

K974640

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 Boston Scientific Corporation
this Premarket Notification: One Boston Scientific Place
Natick, MA 01757
(508) 650.8174

MAR 13 1998

Contact Person: Wanda M. Carpinella
Regulatory Affairs Department

Device Generic Name: Coaxial Dilator
Device Classification: 74 DRE, Dilator, Vessel for Percutaneous Catheterization

B. INDICATIONS FOR USE

The coaxial dilator is used for percutaneous introduction of 0.035 inch or 0.038 inch guide wires into the vascular system following a small 21 Ga. needle stick.

C. DESCRIPTIVE CHARACTERISTICS

The coaxial dilator set consists of an inner, tapered dilator with a slightly shorter outer dilator.

D. SUBSTANTIAL EQUIVALENCE

The proposed coaxial dilator set has been shown to be substantially equivalent to the coaxial dilator provided in Cook's Micropuncture Introducer Set and to Boston Scientific's peelable sheath and dilator.

E. PACKAGING, STERILIZATION, AND PYROGENICITY

The coaxial dilator set is packaged in a heat-sealed Tyvek/mylar pouch. The product is sterilized using ethylene oxide gas. Bacterial endotoxin levels are monitored for sterility release purposes.

F. CONCLUSION

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 1998

Ms. Wanda M. Carpinella
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K974640
Coaxial Dilator Set
Regulatory Class: II (two)
Product Code: 74 DRE
Dated: December 11, 1997
Received: December 15, 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.

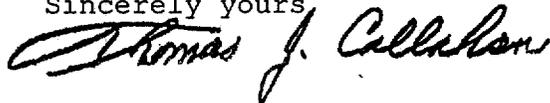
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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: Coaxial Dilator Set

Indications for Use: The coaxial dilator set is used for percutaneous introduction of 0.035 inch or 0.038 inch guide wires into the vascular system following a 21 Ga. needle stick.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K974640

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)