K060959

APR 12 2006

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	Angela Byland Manager, Regulatory Affairs Phone: (763) 494-2887 Fax: (763) 494-2981
Date Prepared	April 6, 2006
Proprietary Name(s)	Symmetry Balloon Dilatation Catheter
Common Name	Balloon Dilatation Catheter
Product Code	LIT
Classification of Device	Class II, 21 CFR Part 870.1250
Predicate Device	Symmetry Balloon Dilatation Catheter — K953602 — October 18, 1995
Device Description	The Symmetry Balloon Dilatation Catheter is an over-the-wire catheter offered in a three lumen catheter shaft design. One lumen, marked "distal", is the central lumen of the catheter which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire. The Symmetry device is designed to be placed over guidewires which have outer diameters of 0.018" or smaller. The lumen marked "balloon" is comprised of two smaller, separate lumens which both communicate with the balloon at one end and terminate in a single balloon hub and lead tube at the proximal end of the device. The Symmetry device is offered in both standard and stiff shaft versions.
Intended Use of Device	Symmetry and Symmetry Stiff Shaft Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty of small, narrowed or obstructed iliac, femoral, or renal vessels in the peripheral vasculature.

Comparison of Technological Characteristics	The materials and design of the Symmetry balloon dilatation catheter are equivalent to the predicate Symmetry Balloon dilatation catheter.
Support of Substantial Equivalence	Boston Scientific Corporation considers the proposed Symmetry Balloon Dilatation Catheter to be substantially equivalent to the existing Symmetry Balloon Dilatation Catheter (K953602 cleared October 18, 1995). This assessment is based upon identical device materials and design characteristics and the only change being initiated is to add a single warning to the Directions for Use.
Conclusion	Based on the indications for use and the technological characteristics, the Symmetry Balloon Dilatation Catheter has been shown to be equivalent in intended use and is considered to be substantially equivalent to the Symmetry Balloon Dilatation Catheter (K000798; cleared October 18, 1995).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2006

Boston Scientific Corporation
c/o Ms. Angela Byland
Manager, Regulatory Affairs
Two Scimed Place
Maple Grove, MN 55311-1566

Re: K060959
Symmetry Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Angioplasty, Peripheral, Transluminal
Regulatory Class: Class II
Product Code: LIT
Dated: April 6, 2006
Received: April 7, 2006

Dear Ms. Byland:

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,

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: _____

Device Name: Symmetry Balloon Dilatation Catheter

Indications for Use:

Symmetry and Symmetry Stiff Shaft Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty of small, narrowed or obstructed iliac, femoral, or renal vessels in the peripheral vasculature.

Prescription Use ___X____ AND/OR Over-the-Counter Use _____
(part 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 K060959