



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

October 12, 2016

Boston Scientific Corporation  
Ka Zoua Xiong  
Regulatory Affairs Specialist  
One Scimed Place  
Maple Grove, MN 55311-1566

Re: K162404  
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: August 26, 2016  
Received: August 29, 2016

Dear Ka Zoua Xiong:

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,

  
**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

## Indications for Use

510(k) Number (if known)

K162404

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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**510(k) Summary**  
**Per 21 CFR §807.92**

<b>Common or Usual Name</b>	Biliary Stent and Balloon Dilatation Catheter	
<b>Trade Name(s)</b>	Express® SD Biliary Monorail® Premounted Stent System	
<b>Product Code</b>	FGE –Catheter, Biliary, Diagnostic	
<b>Classification of Device</b>	Class II - 21 CFR 876.5010	
<b>Submitter's Name and Address</b>	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
<b>Contact Name and Information</b>	Ka Zoua Xiong Regulatory Affairs Specialist Phone: 763-494-2970 Fax: 763-494-2222 Email: Kazoua.Xiong@bsci.com	
<b>Date Prepared</b>	11 October 2016	
<b>Section 514 of the Act Performance Standards</b>	Currently no FDA mandated or voluntary performance standards exist for this device.	
<b>Establishment Registration Numbers</b>	<b>Owner /Operator:</b>	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 9912058
	<b>Manufacturing Facility:</b>	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	<b>Sterilization Facilities:</b>	BSC Coventry 8 Industrial Drive Coventry, RI 02816 USA  Synergy Health (Tullamore) IDA Business & Technology Park Tullamore County Offaly Ireland

<b>Predicate Devices</b>	K152607 - Express® SD Biliary Monorail® Premounted Stent System, cleared 27 October 2015
<b>Device Description</b>	The Express® SD Biliary Monorail® Premounted Stent System (Express SD Biliary) is a traditional Monorail catheter with a balloon near the distal tip. Express SD Biliary consists of a delivery system and a stent that is balloon expandable intended to maintain patency of biliary strictures produced by malignant neoplasms.
<b>Intended Use/ Indications for Use</b>	The Express SD Biliary Monorail Premounted Stent System is indicated for palliation of malignant neoplasms in the biliary tree.
<b>Comparison of Required Technological Characteristics</b>	The proposed Express SD Biliary is substantially equivalent to the existing Express SD Biliary cleared by FDA under premarket notification K152607 (27Oct2015). Express SD Biliary has the same intended use, scientific technology, design (with the exception of the corewire design), materials, sterilization method, and packaging materials as the applicable predicate device.
<b>Summary of Non-Clinical Test Summary</b>	First article and shaft and bond burst testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device with the modified corewire have 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.
<b>Conclusion</b>	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Express SD Biliary with the modified corewire has been shown to be appropriate for its intended use and is considered to be substantially equivalent to its predicate (K152607).