FDA Adds New Premarket Notification 510(k) Submission Requirements for Certain Reusable Medical Devices

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The 21st Century Cures Act included a provision requiring the Food and Drug Administration (FDA) to publish a notice in the Federal Register identifying a list of reusable devices that will be required to include validated instructions for use (IFU) and validation data regarding cleaning, disinfection, and sterilization as part of the premarket notification 510(k) submission.[1] FDA published this notice on June 9, 2017.[2]

Before marketing certain medical devices that do not require a Premarket Approval Application (PMA), a manufacturer must submit to FDA a premarket notification submission (often referred to as a 510(k)). The 510(k) must contain information to allow FDA to determine whether the medical device is substantially equivalent to an existing legally-marketed predicate device.

Reusable medical devices are devices that medical providers can reprocess and reuse on more than one patient.[3] In recent years, the complexity of reusable devices has increased significantly. More complex designs have resulted in increased challenges to ensure proper reprocessing, cleaning, and disinfecting between uses.[4] In order to address these issues, FDA is creating new requirements that highlight the importance of designing complex devices to ensure adequate processing and safe reuse and to have "clear and comprehensive" instructions to ensure that effective reprocessing procedures are utilized by health care providers and facilities that reprocess reusable devices.[5]

Beginning August 8, 2017, FDA expects that the required validation data pertaining to the cleaning, disinfecting, and sterilizing of reusable medical devices and instructions for use will be included in 510(k) submissions for the device types identified in the public notice. A list of the reusable device types identified by FDA can be found here[6] in Table 1. In Table 2 of the public notice, FDA also included a list of specific design features that may pose challenges to effective reprocessing. If any of the device types identified in Table 1 also contain any of the design features listed in Table 2, then manufacturers of the devices must submit validated reprocessing instructions and reprocessing validation data reports as part of the premarket notification submission. Adequate validated instructions for reuse and the reprocessing validation data will be required to obtain FDA clearance of the 510(k).

1 21st Century Cures Act, PUB. L. NO. 114-255, 130 Stat. 1033 (2016).
2 Public Notice, 82 Fed. Reg. 26807 (June 9, 2017).
3 See *Reprocessing of Reusable Medical Devices: Information for Manufactures*, FDA.GOV, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/default.htm (last visited July 7, 2017).
4 Id.
5 Id.
6 https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable

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