DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 27, 2015

Boston Scientific Corporation
Anna Deraney
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K152607
Trade/Device Name: Express® SD Biliary Monorail® Premounted Stent System
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: September 10, 2015
Received: September 11, 2015

Dear Anna Deraney,

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. 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.

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 yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
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)*

K152607

Device Name
Express® SD Biliary Monorail® Premounted Stent System

Indications for Use *(Describe)*
The Express SD Biliary Monorail Premounted 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.

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510k Summary

Per 21 CFR §807.92

Common or Usual Name	Biliary Stent and Balloon Dilatation Catheter	
Trade Name(s)	Boston Scientific Express® SD Biliary Monorail® Premounted Stent System	
Product Code	FGE – Catheter, Biliary, Diagnostic	
Classification of Device	Boston Scientific Corporation Express SD Biliary catheters and accessories have been classified as Class II devices according to 21 CFR 876.5010	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Anna Deraney Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-494-2222 Email: anna.deraney@bsci.com	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	**Owner /Operator:**	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 9912058
	Manufacturing Facility:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facilities:	Synergy Health Ireland Limited IDA Business & Technology Park Tullamore, County Offaly, Ireland BSC Coventry 8 Industrial Drive Coventry, RI 02816, USA
Predicate Devices	Express® SD Biliary Monorail® Premounted Stent System cleared March 30, 2004	

Intended Use/ Indications for Use	The Express SD Biliary Monorail Premounted Stent System is indicated for palliation of malignant neoplasms in the biliary tree.
Comparison of Required Technological Characteristics	The proposed Express SD Biliary device is substantially equivalent to the existing Express SD Biliary device cleared by FDA under premarket notification K040027 (March 30, 2004). Express SD has the same intended use, scientific technology, design, materials, sterilization method, and packaging materials (with the exception of the accessory kit) as the applicable predicate device. The labeling (carton labels, pouch labels, and Directions for Use) are being updated to include language and test data to support the Magnetic Resonance Environment conditions under which the Express SD Biliary device is compatible.
Summary of Non-Clinical Test Summary	Bench testing was performed to support a determination of Magnetic Resonance compatibility. 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 device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Express SD Biliary Premounted Stent System has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Express SD Biliary Monorail Premounted Stent System (K040027).