K033441

NOV 2 1 2003

Section 6 Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

6.1 General Provisions

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Person	Heidi M. Erickson Phone: 763-494-2564 Fax: 763-494-2981 email: ericksoh@bsci.com
Classification of Device	Class II, 21CFR Part 870.1200 Similar to Diagnostic IntravascularCatheters
Common or Usual Name	Coronary or Peripheral Guide Catheter
Proprietary Name	Boston Scientific 6F RunWay Guide Catheter
Product Code	DQY
Date Prepared	October 28, 2003

6.2 Name of Predicate Device

6F Mach1 Guide Catheter
K010874, June 21, 2001

6.3 Device Description

The Boston Scientific 6F RunWay Guide Catheters are similar to the currently marketed 6F Mach1 Guide Catheter, with the addition of Vestodur to the shaft for added strength, a different blend of Hytrel in the tip, a different colorant used in the shaft, and a different braid pattern using thirty-two 0.001" stainless steel wires, eight 0.002" Stainless Steel wires, and eight 0.002" Tungsten wires to strengthen the catheter for better backup support.

Section 6 Summary of Safety and Effectiveness

The Boston Scientific RunWay Guide Catheters are designed to provide a pathway through which medical instruments such as balloon dilatation catheters, guide wires or other diagnostic or therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature. The RunWay catheters will be offered in a 6F outer diameter, available in lengths ranging from 40-125 cm, with optional side holes. The devices are provided sterile and intended for one procedure use only.

The RunWay catheters are manufactured using similar construction techniques as other currently marketed Boston Scientific guide catheters. The catheter shaft consists of three layers: inner, middle, and outer. The outer layer is composed of three segments.

The outer layer segments one and two consist of various durometers of Arnitel. Segment three is a blend of Vestodur 3000 and Arnitel. Vestodur is added to the shaft to strengthen the catheter. The use of varying durometers of Arnitel provides specific flexibility zones at the distal end of the catheter. The tip consists of a reinforced portion and a non-reinforced portion.

6.4 Intended Use

Boston Scientific Guide Catheters are intended for use in general intravascular, coronary and peripheral applications. They provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature.

6.5 Summary of Technological Characteristics

The 6F RunWay Guide Catheter utilizes similar materials and methods of construction as the currently marketed 6F Mach1 guide catheter, cleared for market under K010874, June 21, 2001. The differences in construction are in the braid pattern of the shaft, shaft colorant, shaft material, and the distal tip blend.

6.6 Non-clinical Test Summary

Testing and evaluation of the 6F RunWay Guide Catheter consisted of shaft and distal segment tensile and elongation, tip tensile, tip deflection, hub to shaft tensile, pressure shaft burst and leak, torque response, lumen integrity and radiopacity. Biocompatibility, package pouch burst, and product shelf life testing have also been conducted. Test results verified that the 6F RunWay Guide Catheters are adequate for the intended use. The 6F RunWay guide catheters are considered substantially equivalent to the currently marketed 6F Mach1 Guide Catheters based on a comparison of the intended use, the device design, and the results of *in-vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2003

Boston Scientific Corporation
c/o Ms. Heidi M. Erickson
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K033441
6F Run Way Guide Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 28, 2003
Received: October 29, 2003

Dear Ms. Erickson:

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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 — Indications for Use

510(k) Number (if known) K033441

Device Name: 6F RunWay Guide Catheter

Indications for Use:

Boston Scientific Guide Catheters are intended for use in general intravascular and coronary applications. They provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use
(Per 21 CFR 801.109) 11/2/05

Division of Cardiovascular & Respiratory Devices
510(k) Number K033441
11/2/05