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FDA and SPD – How Federal Government Helps with Instructions for Use

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LEARNING OBJECTIVES

1. Review how the U.S. Food and Drug Administration (FDA) regulates products used in the Sterile Processing Department
2. Describe the FDA and manufacturers' roles and responsibilities for medical device instructions for use (IFU) and reprocessing instructions
3. Discuss how the FDA is working to align IFU and reprocessing instructions

The U.S. Food and Drug Administration (FDA) is an organization within the federal government that has broad regulatory responsibilities focused on protecting the health and safety of the public. As part of its responsibility, the FDA regulates medical devices, thus, playing an indirect but important role in the operation of hospital Sterile Processing departments (SPDs). The FDA's regulatory responsibilities include regulating the content of instructions for use (IFU) and device reprocessing instructions. This lesson explores how the federal government helps the SPD in these important areas.

Objective 1: Review how the FDA regulates products used in the Sterile Processing department

The FDA is part of the federal Department of Health and Human Services (HHS). Like many organizations, the FDA has a mission statement, with the first part of the statement reading: "The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation."[1] The FDA has a broad scope of responsibilities, but its influence on the operation of SPDs is specific to their regulation of medical devices. To better understand how the FDA impacts the SPD, it is necessary to first understand how medical devices are regulated.

The FDA defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

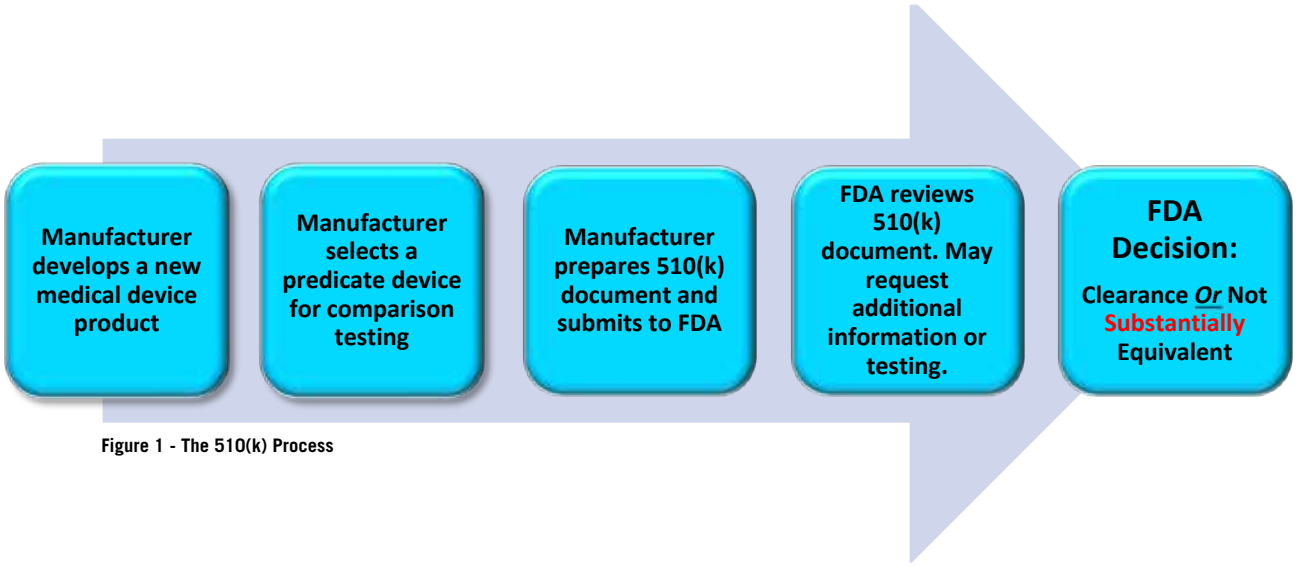

Figure 1 - The 510(k) Process

2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[2]

The key points of this statement are that medical devices are intended to diagnose and/or treat disease, and their primary mode of action is not chemical in nature (chemical action would be consistent with a biologic or drug product). The FDA classifies medical devices based on the level of risk they pose to patients or healthcare workers. Class I medical devices, such as bedpans and enema kits, pose the least risk and are often exempt from direct regulatory oversight by the FDA. Class II medical devices pose a moderate risk and are regulated by the FDA through the 510(k) process (more on this later). Examples of Class II medical devices include catheters and syringes, as well as sterilizers, biological indicators and chemical indicators. Class III medical devices such as pacemakers and implants pose the highest risk and are regulated through the more rigorous premarket approval (PMA) process. While some Class I and Class III medical devices will be present in the SPD, this lesson focuses on Class II devices as these will have the greatest impact on SPD procedures.

Objective 2: Describe the FDA and manufacturers' roles and responsibilities for medical device instructions for use (IFU) and reprocessing instructions

All Class II medical devices must successfully pass through the 510(k) premarket review process before the device can be sold for use on patients. The term "510(k)" is merely a reference to the section number of the federal law that defines this premarket review process. Medical devices that were in use before 1976 are called pre-amendment devices and are not subject to 510(k) requirements.

The 510(k) process requires the manufacturer to compare their new Class II device to a "predicate" device that has already been reviewed by the FDA and is in the marketplace. The predicate device must have the same intended use and technological characteristics as the new device, or it must have the same intended use and technological characteristics that are considered safe.[3]

Figure 1 provides a high-level overview of the 510(k) process. Note that the FDA does not conduct its own testing of the product under review. After reviewing all the information provided by the manufacturer, the FDA may decide that the new device is safe and effective and substantially equivalent to the predicate device. If so, the FDA will "clear" (note the verb is not "approve") the device, and the manufacturer may then begin to market the device. If the FDA believes the new device does not meet the safe and effective and substantially equivalent requirements, it will find the device "not substantially equivalent" (NSE) and the manufacturer will not be allowed to proceed.

The FDA provides guidance to the manufacturer on the specific information and test data to be provided

Item	Exposure Time at 132°C (240°F)	Exposure Time at 135°C (275°F)	Minimum Drying Times
Wrapped Instruments	4 Minutes		20-30 Minutes
		3 Minutes	16 Minutes
Textile Packs	4 Minutes		5-20 Minutes
		3 Minutes	3 Minutes
Wrapped Utencils	4 Minutes		20 Minutes
		3 Minutes	16 Minutes
Nonporous Items (e.g., instruments)	3 Minutes	3 Minutes	N/A
Nonporous and Porous Items in Mixed Load	4 Minutes	3 Minutes	N/A

**Reference: "Reprocessing Medical Devices in Healthcare Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff."*
Table 2 – Cycle Times for Dynamic-Air-Removal Steam Serilization Cycles

in the 510(k), which will also include proposed IFU and, if the device is reusable, the device's reprocessing instructions. The content and quality of the IFU and reprocessing instructions will have a major impact on the work of the SPD when the device is marketed.

A device manufacturer should be willing to share a copy of the clearance letter they received from the FDA for their device, if requested. Also, the FDA maintains a database of cleared 510(k)s on its website, and individuals can search for and read the 510(k) summary for any cleared device in the SPD. To search for 510(k) summaries, visit: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.

The FDA regulates all Class II medical devices found in the SPD. These include many of the medical and surgical instruments processed in the department, as well as many of the tools used to process those devices— including sterilizers, high-level disinfectants, sterilization wraps, containers, and monitoring products such as biological indicators (BIs) and chemical indicators (CIs). While some of the devices used to process surgical instruments are considered medical device "accessories," they are still regulated as medical devices under the normal 510(k) process.

As noted previously, the 510(k) process includes FDA review of the medical device's labeling, which includes the manufacturer's IFU and, if it is a reusable medical device, the manufacturer's reprocessing instructions. The general requirements for IFU include a description of the device, a statement of the device's intended use, detailed use instructions, and use precautions. The FDA will also have some specific requirements for IFU for the accessory devices that are used to reprocess surgical instruments, such as sterile packaging or monitoring products.

The FDA has made a significant effort to help SPDs by requiring the manufacturers of reusable medical devices to improve the quality of their reprocessing instructions. To accomplish this, the FDA published an updated guidance document in 2015 (and revised it again in 2017) titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."[4] This document establishes the FDA's updated requirements for the content and quality of these reprocessing instructions and is part of a reusable device's 510(k) clearance requirements.

The reprocessing guidance document describes the FDA's six main criteria for reprocessing instructions:

1. Labeling should reflect the intended use of the device.
2. Reprocessing instructions for reusable devices should advise users to thoroughly clean the device.
3. Reprocessing instructions should indicate the appropriate microbicidal process for the device.
4. Reprocessing instructions should be technically feasible and include only devices and accessories that are legally marketed.
5. Reprocessing instructions should be comprehensive.
6. Reprocessing instructions should be understandable.

The expectations for each criterion are discussed in detail in the reprocessing guidance document. A few of these criteria warrant some additional discussion. Criterion 2 recognizes the importance of thorough cleaning to the success of the entire disinfection

or sterilization process and specifies critical cleaning information the manufacturer needs to provide in the reprocessing instructions. For example, if the device is complex and some level of disassembly will be required to clean the device, the reprocessing instructions should provide detailed information on how to properly disassemble the device. If the device has lumens or other flushable orifices, the instructions should fully explain how to flush the device, including any requirements for connectors or adapters as well as the type and volume of flushing agent to be used.

Criterion 4 mentions that reprocessing instructions should only include devices and accessories that are legally marketed. The FDA's intent here is to begin to get alignment between the surgical instrument's reprocessing instructions and the IFU of the accessory devices that will be used in the disinfection or sterilization process. As an example, if the surgical instrument manufacturer intends to state that the instrument should be steam sterilized in a dynamic air removal cycle, the manufacturer should choose steam sterilization parameters that are consistent with steam sterilizer cycles already cleared by the FDA. The FDA's guidance provides examples of cleared parameters for steam and ethylene oxide in Appendix C. An example from the guidance document is provided in Table 2.

The FDA also states that accessory devices such as sterilization wraps and containers, and BIs and CIs, typically receive FDA clearance for specific sterilization processes or process parameters which are then listed in the intended use sections of the accessories' IFU. The FDA states that the instrument reprocessing instructions should also align with the cleared cycles or parameters listed in the accessory IFU and should have specific individual parameter combinations instead of ranges (e.g., a temperature range), which are not considered specific enough.[4]

Finally, Criterion 4 discusses the challenges of extended cycles and describes these as "any sterilization cycle that includes specifications that deviate from those found on commonly used, FDA-cleared sterilizers, and for which there are limited, or no FDA-cleared sterilization accessories. Extended cycles typically include longer exposure times and/or higher or intermediate temperatures, which may also deviate from more conventional sterilization cycles."[6] The use of extended cycles complicates the FDA's goal of alignment of all IFU involved with the reprocessing of the surgical instrument.

Criterion 5 requires that reprocessing instructions be comprehensive. This section lists the following 16 aspects of reprocessing that must be addressed in the reprocessing instructions:

1. Special accessories
2. Point-of-use processing
3. Disassembly and reassembly
4. Method of cleaning
5. Cleaning agents
6. Rinsing
7. Lubricating agents
8. Visual inspection
9. Method of disinfection or sterilization
10. Reduction of sterilant residuals
11. Drying
12. Reuse life
13. Additional labeling
14. Patient or lay use
15. References to guidelines
16. Manufacturer's contact information

Objective 3: Discuss how the FDA is working to align IFU and reprocessing instructions

The FDA's goal in raising the bar on the required quality of manufacturer's IFU and reprocessing instructions was to enable the SPD to become more efficient and effective, resulting in improved patient safety. Part of this program involves using the 510(k) review process to drive alignment of the surgical instrument's reprocessing instructions with the IFU of the accessory devices used to reprocess the instrument. The goal is that all surgical instruments would only recommend FDA-cleared and readily available sterilization cycles, and that each accessory device used to reprocess that instrument would also list the specific sterilization cycle in their IFU. In this way, the SP team would not have to spend time and energy trying to reconcile conflicting sterilization cycle or process recommendations provided in the device and supporting accessory product IFU.

The alignment of reprocessing instructions and IFU has begun but is not yet complete. Medical devices cleared before the publication of the updated guidance are still in use, and the FDA does not have legal authority to ask for retroactive actions on existing devices when regulations are updated. As more time passes, older devices will be replaced by newer devices that have been cleared under the updated requirements. Until this alignment is complete, SP technicians will still have situations where reprocessing instructions and IFU do not align. In these situations, they will need to continue to communicate with manufacturers and rely on their facilities' risk review procedures (and their own expertise) to make decisions on the correct sterilization cycle and accessories.

Conclusion

The FDA provides significant benefits to the SPD. It provides an independent technical assessment of the safety and efficacy medical devices and protects patients and teams from devices that do not meet these criteria. The FDA requires manufacturers to provide IFU and reprocessing instructions that are complete and consistent with the validation data for the product. The FDA's goal of alignment of the instrument reprocessing instructions and accessory IFU will simplify the process for SPDs; however, more time is needed before complete alignment is achieved.

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