APR 1 0 2000

K993305

ATTACHMENT H

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed SC 35 Balloon Dilatation Catheter is as follows:

Trade Name: SC 35 Balloon Dilatation Catheter

Manufacturer: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Device Generic Name: Balloon Dilatation Catheter

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices:

The following devices are referenced in this premarket notification as predicate devices for the SC 35 Balloon Dilatation Catheter:

Boston Scientific Corporation – Ultra-thin Diamond™ Balloon Dilatation Catheter
Boston Scientific Corporation – Courier ST™ Balloon Dilatation Catheter

All of the devices mentioned above have been determined substantially equivalent by FDA.

Device Description:

The proposed SC 35 Balloon Dilatation catheter is an over-the-wire catheter indicated for percutaneous transluminal angioplasty of the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, renal arteries and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The proposed device is designed to be placed over guidewires which have outer diameters of .035" or smaller.

Indications for Use:

The SC 35 Balloon Dilatation Catheter is indicated for PTA of the iliac, femoral, ilio-femoral, popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Safety and Performance:

The following in vitro functional tests were performed on the SC 35 Balloon Dilatation Catheter:

- Balloon Burst Testing
- Multiple Inflation Testing
- Inflation/Deflation Time Testing
- Balloon Compliance Testing
- Balloon Proximal Bond Testing
- Sheath Withdrawal Testing
- Wingfolded Balloon Profile Testing
- Coating Coefficient of Friction Testing
- Particulate Analysis Testing
- Solvent Residual Testing

The following biocompatibility tests were performed:

- Cytotoxicity
- Hemolysis
- Acute Intracutaneous Reactivity
- Acute Systemic Toxicity
- Sensitization
- Pyrogenicity

Conclusion:

Based on the Indication for Use, technological characteristics and safety and performance testing, the SC 35 Balloon Dilatation Catheter has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2000

Ms. Terry A. McGovern
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K993305
Semi Compliant (SC) 35 Balloon Dilatation Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: January 12, 2000
Received: January 18, 2000

Dear Ms. McGovern:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): New Application

Device Name: Semi-Compliant 35 Balloon Dilatation Catheter

Indications for Use: The Semi-Compliant 35 Balloon Dilitation Catheter is indicated for percutaneous transluminal angioplasty of the iliac, femoral, ilio-femoral, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christopher Yoh for Dillard

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993305

Prescription Use X OR Over-The-Counter Use
(Per 21 CRF 801.109)

(Optional Format 1-2-96)