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

July 24, 2015

Boston Scientific
Ms. Anna Deraney
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K143193
Trade/Device Name: Symmetry and Symmetry Stiff Shaft Balloon Dilatation Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 5, 2015
Received: June 8, 2015

Dear Ms. 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 801and Part 809), 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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K143193

Device Name
Symmetry™ and Symmetry Stiff Shaft Balloon Dilatation Catheter

Indications for Use *(Describe)*
Symmetry™ and Symmetry Stiff Shaft Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty of narrowed or obstructed iliac, femoral or renal vessels in the peripheral vasculature.

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	Balloon Dilatation Catheter	
Trade Name(s)	Boston Scientific Symmetry™ and Symmetry Stiff Shaft Balloon Dilatation Catheter	
Product Code	LIT – Catheter, Angioplasty, Peripheral, Transluminal	
Classification of Device	Symmetry Balloon Dilatation catheters and accessories have been classified as Class II devices according to 21 CFR 870.1250 – Percutaneous Catheter.	
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
	Manufacturing Facility:	Boston Scientific Ireland Ltd. (BSIL) Ballybrit Business Park Galway, Ireland ERN: 9681260
	Sterilization Facilities:	Synergy Health Ireland Limited IDA Business & Technology Park Tullamore, County Offaly, Ireland
Predicate Devices	Symmetry Balloon Dilatation Catheter K060959 cleared April 12, 2006.	

Intended Use/ Indications for Use	Symmetry™ and Symmetry Stiff Shaft Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty of narrowed or obstructed iliac, femoral, or renal vessels in the peripheral vasculature.
Comparison of Required Technological Characteristics	The proposed Symmetry Balloon Dilatation Catheter is substantially equivalent to the existing Symmetry Balloon Dilatation Catheter cleared by FDA under premarket notification K060959 (April 12, 2006). Symmetry has the same intended use, scientific technology, design, materials (with the exception of the Pebax resin used in the shaft), sterilization method, and packaging materials as the applicable predicate device. The vendor is discontinuing the supply of the current Pebax resin, which is used in the shaft of the device; therefore a new resin is being supplied.
Summary of Non-Clinical Test Summary	Bench testing and biocompatibility testing 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 device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Symmetry Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Symmetry Balloon Dilatation Catheter (K060959).