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ALERTS

2018 Year-End FDA Medical Device Highlights Include Proposed Changes

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In case you thought your year-end was busy, there was quite a bit of activity at the FDA's Center for Devices and Radiological Health (CDRH). This alert summarizes four significant developments: (1) a controversial proposed revision to the 510(k) process; (2) a proposed rule on the *de novo* classification process; (3) a final guidance on the breakthrough device program; and (4) a report on inspections/enforcement and quality.

Proposed Revision to 510(k) Pathway

In late November, FDA Commissioner Scott Gottlieb, M.D., announced a proposed revision to the CDRH's bread and butter, the 510(k) clearance pathway. Under the 510(k) process, a medical device can be cleared for marketing if it is shown to be "substantially equivalent" to an existing, legally marketed device known as a predicate. In light of the technological advances over the last several years, the FDA is proposing that firms seeking clearance of a new device should select predicates that are 10 years old or less. According to the FDA, data shows that approximately 20% of current 510(k)s are based on a predicate that is more than 10 years old.

The FDA's proposal has already been criticized by the industry on a few grounds. Perhaps most importantly, it is far from clear that the FDA has the authority to implement this change without action by Congress. Also, some question whether the proposal will stifle innovation and find it inconsistent with the FDA's previously stated plan to base more clearances on comparison of the proposed device for consensus standards, which may not exist for devices less than 10 years old.

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Proposed Rule on *De Novo* Classification Process

The FDA published a De Novo Classification Proposed Rule in the Federal Register. If finalized, the rule would establish procedures and criteria for the *de novo* classification process and become part of the Medical Device Classification Procedures (21 CFR Part 860). Firms hoping to market truly novel medical devices cannot seek 510(k) clearance because, by definition, there is no predicate device. Instead, they must follow the expensive and lengthy premarket approval (PMA) pathway, which typically requires clinical trials.

The *de novo* pathway is an alternative to the PMA pathway for review of novel devices, as long as the devices present low to moderate risk for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness. The proposed rule would facilitate appropriate classification of new types of medical devices. For example, the proposed regulations will include requirements related to the format and content of *de novo* requests, as well as processes and criteria for accepting, granting, declining, and withdrawing *de novo* requests.

To provide input, individuals may submit either electronic or written comments on the proposed rule by March 7, 2019.

The FDA Issues Final Guidance on Breakthrough Device Program

The 21st Century Cures Act created the breakthrough devices program, which is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and *de novo* marketing authorization.

The 30-page final guidance discusses the program principles, including interactive and timely communication, balancing data collection between pre- and post-market, efficient and flexible clinical design study, review team support, senior FDA management engagement, and priority review.

A manufacturer must submit a request to enter a new device into the breakthrough program. The final guidance discusses the request, including the following criteria:

- Whether a device could provide for more effective treatment or diagnosis relative to the current standard of care (SOC) in the U.S.
- Whether a disease or condition is “life-threatening”
- Whether a disease or condition is “irreversibly debilitating”
- Whether the device represents breakthrough technology
- Whether approved or cleared alternatives to the device exist
- Whether the device offers significant advantages over approved or cleared alternatives

- Whether the device's availability is in the best interests of patients

The guidance concludes with a discussion of several features of the program, including a "sprint" discussion, a data development plan, a clinical protocol agreement, and regular status updates. The FDA states that it will issue a grant or denial decision for each breakthrough device designation request within 60 calendar days of receiving such a request.

The FDA Issues Report on Enforcement and Quality

The CDRH issued a new Medical Device Enforcement and Quality Report in November that includes several key findings. First, the FDA has increased its oversight through additional device inspections. Since 2007, the FDA has increased its annual number of device inspections by 46 percent and has increased annual inspections of foreign firms by 243 percent. The FDA has also helped establish the Medical Device Single Audit Program to allow for the conduct of a single audit of a medical device manufacturer's quality management system on behalf of multiple countries. Second, the FDA has taken a targeted risk-based approach to addressing concerns with specific devices. According to the report, several case studies of devices like infusion pumps and automated external defibrillators show increased compliance actions and voluntary recalls have led to better compliance, improved device quality, and a reduction in reported injuries and deaths in patients. The report also claims the FDA's focus on identifying reporting deficiencies during inspections has led to an increase in voluntary recalls and adverse event reporting. Finally, the report highlights new data showing that most firms have corrected violations on follow-up inspections.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, chair of the firm's Food, Drug & Device group, at 317-231-7392 or lynn.tyler@btlaw.com.