DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 9, 2017

Boston Scientific Corporation
Thomas Hirte
Senior Manager Regulatory affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K171809
Trade/Device Name: Epic Biliary Endoscopic Stent System
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: June 16, 2017
Received: June 19, 2017

Dear Thomas Hirte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William H. Maisel -S

William H. Maisel, MD, MPH
Acting Director, Office of Device Evaluation
Deputy Center Director for Science
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171809

Device Name
Epic Biliary Endoscopic Stent System

Indications for Use *(Describe)*
The Epic Biliary Endoscopic Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5. 510(K) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Thomas Hirte
Senior Manager Regulatory Affairs
Telephone: 508-683-4454
Fax: 508-683-5939

Secondary Contact: Virginia Garcia
Principal, Regulatory Affairs Specialist
Telephone: 508-683-4430
Fax: 508-683-5939

Date Prepared: 16 June 2017

2. Device:

Trade Name:	Epic Biliary Endoscopic Stent System
Device Common Name:	Biliary Catheter and Accessories
Classification Name:	Catheter, Biliary, Diagnostic
Regulation Number:	21CFR 876.5010
Product Code:	FGE
Classification:	Class II

3. Predicate Device:

Trade Name:	Cook Zilver 635 Biliary Stent
510(k) Number:	K163018
Device Common Name:	Biliary Catheter and Accessories
Classification Name:	Catheter, Biliary, Diagnostic
Regulation Number:	21CFR 876.5010
Product Code:	FGE
Classification:	Class II

4. Device Description

The Epic Biliary Endoscopic Stent System is comprised of two components: the implantable stent and the stent delivery system.

Epic Biliary Stent:

The stent is a laser cut self-expanding stent composed of a nickel titanium alloy (Nitinol). The Epic Biliary Endoscopic Stent System is available in 6mm, 8mm, 10mm stent diameters and lengths of 40mm, 60mm, 80mm and 100 mm. On both the proximal and distal ends of the stent, radiopaque markers increase visibility of the stent to aid in placement. The stent is constrained within a 6 French delivery system.

Delivery System:

The delivery system is a coaxial design with an exterior shaft to protect and constrain the stent prior to deployment. The delivery system, with a 6 French outer diameter and 220 cm catheter length, is compatible with 0.035" (0.89 mm) guidewires. The stent is deployed by retracting the exterior shaft of the delivery system using either thumb wheel staged deployment method or the pull-back deployment method. A radiopaque marker at the distal end of the delivery system aids in visibility during deployment.

The Epic Biliary Endoscopic Stent System is provided sterile and is a Single Use Device. The system is intended to track over a guidewire through an endoscope and into the area of a stricture. Table 5-1 below discusses the main features of the Epic Biliary Endoscopic Stent System.

5. Indications for Use:

The Epic Biliary Endoscopic Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

6. Technological Characteristics

The intended use of the proposed Epic Biliary Endoscopic Stent System is identical to the predicate Cook Zilver 635 Biliary Stent. They are both nitinol laser cut stents intended for use in palliation of malignant neoplasms in the biliary tree.

The proposed Epic Biliary Endoscopic Stent System is similar to the predicate Cook Zilver 635 Biliary Stent in terms of performance and technological characteristics with minor differences in the delivery system design. The stent design and materials are similar between the proposed Epic Biliary Endoscopic Stent and the Cook Zilver 635 Biliary Stent cleared in K163018.

7. Performance Data

Testing of the proposed device was performed in accordance with FDA Guidance Document "Guidance of the Content of Premarket Notifications for Metal Expandable Biliary Stents" February 5, 1998.

Bench Testing:
Functional and performance tests were performed on the proposed Epic Biliary Endoscopic stent and delivery system to demonstrate substantial equivalence and to satisfy all design verification requirements. The Epic Biliary Endoscopic Stent System passed all tests. In-vitro testing that has been performed and all components, subassemblies, and/or full devices met the required specifications.

The proposed Epic Biliary Endoscopic Stent System and the Cook Zilver 635 Biliary Stent predicate were also tested to establish substantial equivalence in performance in the following tests: Flexural Rigidity, Stent Hoop Expansion Force, Stent Hoop Compression Force, System Deployment, Stent Dimensions, Delivery System Tensile Strength, and Stent Corrosion.

The proposed Epic Biliary Endoscopic Stent System was evaluated in accordance with EN ISO 10993-1: 2009. The following tests were performed on the stent: Cytotoxicity, Sensitization, Intracutaneous Irritation, Systemic Toxicity, Subchronic Toxicity, Genotoxicity – Ames Assay and Mouse Lymphoma Assay, Implanatation, Chemical characterization. The following tests were performed on the delivery system: Cytotoxicity, Sensitization, Intracutaneous Irritation, Systemic Toxicity, Chemical Characterization Testing.

Conclusion
The information provided in this submission demonstrates that the proposed Epic Biliary Endoscopic Stent System is substantially equivalent to the Cook Zilver 635 Biliary Stent cleared in K163018.