



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2016-N-1813]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Metallic Biliary Stent System for Benign Strictures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the metallic biliary stent system for benign strictures 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 metallic biliary stent system for benign strictures' 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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on June 3, 2016.

FOR FURTHER INFORMATION CONTACT: April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G218, Silver Spring, MD, 20993-0002, 240-402-6510, [april.marrone@fda.hhs.gov](mailto:april.marrone@fda.hhs.gov).

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), 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), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. 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), 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) 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 August 27, 2015, Boston Scientific Corporation submitted a request for classification of the WallFlex Biliary RX Fully Covered Stent System RMV 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). 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 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 June 3, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5011.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a metallic biliary stent system for benign strictures will need

to comply with the special controls named in this final order. The device is assigned the generic name metallic biliary stent system for benign strictures, and it is identified as a prescription device intended for the treatment of benign biliary strictures. The biliary stents are intended to be left indwelling for a limited amount of time and subsequently removed. The device consists of a metallic stent and a delivery system intended to place the stent in the bile duct. This device type is not intended for use in the vasculature.

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.--Metallic Biliary Stent System for Benign Strictures Risks and Mitigation Measures

Identified Risk	Mitigation Measure
Adverse tissue reaction	Biocompatibility Evaluation Labeling
Infection	Sterilization Validation Shelf Life Validation Labeling
Bile duct obstruction Stent migration Stent does not resolve obstruction Stent cannot be placed Expansion/compression forces Foreshortening	Clinical Performance Testing Non-clinical Performance Testing Shelf Life Validation Labeling
Trauma to bile ducts During stent deployment During removal Due to stent migration During stent indwell Inability to safely remove stent Expansion/compression forces	Clinical Performance Testing Non-clinical Performance Testing Shelf Life Validation Labeling

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

A metallic biliary stent system for benign strictures is not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, Prescription devices).

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) 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 metallic biliary stent system for benign strictures they intend to market.

## II. Analysis of 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 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. DEN150040: De Novo request from Boston Scientific Corporation, dated August 27, 2015.

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 part 876 continues to read as follows:

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

2. Add § 876.5011 to subpart F to read as follows:

§ 876.5011 Metallic biliary stent system for benign strictures.

(a) Identification. A metallic biliary stent system for benign strictures is a prescription device intended for the treatment of benign biliary strictures. The biliary stents are intended to be left indwelling for a limited amount of time and subsequently removed. The device consists of a metallic stent and a delivery system intended to place the biliary stent in the bile duct. This device type is not intended for use in the vasculature.

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

(1) Clinical performance testing must demonstrate or provide the following:

(i) The ability to safely place and subsequently remove the stent after the maximum labeled indwell period.

(ii) All adverse event data including bile duct obstruction and trauma to the bile duct.

(iii) The stent resolves strictures during the maximum labeled indwell period.

(iv) Stricture resolution is maintained post-stent removal.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Corrosion testing to demonstrate that the stent maintains its integrity during indwell and does not release potentially toxic levels of leachables.

(ii) Stent dimensional testing supports the intended use.

(iii) Compression and expansion forces must be characterized.

(iv) The delivery catheter must deliver the stent to the intended location and the stent must not be adversely impacted by the delivery catheter during deployment and catheter withdrawal.

(v) The delivery system must withstand clinically anticipated forces.

(vi) Compatibility in a magnetic resonance environment.

(3) All patient contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(5) Shelf life testing must demonstrate that the device maintains its performance characteristics and that packaging maintains sterility for the duration of the labeled shelf life.

(6) Labeling for the device must include:

- (i) A detailed summary of the clinical testing including device effectiveness, and device- and procedure-related adverse events.
- (ii) Appropriate warning(s) to accurately ensure usage of the device for the intended patient population.
- (iii) Shelf life.
- (iv) Compatibility information for use in the magnetic resonance environment.
- (v) Stent foreshortening information supported by dimensional testing.

Dated: July 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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