DEC 16 2005

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311
Contact Name and Information	Maureen Montbriand Specialist, Regulatory Affairs Phone: 763-494-2903 Fax: 763-494-2981 e-mail: montbrim@bsci.com
Date Prepared	November 4, 2005
Proprietary Name(s)	Sterling™ Monorail™ PTA Balloon Dilatation Catheter
Common Name	PTA Balloon Dilatation Catheter
Product Code	DQY
Classification of Device	Class II, 21 CFR Part 870.1250
Predicate Device	Ultra-soft™ SV Balloon Dilatation Catheter — K050389 — May 25, 2005
Device Description	The Sterling™ Monorail™ PTA Balloon Dilatation Catheter is a Monorail brand rapid exchange 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 guidewires 0.014 in / 0.018 in (0.36 mm/ 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 to and through the stenosis. Two radiopaque marker bands, in conjunction with fluoroscopy, enable accurate positioning of the balloon. The working lengths of the balloon catheter are 80 cm and 135 cm. A needle with a luer port is included for flushing the distal inner lumen prior to the insertion of appropriate guidewires.

Intended Use of Device	The Sterling™ Monorail™ PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, renal, and carotid 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™ Monorail™ catheter will incorporate a substantially equivalent design, packaging, fundamental technology, manufacturing, sterilization and intended use as those featured in the predicate BSC Ultra-soft SV 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 raised during the testing regimen.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the Sterling™ Monorail™ PTA Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Ultra-soft SV Balloon Dilatation Catheter (K050389; cleared May 25, 2005).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Boston Scientific Corporattion
c/o Ms. Maureen Montbriand
Regulatory Affairs Specialist
Two Scimed Place
Maple Grove, MN 56311-1566

Re: K053118
Sterling™ Monorail™ PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: November 4, 2005
Received: November 7, 2005

Dear Ms. Montibriand:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmes

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

K053118

510(k) Number (if known)

Device Name Sterling™ Monorail™ PTA Balloon Dilatation Catheter

Indications For Use

The Sterling™ Monorail™ PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, renal, and carotid 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
(Per 21 CFR §801 Subpart D)

OR

Over-The-Counter Use: _____
(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)

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053118