DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 20, 2015

Boston Scientific Corporation
Carah Kucharski
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K152853
Trade/Device Name: WALLSTENT RP Endoprosthesis Transhepatic Biliary and WALLSTENT Endoprosthesis Transhepatic Biliary
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: October 14, 2015
Received: October 15, 2015

Dear Carah Kucharski,

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,

Herbert P. Lerner -S

for 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)*
K152853

Device Name
WALLSTENT RP Endoprosthesis Transhepatic Biliary and WALLSTENT Endoprosthesis Transhepatic Biliary

Indications for Use *(Describe)*
The WALLSTENT RP Endoprosthesis Transhepatic Biliary and WALLSTENT Endoprosthesis Transhepatic Biliary are indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

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.

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510k Summary

Per 21 CFR §807.92

Common or Usual Name	Self-Expanding Biliary Stent	
Trade Name(s)	WALLSTENT™ RP Endoprosthesis Transhepatic Biliary and WALLSTENT™ Endoprosthesis Transhepatic Biliary	
Product Code	FGE— Catheter, Biliary, Diagnostic	
Classification of Device	The WALLSTENT™ RP Endoprosthesis Transhepatic Biliary and WALLSTENT™ Endoprosthesis Transhepatic Biliary devices have been classified as Class II devices according to 21 CFR 876.5010 – Biliary Catheter and Accesories.	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Carah Kucharski Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-255-0738 Email: carah.kucharski@bsci.com	
Establishment Registration Numbers	**Owner / Operator:**	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 3005099803
	Manufacturing Facility:	Boston Scientific Ireland Ltd. (BSIL) Ballybrit Business Park Galway, Ireland ERN: 9681260
Predicate Devices	WALLSTENT™ Biliary Endoprosthesis with Unistep Plus Delivery System (Since changed to "WALLSTENT™ Endoprosthesis Transhepatic Biliary") K993232 cleared September 24, 1999.	
Intended Use/ Indications for Use	The WALLSTENT™ RP Endoprosthesis Transhepatic Biliary and WALLSTENT™ Endoprosthesis Transhepatic Biliary are indicated for use in the treatment of biliary strictures produced by malignant neoplasms.	

Description of Device	The WALLSTENT™ RP Endoprosthesis Transhepatic Biliary and WALLSTENT™ Endoprosthesis Transhepatic Biliary are comprised of two components: The implantable metallic stent and the Unistep Plus delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (8 & 10mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035in (0.89mm) guidewire.
Comparison of Required Technological Characteristics	The proposed WALLSTENT™ RP Endoprosthesis Transhepatic Biliary and WALLSTENT™ Endoprosthesis Transhepatic Biliary is substantially equivalent to the existing WALLSTENT™ Biliary Endoprosthesis with Unistep Plus Delivery System cleared by FDA under premarket notification K993232 (September 24, 1999). WALLSTENT™ RP Endoprosthesis Transhepatic Biliary and WALLSTENT™ Endoprosthesis Transhepatic Biliary have the same intended use, scientific technology, design, sterilization method, and packaging as the applicable predicate device. The only difference is to the MR Safety labeling information within the Directions for Use. Bench testing in accordance with current FDA guidance supports a labeling as MR Conditional.
Summary of Non-Clinical Test Summary	Bench testing was performed in accordance with FDA guidance document *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* dated December 11, 2014) to support labeling as MR Conditional. 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 WALLSTENT™ RP Endoprosthesis Transhepatic Biliary and WALLSTENT™ Endoprosthesis Transhepatic Biliary has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the WALLSTENT™ Biliary Endoprosthesis with Unistep Plus Delivery System (K993232).