JUL 0 2 2014

Attachment 5

510(k) Summary

Submitter	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Person	Renee Mitchell
Phone Number	763-494-1405
Fax Number	763-494-1643
Date Prepared	September 27, 2013
Device Trade Name	Express LD Biliary Premounted Stent System
Common Name	Biliary Premounted Stent
Device Classification	Class II devices by the Gastroenterology/Urology Devices Panel according to 21 CFR Part 876.5010.
Product Code	FGE

Predicate Device
Express LD Biliary Premounted Stent System

Device Description

The Express LD Biliary Premounted Stent System consists of: A 316L surgical grade stainless steel balloon expandable stent. The stent is premounted on an over the wire Stent Delivery System (SDS) equipped with a non-compliant balloon. The SDS balloon catheter has two radiopaque markers embedded in the shaft to aid in the placement of the stent. The SDS is compatible with 0.035 in (0.89 mm) guidewires. The SDS balloon has a maximum inflation pressure of 12 atm (1216 kPa) that can be used for initial stent placement and post stent dilatation. The Premounted Stent System is available in a variety of stent lengths with SDS balloons that expand them from 5 mm to 10 mm in diameter. The SDS balloon catheter is also offered in two shaft lengths.

Indications for Use
The Express LD Biliary Premounted Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

Substantial Equivalence
The proposed Express LD Biliary Premounted Stent System is substantially equivalent to the predicate Express LD Biliary Premounted Stent System which was cleared by FDA under premarket notification K021630 (October 25, 2002). The proposed Express LD Biliary Premounted Stent System has the same intended use and device performance as the predicates Express LD Biliary Premounted Stent System (K021630, K024048, and K032360).

Comparison of Technological Characteristics
The proposed Express LD Biliary Premounted Stent System incorporates existing device materials, sterilization EO methods, and design characteristics as the predicate BSC device (Express LD Biliary Premounted Stent System) and similar materials as BSC reference device Renegade microcatheter (K100892).

Comparison to Predicate Device

Characteristic	**Express LD Biliary Premounted Stent System Predicates (K021630, K024048, and K032360)**
Stent	Same design and function
Stent Delivery System	
Materials	
Balloon	Same balloon material, design, and function
Catheter Shaft	Same catheter shaft material, design, and function
Catheter Tip	Minor resin formulation difference. Same Tip design. Same Function
RO Markers	Same RO marker material, design, and function
Catheter Shaft Coatings	Same catheter shaft coating material, design, and function
Balloon Adhesives	Minor formulation differences in both adhesives Same function
Sterilization	
Sterilization Method	Same sterilization method
SAL	Same level of assurance
Design Characteristics	
Balloon Diameters	Same Catheter Diameters serving same function
Balloon Lengths	Same catheter length ranges serving same function Lengths
Rated Burst Pressure (RBP)	Same rated burst pressure
Usable Catheter Lengths	Same useable catheter lengths serving same function
Intended use	Same intended use
Packaging	Same design and function

Performance Data
Bench testing and biocompatibility were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

Testing Completed:

- Balloon deflation time
- Guidewire Compatibility
- Multiple Balloon Inflations
- Rated Burst Pressure
- RO Marker Location/RO Markers
- MEM Elution Cytotoxicity
- Hemocompatibility – Hemolysis (Direct)
- USP Physicochemical

Conclusion:
Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Express LD Biliary Premounted Stent System has been shown to be appropriate for its intended use and is considered to be substantially equivalent to Express LD Biliary Premounted Stent System (K021630, K024048, and K032360).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 2, 2014

Boston Scientific Corporation
Renee Mitchell
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K133110
Trade/Device Name: Express® LD Biliary Premounted Stent System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: June 9, 2014
Received: June 10, 2014

Dear Renee Mitchell,

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Christy L. Foreman -S

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use

510(k) Number (if known): K133110

Device Name: Express® LD Biliary Premounted Stent System

Indications for Use:

The Express LD Biliary Premounted Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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