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

June 5, 2015

Boston Scientific Corp.
Kurtis Hunsberger
Principal Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K150186
Trade/Device Name: Chariot Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 6, 2015
Received: May 7, 2015

Dear Mr. 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" (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,

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)*
K150186

Device Name
Chariot™ Guiding Sheath

Indications for Use *(Describe)*
The Chariot™ Guiding Sheath is intended for the introduction of interventional and diagnostic devices into 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.

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

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	April 23, 2015
Proprietary Name	Chariot™ Guiding Sheath
Common Name	Guiding Sheath
Product Code	DYB
Classification	Class II, 21 CFR Part 870.1340
Predicate Device	Terumo Pinnacle® Destination® Peripheral Guiding Sheath K091329 May 29, 2009
Device Description	The Chariot™ Guiding Sheath is designed to perform as an introducer sheath for delivering interventional and diagnostic devices into the peripheral vasculature. The guiding sheath has a coiled shaft design and comes with a straight (ST) or preformed multipurpose (MP) tip shape. It is equipped with a cross-cut hemostatic valve or Tuohy-Borst adapter to prevent bleeding and a sidearm with a three-way stopcock to allow for flushing and introduction of contrast medium. It is also packaged with a dilator to facilitate delivery over a guidewire. The guiding sheath can accommodate guidewires with diameters less than or equal to 0.038 in (0.97 mm). The outer surface of the guiding sheath has a hydrophilic coating from the distal tip to approximately 9 cm from the hub. The distal tip has a radiopaque marker band approximately 6 mm from the distal edge, to help with guiding sheath placement. A copolyester elastomer hub is over molded onto the proximal section of the guiding sheath. It incorporates a luer fitting which serves as a junction to the hemostatic valve.
Intended Use / Indications for Use	The Chariot™ Guiding Sheath is intended for the introduction of interventional and diagnostic devices into the peripheral vasculature.

Comparison of Technological Characteristics

The Chariot™ Guiding Sheath 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 Terumo Pinnacle® Destination® Peripheral Guiding Sheath K091329 cleared May 29, 2009. Similarities and differences in technological characteristics between the predicate and subject device are listed below.

Similarities:

- Polymer material construction
- Stainless steel coil
- PTFE inner liner material
- Hydrophilic coating
- Radiopaque marker
- Sheath dimensions
- Dilator, Tuohy-Borst Valve, and Cross-Cut Valve accessories
- Ethylene Oxide sterilization
- Packaging design with same function

Differences:

- Shaft color: Blue (Chariot); Green (predicate)
- Radiopaque marker material: Tantalum (Chariot); Gold (predicate)
- Maximum infusion pressure: 309 psi (Chariot); not labeled (predicate)

Performance Data

The Chariot™ Guiding Sheath 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 Chariot™ Guiding Sheath and its accessories:

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 Chariot™ Guiding Sheath:

Dilator Entry Profile	Valve Leakage
Sheath Length	Dye Flow Rate
Sheath Inner and Outer Diameter	Sheath Burst Pressure
Dilator Inner and Outer Diameter	Device Visual Appearance
Dilator Length	Radiopacity
Sheath Tensile	Sheath Kink Resistance
Sheath to Hub Tensile	Torque Strength
Dilator to Hub Tensile	Particulates
Sheath Tip Tensile	Coating Integrity
Hub Function and Luer Compatibility	

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the Chariot™ Guiding Sheath has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Terumo Pinnacle Destination Peripheral Guiding Sheath.