510(k) Summary
per 21 CFR §807.92

JUL 14 2008

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Mark Murphy Sr. Regulatory Affairs Specialist Phone: 763-494-2377 Fax: 763-494-2981 e-mail: mark.murphy2@bsci.com
Date Prepared	April 4, 2008
Proprietary Name(s)	Sterling™ ES MR and OTW PTA Balloon Dilatation Catheters
Common Name	PTA Balloon Dilatation Catheter
Product Code	LIT
Classification of Device	Class II, 21 CFR Part 870.1250
Predicate Device	Sterling OTW PTA Balloon Dilatation Catheter — K053116 — December 16, 2005
Device Description	The Sterling ES PTA Balloon Dilatation Catheters consist of a Monorail and an Over-The-Wire 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 0.014 in (0.39 mm) guide wires 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. Two radiopaque marker bands (one proximal and one distal), in conjunction with fluoroscopy, enable accurate positioning of the balloon. The working lengths of the balloon catheters are 143 cm.

Intended Use of Device	The Sterling ES MR and OTW PTA Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.00 mm – 4.00 mm balloon devices are also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.
Comparison of Technological Characteristics	The Sterling ES MR and OTW catheters incorporate a substantially equivalent design, packaging, fundamental technology, manufacturing, sterilization and intended use as those featured in the predicate BSC Sterling OTW PTA Balloon Dilatation Catheter.
Support of Substantial Equivalence	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 identified during device testing.
Conclusion	Based on the Indications for Use, technological characteristics, safety and performance testing, the Sterling ES MR and OTW PTA Balloon Dilatation Catheters have 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
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2008

Boston Scientific Corp.
c/o Mr. Mark Murphy
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K080982
Trade Name: Sterling ES Monorail and Over-The-Wire PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: June 25, 2008
Received: June 26, 2008

Dear Mr. Murphy:

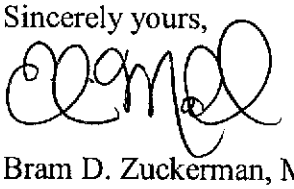
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. 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)	K080982
Device Name	Sterling™ ES Monorail™ and Over-the-Wire PTA Balloon Dilatation Catheters
Indications For Use	The Sterling ES MR and OTW PTA Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, iliofemoral, popliteal, infrapopliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.00 mm – 4.00 mm balloon devices are also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Prescription Use: ___X___ OR Over-The-Counter Use: _____
(Per 21 CFR §801 Subpart D) *(21 CFR 807 Subpart C)*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080982