APR 12 2006

K060960

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	Sara L. Coon Senior Specialist, Regulatory Affairs Phone: 763-494-1500 Fax: 763-494-2981
Date Prepared	April 6, 2006
Proprietary Name(s)	Boston Scientific Talon Balloon Dilatation Catheter
Common Name	Balloon Dilatation Catheter
Product Code	LIT
Classification of Device	Class II, 21 CFR Part 870.1250
Predicate Device	Talon Balloon Dilatation Catheter — K000798 — June 8, 2000
Device Description	The Talon Balloon Dilatation Catheter is an over-the-wire catheter offered in a two lumen catheter shaft design. One lumen is used to pass the catheter over a guidewire. The device is designed to be placed over guidewires which have outer diameters of 0.018" or smaller. The second lumen communicates with the balloon and is used to inflate and deflate the balloon during the procedure. The guidewire lumen and the balloon lumen terminate at the proximal end of the catheter by means of a bifurcated hub with luer lock fittings. The device is offered in two lengths of 90 cm and 135 cm. The shaft tapers proximally from 4.0 Fr to a distal 3.4 Fr. A non-compliant balloon is bonded to the distal tip of the catheter, which inflates to a known diameter and length at a specific pressure. The balloon is offered in diameters of 4.0 mm, 5.0 mm, 6.0 mm, and 7.0 mm and is available in lengths of 15 mm, 20 mm and 40 mm. The balloon is designed to exhibit controlled compliance, high rated burst pressure, and safe failure modes (longitudinal tearing).

Device Description, continued	Two radiopaque markerbands are located under the effective dilatation area of the balloon, one at the proximal transition area and the other at the distal transition area. These markerbands enable accurate positioning of the balloon in the stenosis. Proximally the balloon lumen ends in a female luer fitting for attachment of a manometer and inflation device. Each catheter is shipped with a wing-folding tool in place over the balloon. It is designed to protect the balloon and to hold it tightly during shipping and prior to use.
Intended Use of Device	The Boston Scientific Talon Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) of the iliac, femoral, ilio-femoral, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Comparison of Technological Characteristics	The materials and design of the Talon balloon dilatation catheter are equivalent to the predicate Talon Balloon dilatation catheter.
Support of Substantial Equivalence	Boston Scientific Corporation considers the proposed Talon Balloon Dilatation Catheter to be substantially equivalent to the existing Talon Balloon Dilatation Catheter (K000798 cleared June 8, 2000). 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 Talon Balloon Dilatation Catheter has been shown to be equivalent in intended use and is considered to be substantially equivalent to the Talon Balloon Dilatation Catheter (K000798; cleared June 8, 2000).

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: K060960
Talon 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: Boston Scientific Talon Balloon Dilatation Catheter

Indications for Use:

The Boston Scientific Talon Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) of the iliac, femoral, ilio-femoral, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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

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