K071042

ATTACHMENT 4

JUN 13 2007

510(k) Summary

per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Monica Morrison Regulatory Affairs Phone: (763) 494-2676 Fax: (763) 494-2981 Email: morrisom@bsci.com
Date Prepared	April 11, 2007
Proprietary Name(s)	PolarCath™ Peripheral Dilatation System
Common Name	Percutaneous Transluminal Angioplasty Catheter
Product Code	LIT/DQY
Classification of Device	Class II, 21 CFR Part 870.1250
Predicate Device	PolarCath™ Peripheral Dilatation System K062594 September 28, 2006
Device Description	The PolarCath™ Peripheral Dilatation System consists of a Catheter, Inflation Unit, connecting cable and a rechargeable battery pack with recharging unit and battery receptacle. The inflation medium (liquid nitrous oxide) is provided in a disposable 14 gram cartridge.
Intended Use of Device	The PolarCath™ Peripheral Dilatation System is indicated to dilate stenoses in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene (PTFE) access grafts or arteriovenous dialysis fistulae. The PolarCath™ Peripheral Dilatation System is also indicated for post-deployed stent expansion of self-expanding peripheral vascular stents.

Comparison of Technological Characteristics	The proposed changes to the PolarCath™ Peripheral Dilatation System apply only to the circuit board within the Inflation Unit. These changes include the addition of resistors, fuses, capacitors, a voltage suppressor and an update to the circuit board layout. There are no changes to the other materials or design elements of this product as compared to the currently cleared PolarCath™ Peripheral Dilatation System.
Support of Substantial Equivalence	Boston Scientific Corporation considers the proposed PolarCath™ Peripheral Dilatation System to be substantially equivalent to the existing PolarCath™ Peripheral Dilatation System (K062594, Cleared September 28, 2006). This assessment is based upon the successful completion of verification testing (refer to **Section 5.2** and **Attachment 3**) which assessed the function of inflation units and their circuitry through 12 sequential runs, or inflations, of the balloon. In addition, there have been no changes to the overall design, function, material, intended use, labeling, or directions for use of the PolarCath™ Peripheral Dilatation System. The changes only affect the Inflation Unit circuit board and have been proven not to adversely affect the function of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2007

Boston Scientific Corp.
c/o Ms. Monica Morrison
Regulatory Affiars
One Scimed Place
Maple Grove, MN 55311

Re: K071042
PolarCath™ Peripheral Dilation System
Regulation Number: 21 CFR 870.1250
Regulation Name: Peripheral Dilation Catheter
Regulatory Class: Class II
Product Code: LIT/DQY
Dated: April 16, 2007
Received: May 29, 2007

Dear Ms. Morrison:

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 (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
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Indications for Use Statement

510(k) Number: K071042

Device Name: PolarCath™ Peripheral Dilatation System

Indications for Use:

The PolarCath™ Peripheral Dilatation System is indicated to dilate stenoses in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene (PTFE) access grafts or arteriovenous dialysis fistulae. The PolarCath™ Peripheral Dilatation System is also indicated for post-deployed stent expansion of self-expanding peripheral vascular stents.

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 K071042