ML STRATEGIES

Device Modernization Series: FDA's Changes to the 510(k) Program

February 21, 2019 | |

In our "**FDA 2018 Year in Review (and a Few Thoughts on 2019)**" post and recent webinar, we observed that we may look back at 2018 as the beginning of the end for the 510(k) program as it has existed since the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. The 510(k) pathway has been scrutinized for years and among the most damning criticisms leveled against it is that it is a loophole that lets unsafe products on the market by allowing manufacturers to, in most cases, avoid clinical testing. As long as the Federal Food, Drug, and Cosmetic Act allows for 510(k)s, though, FDA has to make the review program work, so the agency is looking for ways to improve the safety of 510(k)-cleared devices rather than burying its head in the sand.

FDA has **said** that one of the key issues with respect to 510(k)s is the ability for a manufacturer to cite older predicate devices. Older predicates, FDA posited, by virtue of their age do not have modern safety mitigations, which means manufacturers of new devices who cite older predicates may also not have those mitigations.

FDA kick-started discussion around predicate age by proposing to publish on its website a list of devices that were cleared based on comparison to a predicate older than 10 years. FDA's thinking here brings to mind the adage "sunshine is the best disinfectant": by publicizing devices cleared with older predicates, FDA is looking to put public pressure on manufacturers to use more modern predicates. Among the problems with this approach are that the average predicate age is less than 10 years old (one analysis determined the average age is about 5 years), so a 10-year cutoff may not make a meaningful difference, and sometimes an older predicate is appropriate considering medical technology advances at different rates. Still, FDA says nearly 20% of currently cleared 510(k)s relied on a predicate older than 10 years, so out of the approximately 3,400 devices cleared in FY 2018, approximately 680 may have been cleared with predicates older than 10 years. The extent to which this is a problem largely depends on those particular devices. What's clear, though, is that FDA is looking to raise the bar for devices by moving away from predicates that satisfy the most basic requirements toward predicates that are truly models for safe and effective devices.

Furthering this discussion, on February 1, 2019, FDA issued its final *Safety and Performance Based Pathway* **guidance**, which was previously known as the *Expansion of the Abbreviated 510(k) Program* guidance. The abbreviated 510(k) program has been around since 1998 and relies on use of guidance documents, standards, and special controls to streamline 510(k) review. The Safety and Performance Based pathway is—by FDA's own admission—a new name for the Abbreviated 510(k) program.

In the guidance, FDA says it may be less burdensome for a device manufacturer to demonstrate conformance with a standard than to test their device against a predicate. For new devices that have different technological characteristics than predicate devices, FDA would establish criteria the new device needs to meet to be considered substantially equivalent. FDA would establish those criteria with public input. One key point, though, is that device manufacturers will still need to cite a predicate whose intended use matches their new device. That's a requirement in the law that FDA cannot change or re-interpret via guidance. FDA suggests they will pursue or otherwise supports a change to the statute to eliminate comparison to a predicate; the agency's November 26, 2018 **statement** says they would like the new pathway to "eventually supplant" the current model. This would be a major change to the 510(k) program and would, among other features, contribute to harmonizing the U.S. device review model with other global regulatory bodies.

FDA is **continuing to solicit feedback** on how to modernize 510(k) review, including what criteria (other than predicate age) should be considered to help improve the safety and effectiveness of devices. As FDA continues to make policy changes to modernize its device review program, look here for our thoughts and analysis. The next post in our Device Modernization series will cover the proposed De Novo regulation.

Authors