K971165

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and cosmetic Act, Boston Scientific Corporation submits this summary of safety and effectiveness.

A. GENERAL INFORMATION

Owner Operator Submitting this Premarket Notification:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01757 (508) 650.8174
Contact Person:	Wanda M. Carpinella Regulatory Affairs Department
Device Generic Name:	Introuducer Sheath and Dilator
Device Classification:	74 DYB, Catheter, Introducer

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B. INDICATIONS FOR USE

The introducer sheath and dilator are intended to be used in percutaneous access for the purpose of facilitating catheter placement by allowing multiple catheter and/or guidewire exchanges.

C. DESCRIPTIVE CHARACTERISTICS

The introducer set consists of a tapered dilator with a slightly shorter sheath that splits for removal after catheter placement. The sheath is peeled away from the catheter by breaking the handle at the hub.

D. SUBSTANTIAL EQUIVALENCE

The proposed introducer dilator has been shown to be substantially equivalent to Cook's Peel-Away® Introducers and to B. Braun's Tearaway Introducer.

E. PACKAGING, STERILIZATION, AND PYROGENICITY

The introducer sheath and dilator is packaged in a heat-sealed Tyvek/mylar pouch. The product is sterilized using either ethylene oxide gas or gamma radiation . Bacterial endotoxin levels are monitored for sterility release purposes.

F. CONCLUSION

Based on the information presented, Boston Scientific Corporation believes that the proposed introducer sheath and dilator meets the minimum requirements that are considered acceptable for its intended use and is substantially equivalent to other currently marketed introducer sheath and dilators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Wanda M. Carpinella
Project Manager, Regulatory Affairs
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

JUL 23 1997

Re: K971165
Introducer Sheath and Dilator
Regulatory Class: II (two)
Product Code: LDF
Dated: July 9, 1997
Received: July 10, 1997

Dear Ms. Carpinella:

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 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 requirement, 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Device Name: Introducer Sheath and Dilator

Indications for Use: The Introducer Sheath and Dilator is used for percutaneous introduction of catheters and guide wires.

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

Concurrence of CDRH, Office of Device Evaluaiton (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K971165

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

(Optional Format 1-2-96)