K093720

510(k) Summary

Submitter: Boston Scientific Corporation
One Scimed Place Maple Grove, MN 55311

DEC 23 2009

Contact Person: Mark Murphy
Phone Number: 763-494-2377
Fax Number: 763-494-2981
Date Prepared: November 25, 2009
Device Trade Name: Sterling SL Monorail and OTW PTA Balloon Dilatation Catheters
Common Name: Percutaneous Transluminal Angioplasty Dilatation Catheter
Device Classification: Class II 21 CFR 870.1250 Product Code: LIT

Predicate Devices
Sterling ES PTA Balloon Dilatation Catheters, Sterling Monorail and OTW PTA Balloon Dilatation Catheters and Polarcath Peripheral Dilatation System.

Device Description
The Sterling SL PTA Balloon Dilatation Catheters has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires 0.014 in (0.36 mm) or 0.018 in (0.46 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. The working lengths of the balloon catheter are 90 cm and 150 cm.

Indications for Use
The Sterling SL PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, infrapopliteal, popliteal, renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Substantial Equivalence
The Sterling SL PTA Balloon Dilatation Catheters line extension design, materials, manufacturing process and intended use are substantially equivalent to predicate devices Sterling ES (K080982), Sterling Monorail (K053118), Sterling OTW (K053116)

Performance Data
The substantial equivalence of the modified Sterling PTA Balloon Dilatation Catheters is demonstrated with design control activities and bench testing on file at Boston Scientific.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o Mark Murphy
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

DEC 23 2009

Re: K093720
Trade/Device Name: Sterling SL Monorail and Over-the-Wire Dilatation Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT, DQY
Dated: December 1, 2009
Received: December 2, 2009

Dear Mr. Murphy:

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.

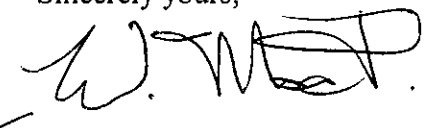
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,



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

Enclosure

Indications for Use Statement

510(k) Number (if known) K093720

Device Name **Sterling SL MR & OTW PTA Balloon Dilatation Catheters**

Indications for Use Sterling SL PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, infrapopliteal, popliteal, renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **(Per 21 CFR 801.109** **OR** **Over-The-Counter Use**____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093720