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Food, Drug & Device Law Alert - FDA Issues Final Guidance On Reprocessing Medical Devices

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The FDA recently issued a final guidance document titled, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.” The timing of this release is not surprising in light of the recent outbreak of infections in California relating to reprocessed duodenoscopes. The guidance sets forth FDA’s expectations for labeling reusable devices, validation of reprocessing instructions, and submission of reprocessing instruction in pre-market submissions.

With respect to labeling, the guidance advises manufacturers to consider certain recommendations regarding human factors when developing their reprocessing instructions. The recommendations include using a consistent format for instructions across each product line and to address any known post-market human factors for the relevant device. For devices subject to design controls, the guidance recommends human factors testing to assess users understanding of and compliance with the instructions.

The guidance discusses in some detail six criteria for clear reprocessing instructions:

1. Labeling should address the intended use of the device.
2. The instructions should advise users to thoroughly clean the device.
3. The instructions should include the appropriate microbicidal process for the device.
4. The instructions should be technically feasible and include only legally-marketed devices.
5. The instructions should be comprehensive.
6. The instructions should be understandable.

Under the “comprehensive” criterion, the guidance discusses the following factors: special accessories, point-of-use processing, disassembly and reassembly, method of cleaning, cleaning agents, rinsing, lubricating agents, method of inspection, method of disinfection or sterilization, reduction of sterilant residuals, drying, reuse life, additional labeling recommendations, patient or lay use, reference to guidelines or accessory labeling, and manufacturer’s contact information.

With respect to validation, the guidance cites several quality system regulation and notes that FDA interprets the regulations “to require manufacturers to validate the design, including reprocessing instructions, of reusable devices to ensure that the device can be effectively reprocessed and safely reused over its use life, as intended.”

The manufacturer must validate the cleaning process using “worst-case”

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testing. The simulated cleaning process should use artificial soil similar to what the device will encounter in actual use. The artificial soil should be placed on, or in, sites likely to be exposed in actual use. Validation studies should include several full use cycles and should also be designed to assess the accumulation of soil over time. The validation process must be documented. The FDA recommends that manufacturers use at least two methods of testing for residual soil and that they validate the test methods as well. Manufacturers should subject devices to a validated method of extraction for recovery of residual soil and the extraction method should be completely described for each device. Manufacturers should determine the recovery efficiency of the extraction method as part of its validation.

Per the guidance, the validation of the cleaning and disinfection or sterilization methods should be completed prior to making a pre-market submission. Although the underlying data need not be submitted with every 510(k) application, the guidance does include an Appendix E that lists device types for which a 510(k) "should include protocols and complete test reports of the validation of the reprocessing instructions for FDA review, so that FDA has the information it needs to evaluate substantial equivalence."

The manufacturing and design section of a PMA, HDE, or *de novo* submission should include the protocols and complete test reports of the validation of the reprocessing instructions. FDA interprets the IDE regulations to require a summary of the validation testing of the reprocessing instructions.
A copy of the final guidance document can be found here.

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