K011909

ATTACHMENT H

NOV 2 8 2001

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 Ultra-Thin SDS Balloon Dilatation Catheter is as follows:

Trade Name: Ultra-Thin SDS Balloon Dilatation Catheter

Manufacturer: Boston Scientific Corporation
Ballybrit Business Park
Galway, Ireland

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 device is referenced in this premarket notification as the predicate device for the Ultra-Thin SDS Balloon Dilatation Catheter:

Boston Scientific Corporation -- Marshal Balloon Dilatation Catheter (K973008)

The device mentioned above has been determined substantially equivalent by FDA.

Ultra-Thin SDS Balloon Dilatation Catheter

June 14, 2001

K011909

Device Description: The proposed Ultra-Thin SDS Balloon Dilatation Catheter is an over-the-wire catheter designed to be placed over guidewires which have outer diameters of .035" or smaller.

Indications for Use: Ultra-Thin SDS Balloon Dilatation Catheters are indicated for stent deployement/optimization of the J&J Palmaz® Biliary Stent and for the treatment of obstructive lesions of biliary strictures.

Safety and Performance: Functional and integrity bench testing and biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memorandum #G95-1, May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" were performed, and the data supported the substantial equivalence of the Ultra-Thin SDS Balloon Dilatation Catheter to the Marshal Balloon Dilatation Catheter.

Conclusion: Based on the Indication for Use, technological characteristics and safety and performance testing, the Ultra-Thin SDS 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

NOV 2 8 2001

Ms. Jennifer Bolton, RAC
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K011909
Trade/Device Name: Ultra-Thin SDS Balloon Dilatation Catheter for the Deployment/Optimization of the Johnson & Johnson Palmaz® Biliary Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: Class II
Product Code: FGE 78
Dated: October 2, 2001
Received: October 3, 2001

Dear Ms. Bolton:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~New Application~~ K011909

Device Name: Ultra-Thin SDS Balloon Dilatation Catheter

Indications for Use:

Ultra-Thin SDS Balloon Dilatation Catheters are indicated for stent deployent/optimization of the Johnson & Johnson Palmaz® Biliary Stent and for the treatment of biliary strictures.

(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)

David C. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011909