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

December 4, 2015

Boston Scientific Corporation
Kurtis Hunsberger
Principal Regulatory Affairs Specialist, Interventional Cardiology
One Scimed Place
Maple Grove, MN 55311

Re: K152401
Trade/Device Name: Stingray LP Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 5, 2015
Received: November 6, 2015

Dear Kurtis Hunsberger:

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" (21CFR 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)*

K152401

Device Name
Stingray™ LP Catheter

Indications for Use *(Describe)*
The Stingray LP Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the coronary and peripheral vasculature.

When used as part of the system consisting of the CrossBoss™ Catheter, Stingray LP Catheter, and Stingray Guidewire, the Stingray LP Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311 Phone: 763-494-1700 Fax: 763-494-2222
Contact Name and Information	Kurtis Hunsberger Principal Regulatory Affairs Specialist Phone: 763-494-1204 Fax: 763-494-2222 e-mail: kurtis.hunsberger@bsci.com
Date Prepared	August 24, 2015
Proprietary Name	Stingray™ LP Catheter
Common Name	Percutaneous Catheter
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Device	BridgePoint Medical K102725 May 10, 2011 Stingray ™ Orienting Balloon Catheter
Device Description	The Stingray LP Catheter facilitates the placement, support and steering of a guidewire into discrete regions of the coronary and peripheral vasculature through the central guidewire lumen or through one of two side-ports. These side-ports are on opposite sides of the balloon and are identified by radiopaque markers. The side-ports communicate with the central guidewire lumen and facilitate guidewire steering (at an angle to the central lumen) by allowing the guidewire to exit the Stingray LP Catheter. The Stingray LP Catheter contains a small balloon used for fluoroscopic orientation on the distal tip of a flexible shaft. The distal end of the catheter is hydrophilic coated. The Stingray LP Catheter is compatible with 6F guide catheters with minimum inner diameter of 0.070 in (1.7 mm), and may be used with guidewires ≤0.014 in (0.36 mm).
Intended Use / Indications for Use	The Stingray LP Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the coronary and peripheral vasculature. When used as part of the system consisting of the CrossBoss™ Catheter, Stingray LP Catheter, and Stingray Guidewire, the Stingray LP Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention.

Comparison of Technological Characteristics

The Stingray™ LP Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Stingray™ Orienting Balloon Catheter K102725 cleared May 10, 2011. Similarities and differences in technological characteristics between the predicate and subject device are listed below.

Similarities:

- Polymer material construction
- Hydrophilic coating
- Radiopaque proximal markers
- Manifold and strain relief
- Identical balloon segment
- Ethylene Oxide sterilization
- Packaging design with same function

Differences:

- Shaft Outer Diameter: Stingray LP has a lower profile than the predicate Stingray.

Performance Data

The Stingray™ LP Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010. 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 testing; therefore, this device may be considered substantially equivalent to the predicate device.

The following biocompatibility and chemical characterization tests were completed on the Stingray™ LP Catheter:

Cytotoxicity	Hemolysis (Extract Method)
Sensitization	Partial Thromboplastin Time
Intracutaneous Reactivity	*In Vitro* Hemocompatibility
Acute Systemic Toxicity	Complement Activation
Materials Mediated Pyrogenicity	*In Vivo* Thromboresistance
Hemolysis (Direct Contact)	USP <661> Physicochemical

The following in-vitro performance tests were completed on the Stingray™ LP Catheter:

Effective Length	Inflation and Deflation Time
Shaft Outer Diameter	Full Unit Tensile
Crossing Profile	Distal Reflow Bond Yield Strength
Delivery	Kink – Proximal End
Catheter Torque / Guidewire Movement	Kink – Distal End of Gradient Outer
Guidewire Movement at Rated Burst Pressure	Kink – Distal End
Withdrawal into a Guide	Catheter Torque
Two Catheters in a 7F Guide	Marker Visibility
Rated Burst Pressure (RPB)	System Radiopacity
Balloon Burst Mode	Coating Integrity (Balloon and Shaft)
Repeat Inflation	Particulates (Sim Use)
Balloon Dimensional	Corrosion Resistance

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the Stingray™ LP Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Stingray™ Orienting Balloon Catheter.