Hogan Lovells

FDA announces planned modernization of 510(k) pathway and seeks a more active role in driving technological innovation

28 November 2018

On 26 November 2018 Food and Drug Administration (FDA) Commissioner Scott Gottlieb and Center for Devices and Radiological Health (CDRH) Director Jeffrey Shuren issued a joint statement proposing to rebrand and modernize the 510(k) premarket review pathway with the goal of "efficiently advancing beneficial technology to patients, while solidifying FDA's gold standard for safety."

FDA states that its proposal arises out of advances and changes in modern technology in many devices, where new devices generally have increased complexity compared to predicate devices, which may impact safety and performance. FDA issues thousands of 510(k) clearances each year, and changes to this pathway have the potential to have significant impact on the medical device industry. Issuance of the joint statement and proposed modernization plan coincides with mounting negative press calling into question the safety of medical devices that go through the 510(k) pathway. The joint statement paints a high-level picture of how FDA envisions modernizing the current framework, described more fully below. However, the statement provides very few details around the specific changes FDA would seek to implement – changes that may well require congressional action. For example, FDA's statement makes clear that the agency believes new medical devices that come to market under the 510(k) pathway should essentially be better than existing predicates, which is inconsistent with the legal/regulatory standard, which only requires a demonstration of "substantial equivalence."

The statement addresses FDA's plan to update the 510(k) pathway by emphasizing use of newer, more recently cleared predicate devices to establish substantial equivalence. However, it is not clear that changes to the program are needed to achieve this goal. A preference for more recent predicate devices is consistent with our experience in recent years, where new devices have often been held by FDA to more stringent standards and higher data requirements than those required for older devices, especially when the predicates relied on different technology. FDA's statement also indicates that for well-established technologies (to be identified and designated by FDA), the agency will work to develop objective performance criteria that may be used to support clearance of these devices instead of direct comparative testing to a predicate. FDA has historically been reluctant to rely on objective performance criteria to establish substantial equivalence for 510(k) devices, and it remains to be seen how FDA will develop these standards and whether failure to

meet these standards for devices with a different benefit/risk profile will inherently push a device into the De Novo pathway or render them not substantially equivalent.

These proposed and forthcoming updates to the 510(k) paradigm follow other developments in the regulatory decision-making process for medical devices in recent years including use of real world evidence, modernizing the De Novo pathway, updating the pathway for breakthrough products, and developing a new regulatory paradigm for digital health products. This latest announcement follows FDA's statement last week on 20 November 2018 announcing updates to the agency's Medical Device Safety Action Plan to enhance postmarket safety and was issued in concert with a document detailing the steps that FDA has already taken to strengthen the 510(k) program by increasing requirements for premarket review and up-classifying certain device types.

Modernizing the 510(k) pathway

FDA has proposed the following initiatives to modernize the 510(k) pathway in an effort to encourage the "right kind of innovation for patients," improving safety and performance of medical devices in the United States by

- making public on its website those cleared devices that demonstrated substantial equivalence to predicate devices cleared more than 10 years ago; and
- establishing a new "Safety and Performance Based Pathway" to 510(k) clearance.

FDA appears to believe that the most impactful way it can promote medical device safety and innovation is by driving innovators toward reliance on more modern predicate devices. Among other steps, the agency states that it is developing proposals to "sunset" certain older predicates and to promote the use of "modern" predicates. Notably, FDA does not currently have legal authority to "sunset" predicate devices, which is hinted at in FDA's statement that it may "need to seek additional guidance from Congress" to achieve some of its goals. Despite this disconnect, the agency arguably has already taken subtle steps to discourage use of older predicates and encourage reliance on modern predicates by, for example, removing 510(k) summaries for much older technologies from its databases, while at the same time requiring additional detailed information in the 510(k) summaries of newer devices, making them more attractive as predicates.

To further encourage comparisons to newer technology, CDRH is now considering listing devices on its website that were cleared based on a demonstration of substantial equivalence to a predicate that is more than 10 years old, in effect "shaming" those companies for relying on older technology. Interestingly, FDA's press release states that nearly 20 percent of current 510(k)s are cleared based on a predicate that's more than 10 years old. It is unclear how many of these relate to companies updating their own devices, and it remains to be seen whether FDA will uniformly request additional or more robust data when a new device is compared to an older predicate, even when no technological difference is included or necessary for the device to provide patients with the intended clinical benefit. Although FDA states that use of an older predicate does not inherently make a new device or technology unsafe and older devices do not need to be removed from the market, the implications of the agency's current proposal is to foreclose reliance on older device clearances as predicates notwithstanding the fact that there may be no technological differences between the two devices that raise "different questions of safety or efficacy." The agency's initial statement that the public should be made aware of such devices and FDA's subsequent public statement on 27 November 2018 that the agency will "seek public feedback on whether predicates older than 10 years are the right starting point and if there are other actions we should take to advance the use of modern predicates" suggests that users should approach

those technologies with some level of skepticism. Such a list appears to raise more questions than it answers. For example, it is unclear whether FDA is attempting to suggest to users that there is risk associated with devices cleared based on comparison to an older predicate. It will also be important to consider what impact such a list will have on FDA's credibility and other areas, such as product liability suits.

FDA also intends to finalize guidance in 2019 establishing an alternative 510(k) pathway – the "Safety and Performance Based Pathway" – for certain well-understood device types, whereby clearance can be based on performance-based criteria that have been established or recognized by FDA, which is also the stated goal of the "Expanded Abbreviated 510(k) program." It is not clear how these two programs would differ; both appear to be aimed at avoiding performance comparisons between new, modern technology, and older predicate technology that may not meet modern expectations for safety and performance. FDA states that it would like this new Safety and Performance Based Pathway "to eventually supplant" the predicate-based 510(k) system.

It is noted that FDA's proposals could well have the opposite effect of what is intended (e.g., encouraging innovation). Maintaining a public list of specific companies and devices that cite a predicate that is more than 10 years old would certainly discourage companies from making improvements to older technologies, improvements which often could be made using the existing 510(k) program, which allows room for such technological advancement. Second, the proposal to move towards a 510(k) system that relies on established performance-based criteria rather than predicates would essentially make the 510(k) pathway ineligible for any new technology. Development of objective performance criteria has in the past required multiple studies and a large amount of data to establish, in a process that can take many years. It is likely that the more innovative technologies would not have standardized performance-based criteria to rely on and would therefore be ineligible for the new pathway, presumably also forcing them to the De Novo pathway (with a steep user fee), which could discourage the development of such products, especially for smaller companies.

FDA acknowledges that its 510(k) policy proposals likely will lead to a larger number of devices being cleared via the De Novo pathway, which is also consistent with our recent experience. In recent years, FDA has been routing more devices to the De Novo pathway when they have novel technology (e.g., artificial intelligence) and differences in indications for use than already 510(k) cleared devices. This is reflected in the number of De Novo requests filed, which has been steadily rising, from approximately 40 petitions in fiscal years 2013 and 2014 to over 100 filed in fiscal year 2017. FDA intends to issue a proposed rule clarifying procedures and requirements for submissions of De Novo requests in the coming weeks.

Promoting greater transparency and postmarket surveillance

FDA's proposed 510(k) program reforms are aimed at improving product safety and are intended to be in addition to the agency's program improvements over the last several years, including issuance of more than 50 final guidance documents since 2009. Consistent with our experience, FDA clearly states that, over the years, it has increased expectations for the quality and quantity of information required in support of 510(k) submissions. In addition, new postmarket surveillance programs, such as the National Evaluation System for health Technology (NEST), have been established to collect data on real-world performance of marketed devices, and CDRH has taken steps to eliminate the use of predicate devices with known safety concerns, which are more appropriately considered "high-risk" technologies. Vaginal mesh for treatment of pelvic organ prolapse, automated external defibrillators, and metal-on-metal hip implants, for example, have been "up-classified" to class III in response to public health concerns and may no longer be

brought to market through the 510(k) program. As a result of FDA's continuing efforts, some 1,758 devices with demonstrated safety concerns and/or calls for premarket approvals (PMAs) for unclassified devices have been made ineligible as predicates in the 510(k) program since the Medical Device Amendments of 1976. Of these, 1,477 (84 percent) have been up-classified and/or are no longer eligible as predicate devices since 2012.

Despite these efforts, FDA believes the postmarket tools currently at its disposal are not agile enough to address significant safety concerns in an efficient and timely manner. Accordingly, the proposed 510(k) reforms reflect an understanding by FDA that new postmarket tools, such as the ability to implement new special controls to address safety concerns more quickly, or to up-classify an entire device type, when appropriate, may be needed for the agency to address time-sensitive health concerns.

Key takeaways

FDA's recent statement raises a number of questions about the underlying impetus for FDA's proposal, whether the proposed changes are necessary to meet FDA's objectives, and how the proposed changes will impact industry and the availability of technological advances for patients in a timely manner. Lack of details about the specific changes to the program makes it hard to fully grasp the potential impact of what FDA is proposing at this time. More importantly, it is not clear that the agency's proposals are truly necessary, as FDA's objectives arguably can be and have been met using the existing framework. It is clear that these proposals are driven by the recent negative publicity surrounding FDA's regulation of medical devices. However, as has been pointed out numerous times, when FDA's track record with respect to clearing safe and effective devices and making them available to the public in a timely manner is fully evaluated, FDA's 510(k) program has actually worked well over the years.

While well intentioned, the proposals may have unintended consequences. With respect to product performance, certain of the proposals also could actually have a negative impact on innovation by discouraging companies from improving older technologies, or routing newer technologies to the more expensive De Novo pathway. FDA's proposal also seems to suggest that "newer" predicates are safer and have better performance, but it is not clear that this is always the case. Older devices may have been upgraded over time although some of those upgrades may not have required the filing of a new 510(k) submission that could be cited as a predicate.

While FDA's announcement raises many questions, implementation of significant revisions to the 510(k) pathway would likely require notice and comment rule-making and, potentially, congressional action. This week's announcement appears, in part, to be a plea for congressional support. FDA has indicated that it will be publishing its detailed proposals for public comment in the coming months – no doubt, medical device stakeholders will have a lot to say about the proposed reforms.

Contacts

Danielle C. Humphrey
Counsel, Washington, D.C.
T +1 202 637 8853
danielle.humphrey@hoganlovells.com

Lina R. Kontos
Counsel, Washington, D.C.
T +1 202 637 5713
lina.kontos@hoganlovells.com

Jennifer Agraz Henderson
Partner, Washington, D.C.
T +1 202 637 5783
jennifer.henderson@hoganlovells.com

Yarmela Pavlovic
Partner, San Francisco
T +1 415 374 2336
yarmela.pavlovic@hoganlovells.com

Arthur E. Kim
Senior Associate, Washington, D.C.
T +1 202 637 4648
arthur.kim@hoganlovells.com

Randy J. Prebula
Partner, Washington, D.C.
T +1 202 637 6548
randy.prebula@hoganlovells.com

Kristin Zielinski Duggan
Counsel, Washington, D.C.
T +1 202 637 8894
kristin.duggan@hoganlovells.com

Jonathan S. Kahan
Partner, Washington, D.C.
T +1 202 637 5794
jonathan.kahan@hoganlovells.com

Janice M. Hogan
Partner, Philadelphia,
Washington, D.C.
T +1 267 675 4611 (Philadelphia)
+1 202 637 5600 (Washington, D.C.)
janice.hogan@hoganlovells.com

www.hoganlovells.com