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 Senior Regulatory Affairs Specialist Phone: 763-255-0303 Fax: 763-494-2222 e-mail: kurtis.hunsberger@bsci.com
Date Prepared	June 26, 2014
Proprietary Name	Vessix™ Guide Sheath
Common Name	Guide Sheath
Product Code	DYB
Classification	Class II, 21 CFR Part 870.1340
Predicate Device	Terumo Destination Renal Guiding Sheath K081045 May 28, 2008
Device Description	Vessix™ Guide Sheath is a 7F guide sheath designed to perform as an introducer sheath and guide catheter for the introduction of interventional and diagnostic devices through the vasculature to the renal arteries. The Vessix Guide Sheath has been optimized for torque to allow access to both renal arteries during procedures. The guide sheath has an effective length of 45 cm and is available in two curve shapes: RDC (renal double curve) and LIMA (left internal mammary artery). The guide sheath has a braided shaft design to maximize torque response, and a pre-formed tip shape (either RDC or LIMA) to enable access. It is equipped with a Tuohy-Borst valve (hemostatic valve) to prevent bleeding and a sidearm with a three-way stopcock to allow for flushing and introduction of contrast media. It is also packaged with a dilator to help with delivery over a guidewire. The guide sheath can accommodate guidewires with diameters less than or equal to 0.038 in (0.97 mm). The distal 15 cm of the outer surface of the guide sheath has a hydrophilic coating (Bioslide™). The distal tip is radiopaque to help with placement. A polycarbonate hub is adhesively bonded to the proximal section of the guide sheath. It incorporates a luer fitting which serves as a junction to the hemostatic valve.
Intended Use / Indications for Use	The Vessix™ Guide Sheath is designed to be used for the introduction of interventional and diagnostic devices through the vasculature to the renal arteries.

Comparison of Technological Characteristics

The Vessix™ Guide 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 Destination Renal Guiding Sheath K081045 cleared May 28, 2008. Similarities and differences in technological characteristics between the predicate and subject device are listed below.

Similarities:

- Polymer material construction
- PTFE inner liner material
- Hydrophilic coating
- Sheath dimensions and shapes
- Dilator and Tuohy-Borst valve accessories
- Ethylene Oxide sterilization
- Packaging design with same function

Differences:

- Radiopaque extrusion (Vessix) versus radiopaque marker (predicate) for visibility
- Stainless steel braid (Vessix) versus stainless steel coil (predicate) to provide wall support

Performance Data

The Vessix™ Guide 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 and, therefore, this device may be considered substantially equivalent to the predicate device.

The following biocompatibility and chemical characterization tests were completed on the Vessix™ Guide 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

*This test was performed only on the Dilator accessory.

The following in-vitro performance tests were completed on the Vessix™ Guide Sheath:

Sheath Effective Length	Dye Flow Rate
Sheath Inner and Outer Diameter	Sheath Burst Pressure
Dilator Inner Diameter	Device Visual Appearance
Dilator Length	Radiopacity
Dilator to Sheath Compatibility (OD)	Sheath Kink Resistance
Sheath Tensile	Particulates
Sheath to Hub Tensile	Torque Strength
Dilator to Hub Tensile	Coating Integrity
Tuohy-Borst Valve Leakage	

Conclusion

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

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

July 3, 2014

Boston Scientific Corporation
Attention: Mr. Kurtis Hunsberger
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K140641
Trade/Device Name: Vessix™ Guide Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 5, 2014
Received: June 6, 2014

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" (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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Vessix™ Guide Sheath

Indications for Use:

The Vessix™ Guide Sheath is designed to be used for the introduction of interventional and diagnostic devices through the vasculature to the renal arteries.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)