivalence determinations. This would fundamentally change the 510(k) approach and could require the involvement of Congress. In the meantime, to encourage voluntary use of newer predicate devices, FDA is considering calling out on its web site those devices that were cleared based on predicate devices that were greater than 10 years old, though the exact manner of how FDA will do
FDA’s Plans to Fundamentally Modernize the 510(k) Process

this is unclear. The stated reason for phasing out reliance on older predicates is to “promote” the use of more modern predicates and drive sponsors to offer devices with the latest improvements.

FDA’s announcement raises many issues and may be met with strong pushback from industry. This could be part of the reason FDA made a second announcement the following day, further justifying its position. While FDA insists that its publication of devices that are based on older predicates does not mean that a device is unsafe or should be pulled off the market, the negative implication seems undeniable. It is implying that the older devices could not satisfy the new performance-based principles. While on the one hand FDA insists that its market authorization processes remain science-based in order to assure public confidence in the devices they are using. Such an across-the-board undermining of older devices without a data-driven basis, would undercut the credibility of the agency as one governed by safety-through-science priorities. Additionally, the proposal to sunset certain devices for use as predicates in a substantial equivalence determination raises “legacy” issues, as well. What if a device is based on a predicate that was cleared in the past 10 years, but that predicate device was based on an older predicate? In other words, would the sunset reach back to predicates of the predicate? If not, should manufacturers line up now to file long-awaited updates to their legacy devices so that they can restart the 10-year sunset clock limit before it’s too late?

What does seem clear is that the elimination of older predicates and the new performance based approach forecasts a significant increase in de novo pathway submissions. In the former case, there may be no acceptable predicate devices available upon which a manufacturer can base its new device after the predicate sunset, and in the latter case, manufacturers may want to help establish the performance standards that FDA is supposed to create or recognize under the new approach. Indeed, FDA anticipates this potential increase in de novo submissions and will issue proposed rules clarifying procedures and requirements for de novo requests in the next few weeks.

For more information on the 510(k) process, please contact Tricia Kaufman, Sheva Sanders, Joshua Kim, Joel Schwartz or the Stinson Leonard Street contact with whom you regularly work.

ATTORNEYS
Patricia F. Kaufman
Joel D. Schwartz