DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2014–N–0430]

Medical Devices; Gastroenterology-Urology Devices; Classification of Pancreatic Drainage Stent and Delivery System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the pancreatic drainage stent and delivery system into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the pancreatic drainage stent and delivery system classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective June 30, 2014. The classification was applicable beginning December 18, 2013.

FOR FURTHER INFORMATION CONTACT: Jeffrey Cooper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G228, Silver Spring, MD 20993–0002, 301–796–6517.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144, July 9, 2012, 126 Stat. 1054), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On February 15, 2013, Xlumena, Inc., submitted a request for classification of the AXIOS Stent and Delivery System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 18, 2013, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 876.5015.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for a pancreatic drainage stent and delivery system will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name pancreatic drainage stent and delivery system, and it is identified as a prescription device that consists of a self-expanding, covered, metallic stent, intended for placement to facilitate transmural endoscopic drainage of pancreatic pseudocysts. This stent is intended to be removed upon confirmation of pseudocyst resolution. This device may also include a delivery system.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks in table 1:

TABLE 1—PANCREATIC DRAINAGE STENT AND DELIVERY SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Adverse tissue reaction or infection	Biocompatibility testing. Sterility testing. Labeling.
Partial expansion of stent	Clinical experience. In-vitro (bench) testing. Labeling.

TABLE 1—PANCREATIC DRAINAGE STENT AND DELIVERY SYSTEM RISKS AND MITIGATION MEASURES—Continued

Identified risk	Mitigation measure
Failure to deliver stent	Clinical experience. In-vitro (bench) testing. Labeling.
Stent occlusion	Clinical experience. Labeling.
Stent ingrowth/failure to remove stent	Clinical experience. Labeling.
Stent migration (passive dislocation)	Clinical experience. In-vitro (bench) testing. Labeling.
Stent dislodgement (active dislocation)	Clinical experience. In-vitro (bench) testing. Labeling.
Tissue ulceration	Clinical experience. In-vitro (bench) testing. Labeling.
Procedural complications	Clinical experience. Labeling.

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

1. The device and elements of the delivery device that may contact the patient must be demonstrated to be biocompatible.

2. Performance data must demonstrate the sterility of patient-contacting components of the device.

3. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.

4. Non-clinical testing data must demonstrate that the stent and delivery system perform as intended under anticipated conditions of use. The following performance characteristics must be tested:

- Deployment testing of the stent and delivery system must be conducted under simulated use conditions.
- Removal force testing must be conducted. The removal force testing must demonstrate that the stent can be safely removed, and that the stent will remain in place when subjected to forces encountered during use.
- Expansion force testing must be conducted. The expansion force must demonstrate that the forces exerted by the stent will not damage the tissue surrounding the stent.
- Compression force testing must be conducted. The compression force must demonstrate that the stent will withstand the forces encountered during use.
- Dimensional verification testing must be conducted.
- Tensile testing of joints and materials must be conducted. The minimum acceptance criteria must be adequate for its intended use.
- Fatigue testing must be conducted. Material strength must demonstrate that the stent will withstand forces encountered during use.
- Corrosion testing must be conducted. Corrosion resistance must demonstrate that the stent will withstand conditions encountered during use.

5. Non-clinical testing must evaluate the compatibility of the stent in a magnetic resonance environment.

6. Well-documented clinical experience must demonstrate safe and effective use, and capture any adverse events observed during clinical use.

7. Labeling must include the following:

- Appropriate instructions, warnings, cautions, limitations, and information related to the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.
- A warning that the safety and patency of the stent has not been established beyond the duration of the documented clinical experience.
- Specific instructions and the qualifications and clinical training needed for the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.
- Information on the patient population for which the device has been demonstrated to be effective.
- A detailed summary of the clinical experience pertinent to use of the device.
- A detailed summary of the device technical parameters.
- A detailed summary of the device- and procedure-related complications pertinent to use of the device.
- An expiration date/shelf life.

Pancreatic drainage stents and delivery systems are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed § 876.5015(a); see section 520(e) of the FD&C Act (21 U.S.C. 360j(e)) and 21 CFR 801.109 (Prescription devices).) Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification prior to marketing the device, which contains information about the pancreatic drainage stent and delivery system they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other 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 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. K123250: De Novo Request per section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act From Xlumena, Inc., dated February 15, 2013.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5015 to subpart F to read as follows:

§ 876.5015 Pancreatic drainage stent and delivery system.

(a) Identification. A pancreatic drainage stent is a prescription device that consists of a self-expanding, covered, metallic stent, intended for placement to facilitate transmural endoscopic drainage of pancreatic pseudocysts. This stent is intended to be removed upon confirmation of pseudocyst resolution. This device may also include a delivery system.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) The device and elements of the delivery device that may contact the patient must be demonstrated to be biocompatible.

(2) Performance data must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.

(4) Non-clinical testing data must demonstrate that the stent and delivery system perform as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Deployment testing of the stent and delivery system must be conducted under simulated use conditions.

(ii) Removal force testing must be conducted. The removal force testing must demonstrate that the stent can be safely removed, and that the stent will remain in place when subjected to forces encountered during use.

(iii) Expansion force testing must be conducted. The expansion force must demonstrate that the forces exerted by the stent will not damage the tissue surrounding the stent.

(iv) Compression force testing must be conducted. The compression force must demonstrate that the stent will withstand the forces encountered during use.

(v) Dimensional verification testing must be conducted.

(vi) Tensile testing of joints and materials must be conducted. The minimum acceptance criteria must be adequate for its intended use.

(vii) Fatigue testing must be conducted. Material strength must demonstrate that the stent will withstand forces encountered during use.

(viii) Corrosion testing must be conducted. Corrosion resistance must demonstrate that the stent will withstand conditions encountered during use.

(5) Non-clinical testing must evaluate the compatibility of the stent in a magnetic resonance (MR) environment.

(6) Well-documented clinical experience must demonstrate safe and effective use, and capture any adverse events observed during clinical use.

(7) Labeling must include the following:

(i) Appropriate instructions, warnings, cautions, limitations, and information related to the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.

(ii) A warning that the safety and patency of the stent has not been established beyond the duration of the documented clinical experience.

(iii) Specific instructions and the qualifications and clinical training needed for the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.

(iv) Information on the patient population for which the device has been demonstrated to be effective.

(v) A detailed summary of the clinical experience pertinent to use of the device.

(vi) A detailed summary of the device technical parameters.

(vii) A detailed summary of the device- and procedure-related complications pertinent to use of the device.

(viii) An expiration date/shelf life.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Bureau of Engraving and Printing

31 CFR Part 100

Exchange of Mutilated Paper Currency

AGENCY: Bureau of Engraving and Printing, Treasury.

ACTION: Interim rule.

SUMMARY: The Department of the Treasury, Bureau of Engraving and Printing is amending its regulations on exchange of mutilated paper currency in order to update mutilated currency procedures and eliminate references to obsolete practices and terms. The amendments will serve to deter fraud and abuse in the mutilated currency redemption process.

DATES: Comments must be received no later than July 28, 2014. *Effective date:* May 29, 2014.

ADDRESSES: The Bureau of Engraving and Printing invites comments on all aspects of this interim rule. Comments may be submitted through one of these methods:

Electronic Submission of Comments: Interested persons are encouraged to submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables the Department to make them available to the public.