4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2901]

Medical Devices; Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that it is necessary for manufacturers of certain reusable medical devices to include in their premarket notifications (510(k)s) instructions for use which have been validated and validation data regarding cleaning, disinfection, and sterilization, for which a substantial equivalence determination may be based. This notice includes a list of these reusable devices that will require validated instructions for use and validation data in their premarket notification. FDA is publishing this list in accordance with the requirements established by the 21st Century Cures Act. This action ensures that the premarket requirements for these device types are clear and predictable which facilitates more efficient review of these 510(k)s.

DATES: These actions are effective on [INSERT 60 DAYS AFTER DATE OF PUBLICATION].

FOR FURTHER INFORMATION CONTACT: Constance Soves, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1437, Silver Spring, MD 20993-0002, 301-796-6951.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 et seq.), as amended, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) establishes three categories (classes) of devices, based on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as post-amendments devices), are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA initiates one of the following procedures: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i), to a predicate device that is already legally marketed. The Agency determines whether new devices are substantially equivalent to predicate devices through review of premarket notifications under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and its implementing regulations, codified in Title 21 of the Code of Federal Regulations (21 CFR part 807, subpart E), require persons who intend to market a new device that does not require a premarket approval application under section 515 of the FD&C Act (21 U.S.C. 360e) to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On December 13, 2016, the President signed into law the 21st Century Cures Act (Pub. L. 114-255) (Ref. 1). Section 3059 of the 21st Century Cures Act, in part, amends section 510 of the FD&C Act to require FDA to publish in the Federal Register a notice identifying a list of reusable device types that must include validated instructions for use and validation data regarding cleaning, disinfection, and sterilization in their 510(k) submissions. This section also provides that a 510(k) submission for a reusable device may not be substantially equivalent to a predicate device if the validated instructions for use and reprocessing validation data submitted as part of the 510(k) are inadequate.

Manufacturers of reusable medical devices are responsible for having labeling that bears adequate directions for use, including instructions on preparing a device for use under 21 CFR 801.5 and 801.109. However, in recent years, there have been significant changes in knowledge and technology involved in reprocessing reusable medical devices. Additionally, there has been an evolution towards more complex reusable medical device designs that are more difficult to clean, disinfect, and sterilize. FDA believes reusable devices must be designed for adequate reprocessing and safe reuse, with comprehensive and clear instructions for effective reprocessing procedures for use by health care facilities that reprocess these devices.

II. Requirements for Validated Reprocessing Instructions and Reprocessing Validation Data for Reusable Medical Devices

A reusable medical device is one intended for repeated use either on the same or different patients, with appropriate cleaning and other reprocessing steps between uses. FDA has issued recommendations for reprocessing reusable devices in relevant documents, including the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," as information on the reprocessing validation methods necessary to be reported in a

510(k) submission (Ref. 2). FDA expects specific required validation data regarding cleaning, disinfection, and sterilization to be included in 510(k) submissions for certain reusable medical device types as outlined in tables 1 and 2 below.

FDA believes that a majority of manufacturers for the reusable devices listed below are already conducting validation of their reprocessing instructions because FDA already has provided recommendations for reprocessing validation in relevant FDA documents. Sponsors of new 510(k) notifications for reusable devices identified in the tables below must also include validation data regarding cleaning, disinfection, and sterilization, in addition to all the other required elements of a 510(k) identified in 21 CFR 807.87, starting on [INSERT 60 DAYS AFTER DATE OF PUBLICATION].

III. List of Certain Reusable Medical Devices and Design Features

The 21st Century Cures Act (section 3059) requires the Agency to identify and publish a list of reusable device types that are required to include "instructions for use" and "validation data" regarding cleaning, disinfection, and sterilization in 510(k) notifications. Accordingly, FDA is publishing the list in table 1 that identifies those reusable medical devices that FDA has determined pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed.

FDA believes arthroscopes, laparoscopic instruments, and electrosurgical instruments, and their respective accessories with specific design features, identified in table 2, may pose a challenge to adequate reprocessing. 510(k) notifications for such devices that incorporate any of the design features listed in table 2 must include validated reprocessing instructions and reprocessing validation data reports, and if such are determined to be inadequate, FDA will find the device not substantially equivalent.

Table 1.--Reusable Devices that Require Validation Data and Validated Reprocessing Instructions Be Included in 510(k) Notification and Upon Which FDA Will Determine Substantial Equivalence

Device Type	Product Code	Device Name	21 CFR Section
Bronchoscopes (flexible or rigid) and accessories	EOQ	Bronchoscope (flexible or rigid)	21 CFR 874.4680
	PSV	Ultrasound bronchoscope	21 CFR 892.1550
	KTI	Bronchoscope accessory	21 CFR 874.4680
	BTG	Brush, biopsy, bronchoscope (non-rigid)	21 CFR 874.4680
	JEI	Claw, foreign body, bronchoscope (non-rigid)	21 CFR 874.4680
	JEL	Curette, biopsy, bronchoscope (rigid)	21 CFR 874.4680
	BST	Curette, biopsy, bronchoscope (non-rigid)	21 CFR 874.4680
	BWH	Forceps, biopsy, bronchoscope (non-rigid)	21 CFR 874.4680
	JEK	Forceps, biopsy, bronchoscope (rigid)	21 CFR 874.4680
	ENZ	Telescope, laryngeal-bronchial	21 CFR 874.4680
	KTR	Tube, aspirating, bronchoscope (rigid)	21 CFR 874.4680
	JEJ	Tubing, Instrumentation, bronchoscope (brush sheath A/O aspirating)	21 CFR 874.4680
Ear, Nose, and Throat (ENT) endoscopes and accessories	EOX	Esophagoscope (flexible or rigid)	21 CFR 874.4710
	GCL	Esophagoscope, general & plastic surgery	21 CFR 876.1500
	FDW	Esophagoscope, rigid, gastro-urology	21 CFR 876.1500
	EOB	Nasopharyngoscope (flexible or rigid)	21 CFR 874.4760
	EQN	Laryngoscope, nasopharyngoscope	21 CFR 874.4760
	EWY	Mediastinoscope, surgical, and accessories	21 CFR 874.4720
Gastroenterology and Urology Endoscopes that have elevator channels (not including accessories) [e.g., duodenoscopes used for endoscopic retrograde cholangiopancreatography (ERCP)]	FDT	Duodenoscope and accessories, flexible/rigid	21 CFR 876.1500
	FAK	Panendoscope (gastroduodenoscope)	21 CFR 876.1500
	ODF	Mini endoscope, gastroenterology-urology	21 CFR 876.1500
Automated Reprocessors for Reusable Devices	FEB	Accessories, cleaning, for endoscopes	21 CFR 876.1500
	NZA	Accessories, germicide, cleaning, for endoscopes	21 CFR 876.1500
	OUJ	High level disinfection reprocessing instrument for ultrasonic transducers, mist	21 CFR 892.1570
	NVE	Washer, cleaner, automated, endoscope	21 CFR 876.1500
	PSW	High level disinfection reprocessing instrument for ultrasonic transducers, liquid	21 CFR 892.1570
Other Flexible Gastroenterology and Urology Endoscopes[1] (not including accessories)	FDF	Colonoscope and accessories, flexible/rigid	21 CFR 876.1500
	FBN	Choledochoscope and accessories, flexible/rigid	21 CFR 876.1500
	FDA	Enteroscope and accessories	21 CFR 876.1500
	FDS	Gastroscope and accessories, flexible/rigid	21 CFR 876.1500
	FAJ	Cystoscope and accessories, flexible/rigid	21 CFR 876.1500
	FGB	Ureteroscope and accessories, flexible/rigid	21 CFR 876.1500
	ODG	Endoscopic ultrasound system, gastroenterology-urology	21 CFR 876.1500
Neurological endoscopes (not including accessories)	GWG	Endoscope, neurological	21 CFR 882.1480
Water-based heater-cooler systems for use in operating rooms	DWC	Controller, Temperature, Cardiopulmonary Bypass	21 CFR 870.4250
	DWJ	System, Thermal Regulating	21 CFR 870.5900
System, Surgical, Computer Controlled Instrument	NAY	System, Surgical, Computer Controlled Instrument	21 CFR 876.1500
Arthroscopes and accessories[2]	HRX	Arthroscope	21 CFR 888.1100

Device Type	Product Code	Device Name	21 CFR Section
Laparoscopic instruments and accessories[2]	GCJ	Laparoscope, general and plastic surgery	21 CFR 876.1500
Electrosurgical instruments and accessories[2]	GEI	Electrosurgical, cutting and coagulation and accessories	21 CFR 878.4400

[1] For endoscopes that fall under these product codes, 510(k) submissions must include reprocessing validation data for those endoscopes which are flexible.

[2] For devices that fall under these product codes, 510(k) submissions must include reprocessing validation data if the device possesses any of the design features listed in table 2 below.

Table 2.--Design Features Which May Pose a Challenge to Adequate Reprocessing for Arthroscopes, Laparoscopic Instruments, and Electrosurgical Instruments, and their Respective Accessories

Lumens (especially lumens of flexible design, multiple internal lumens, lumens that are not freely accessible, bifurcated lumens, lumens with internal surfaces that are not smooth, have internal ridges or sharp angles, or are too small to permit a brush to pass through)
Hinges, depressions, joints with gaps, overlapping or butted joints that result in acute angles, or ribbed or otherwise “roughened” surfaces (e.g., jaws)
Interior device channels
Sleeves surrounding rods, blades, activators, inserters, etc.
Shafts within lumens
Adjacent device surfaces between which debris can be forced or caught during use
O-rings
Stopcocks/Valves
Crevices
Fittings with very close tolerances
Clamps that cannot be fully opened for cleaning
Small internal parts (e.g., springs, magnets, etc.) that may become soiled
Ridges, articulations or grooves
Rough, irregular, discontinuous surfaces that can entrap or retain soil
Capillary gaps
Luer locks
Porous materials (smooth surfaces are desirable, where possible)
Junctions between insulating sheaths and activating mechanisms (as in certain laparoscopic instruments)
Dead-ended chambers
Internal movable device components such as multiple cables
Device features that may entrap debris that can later become aerosolized (e.g., through application of power, etc.)
Devices with these or other design features that cannot be disassembled for reprocessing

The Agency believes that these devices currently have the greatest risk of infection transmission and inadequate performance if not adequately reprocessed. In the future, the Agency may reevaluate and revise both tables as it deems necessary.

IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The

collections of information in part 801 have been approved under OMB control number 0910-0485 (medical device labeling); the collections of information in part 807, subpart E have been approved under OMB control number 0910-0120 (premarket notification); and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073 (quality system regulation).

V. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. 21st Century Cures Act, Pub. L. 114-255, available at https://www.congress.gov/114/bills/hr34/BILLS-114hr34eah.pdf.

2. FDA's Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, March 2015, available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf.

Dated: June 5, 2017.

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Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
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