510(k) Summary

per 21 CFR §807.92

OCT 17 2013

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Christopher Dachel Senior Regulatory Affairs Specialist Phone: 763-494-2718 Fax: 763-494-2222 e-mail: dachelc@bsci.com
Date Prepared	17 October 2013
Proprietary Name	Sterling™ Over-the-Wire™ (OTW) PTA Balloon Dilatation Catheter
Common Name	Percutaneous Catheter
Product Code	LIT – Catheter, Angioplasty, Peripheral, Transluminal
Classification	Class II, 21 CFR Part 870.1250 – Percutaneous Catheter
Predicate Device(s)	Sterling OTW PTA Balloon Dilatation Catheter, K053116, December 16, 2005
Device Description	The Sterling OTW Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is a high performance balloon catheter for peripheral indications. The device features an ultra low profile, semi-compliant balloon combined with a low profile tip. The catheter is compatible with either 0.014 in (.36 mm) or 0.018 in (.46 mm) guidewires. The Sterling OTW PTA Balloon Dilatation Catheter is an Over-The-Wire (OTW) catheter with a semi-compliant balloon fixed at the distal tip. The balloon catheter has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guide wires 0.014 in or 0.018 in (.36 mm or .46 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the stenosis. Two radiopaque marker bands (one proximal and one distal), in conjunction with fluoroscopy, enable accurate positioning of the balloon. The balloon lengths are available in 120, 150, 200 and 220 mm sizes with diameters of 5.0, 6.0 and 7.0 mm for each balloon length. The effective lengths of the balloon catheter are 90 cm and 150 cm. Markers on the 90 cm effective length catheter indicate the exit of the dilatation catheter tip out of the guiding catheter (one at 50 cm and two at 60 cm). Markers on the 150 cm effective length catheter indicate the exit of the dilatation catheter tip out of the guiding catheter (one at 90 cm and two at 100 cm). The proximal portion of the catheter includes one female Luer-lock port connected to the inflation lumen, and one female Luer-lock port for guidewire lumen.

Intended Use/ Indications for Use of Device	The Sterling OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Comparison of Technological Characteristics

The Sterling OTW PTA Balloon Dilatation Catheter will incorporate a substantially equivalent design, packaging, fundamental technology, materials, manufacturing, sterilization and intended use as those featured in the predicate BSC Sterling OTW Balloon Dilatation Catheter.

Comparison to Predicate Device in Materials and Manufacturing

Characteristic	Comparison to Sterling OTW Predicate
Manifold	Same material. Same design serving the same function.
Manifold Bond Adhesive	Same material. Same design serving the same function.
Strain Relief	Same material. Same design serving the same function.
Corewire	Same material. Same design serving the same function.
Outer Shaft	Same material. Same design serving the same function.
Inner Shaft	Same material. Same colorants. Same design serving the same function.
Balloon	Same material. Same design serving the same function and fundamental technology.
Markerbands	Same component serving the same function.
Proximal Marks	Same material. Same design serving the same function.
Coating	Same coating serving same function.
Bumper Tip	Same material. Same colorant. Same design serving the same function.
Sterilization Method	Same method
SAL	Same level of assurance
Balloon Diameters	Diameters within the predicate diameter range, service the same function.
Balloon Lengths	Additional balloon lengths; 120, 150, 200, and 220 mm
Usable Catheter Lengths	Additional catheter lengths; 90 and 150 cm
Rated Burst Pressure (RBP)	Same Rated Burst Pressure
Recommended Introducer Sheath Compatibility	Sheath compatibility within the predicate compatibility range, same function
Recommended Guidewire	Same compatability
Packaging	Same function and design

Performance Data

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. The Sterling OTW PTA Balloon Dilatation Catheter met all acceptance criteria for the bench and biocompatibility testing with results similar to the predicate. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

The following biocompatibility and bench testing were completed on the Sterling OTW PTA Balloon Dilatation Catheter:

Biocompatibility

The device was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). The testing included MEM Elution Cytotoxicity, Hemocompatibility (Direct Contact), Chemical Characterization-USP Physicochemical, and Natural Rubber Latex

The following in-vitro performance tests were completed on the Sterling OTW PTA Balloon Dilatation Catheter:

Bench

Bond Integrity	Balloon Burst Mode
Working Length	Balloon Compliance
Deflation Time	Balloon Nominal Diameter
Balloon Rated Burst Pressure (RBP)	Burst in a Stent
Balloon Multiple Inflation	Balloon Body Length
Crossing Profile	Guidewire Movement
Full Catheter Tensile Extension and Deflation	Sheath Withdrawal
Balloon Multiple Inflation in a Stent	Marker Band to Balloon Alignment
Particulate Evaluation	Torque after Conditioning
Proximal Balloon Bond and Shaft Tensile Strength	

Conclusion

Based on the Indications for Use, technological characteristics, safety and performance testing, the Sterling OTW PTA Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Sterling OTW PTA Balloon Dilatation Catheter (K053116 cleared December 16, 2005).

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

October 17, 2013

Boston Scientific Corporation
Mr. Christopher Dachel
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K132430
Trade/Device Name: Sterling™ Over-the-Wire™ (OTW) PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: August 22, 2013
Received: August 23, 2013

Dear Mr. Dachel:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman -S

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): K132430

Device Name: **Sterling™** Over-the-Wire™ (OTW) PTA Balloon Dilatation Catheter

Indications for Use:

The Sterling OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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