wiley

ALERT

FDA Provides New Draft Guidance on Premarket Submissions for Device Software Functions

November 8, 2021

On November 3, 2021, the U.S. Food and Drug Administration (FDA) issued the draft guidance, Content of Premarket Submissions for Device Software Functions, a significant publication that has the potential to impact a variety of medical devices. The draft guidance is intended to provide information regarding the recommended documentation to include in premarket submissions for the FDA to evaluate the safety and effectiveness of device software functions, including both software in a medical device (SiMD) and software as a medical device (SaMD). The guidance applies to all types of premarket submissions for software devices, including Premarket Notification (510(k)), De Novo Classification Request, Premarket Approval Application (PMA), Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE), and Biologics License Application (BLA).

When final, it will replace the May 11, 2005 Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. This draft guidance is open for public comments for 90 days at https://www.regulations.gov under Docket Number FDA-2021-D-0775. The final due date for submitting comments is **February 2, 2022**.

The draft guidance, once finalized, will hopefully streamline the type of information and documentation FDA needs to evaluate the safety and effectiveness of a device during a premarket submission review. For example, the draft guidance proposes two documentation levels—"Basic" and "Enhanced"—to supplant the existing (2005 guidance) approach of categorizing deliverables based on Level of Concern. Basic Documentation is required for any premarket submission that

Practice Areas

FDA and USDA Regulatory Compliance
Food & Drug
Medical Devices

includes device software functions where Enhanced Documentation does not apply. Enhanced Documentation is required when the device meets any one of four criteria (e.g., device is classified as class III). This guidance may prove helpful at offering a better understanding on what FDA wants to see from the vast documentation generated during software development, verification, and design validation in a premarket submission review for devices that include software.

On **December 16, 2021,** FDA will host a webinar for stakeholders interested in learning about the draft guidance.

Jasmine Su, a Law Clerk at Wiley Rein LLP, contributed to this alert.