Medical Device Landscape: Additional Developments for the 510(k) Pathway

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In 2018, the Food and Drug Administration (FDA) announced several actions relevant to the 510(k) premarket notification regulatory pathway. AGG has previously written about some of these, such as the pilot expansion of the Special 510(k) Program.[1] In this Bulletin, we briefly address a few notable developments from late 2018 with potential relevance for 510(k) products. These include ongoing modernization of the 510(k) pathway and related initiatives, particularly FDA's focus on the use of modern predicate devices. These developments are relevant to determining whether the 510(k) pathway is appropriate for a specific device, and will likely be of particular interest to device companies that: (i) market devices with "older" 510(k) clearances (*i.e.*, those cleared more than 10 years ago), or (ii) are planning to use an older device as a predicate for clearance of a newer device.

In December 2018, FDA issued a proposed rule regarding the De Novo classification process for medical devices.[2] We address that proposed rule in a separate Bulletin.

Background

A 510(k) submission is a premarket submission to the FDA for the purposes of demonstrating that a medical device is "substantially equivalent" to (*i.e.*, at least as safe and effective as, and otherwise equivalent to) a legally marketed device (known as a "predicate device") that is not subject to premarket approval (PMA) requirements.[3] The 510(k) is the most common regulatory pathway for medical devices, but is not appropriate or available for all devices. Some 510(k) predicate devices were cleared by FDA decades ago, and the agency has indicated that, in some cases, this can raise concerns when such devices are used as the basis for clearance of a newer device.

Modernization of the 510(k) Pathway

In November 2018, FDA Commissioner Scott Gottlieb and Jeff Shuren, Director of FDA's Center for Devices and Radiological Health, announced a number of steps the agency has taken or plans to take to modernize the 510(k) regulatory pathway.[4] Among other things, these statements highlighted:

- FDA's current thinking about ways that the agency can move innovators toward reliance on more modern predicate devices or objective performance criteria when they seek to bring new devices to market;
- Ways that the agency has promoted greater predictability and transparency in the 510(k)

1 *See* A. Minsk and G. Razick, AGG Client Bulletin, *FDA Launches Pilot to Expand the Special 510(k) Program* (Oct. 23, 2018), available at: https://www.agg.com/FDA-Launches-Pilot-to-Expand-the-Special-510k-Program-10-23-2018/.
2 *See* FDA, Proposed Rule, *Medical Device De Novo Classification Process*, 83 Fed. Reg. 63127 (Dec. 7, 2018).
3 *See*, *e.g.*, 21 U.S.C. § 360(k) and 21 C.F.R. § 807.92(a)(3).
4 *See 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), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626572.htm; *see also 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), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626838.htm.

process (*e.g.*, a summary 510(k) performance report is available online);[5]
- Increased FDA expectations regarding the quality and quantity of information required in 510(k) submissions.
- Ways that the agency has improved and plans to enhance device post-market surveillance systems; and
- FDA's increased use of an "up-classifying" process to address certain older predicate devices (*i.e.*, re-assigning a device to Class III and requiring premarket approval); these devices are then ineligible to use as predicates for the 510(k) process.[6]
- The agency also indicated that current and planned future 510(k) policy proposals are likely to result in more use of the De Novo classification pathway.

Modern Predicate Devices

FDA has indicated that it is exploring multiple policy vehicles to move the market toward reliance on newer predicates.[7] We summarize some notable information below.

- The agency indicates that there are multiple safety and innovation reasons to focus on modern predicates. For example:
  - older predicates may not reflect technology in newer devices;
  - risk-benefit evaluation may differ;
  - 510(k) devices are increasingly complex;
  - devices may be interconnected with related cybersecurity threats; and
  - miniaturization, robotics, and other advances are changing how providers and patients interact with newer devices.
- To advance the goal of moving away from older predicate devices, FDA plans to publicize certain information about cleared devices that demonstrated substantial equivalence to devices that are more than 10 years old.
  - The agency will seek public input on whether 10 years is the right starting point, if other criteria are relevant, and other actions the agency should take.
- Importantly, FDA notes that the agency does not believe that devices that rely on old predicates are unsafe, or that older devices need to be removed from the market.
  - Rather, the agency believes that the use of more modern predicates would provide a choice among older and newer versions, promote greater competition to adopt modern features, and help improve patient care and outcomes.
- FDA is developing proposals to potentially sunset certain older predicates and promote the use of more modern predicates.
- The agency intends to finalize guidance establishing an alternative 510(k) pathway in 2019, but has not provided a specific date.
  - The goal is to finalize the pathway and expand its use broadly across the 510(k) program, with the new pathway eventually supplanting the comparison of a new device technologically to a specific (and sometimes old) predicate device.
- FDA states that this approach may allow companies to more readily demonstrate to payors that their products perform better than other devices on the market.

AGG Observations

- FDA is taking action in a number of areas relevant to the 510(k) regulatory pathway and additional changes are expected in 2019.
  - Firms with current or future 510(k) devices should review these changes to determine how their products may be affected.
- Firms planning to reference predicate devices cleared more than 10 years ago should closely track developments

5 *See* FDA, Performance Report, *FDA Has Taken Steps to Strengthen the 510(k) Program* (Nov. 2018), available at: https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM626541.pdf.

6 The agency notes this is part of ongoing work to eliminate the use of 510(k)-cleared predicates that raise safety concerns or should be treated as high-risk.

7 *See*, *e.g.*, FDA, *Statements* of November 26 and 27, 2018, *supra* note 54

regarding these older predicate devices.

- FDA is also taking actions that affect medical devices more broadly, such as the December 2018 proposed rule on the De Novo classification pathway, which we have described in a separate Bulletin.

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