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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 choose 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 **BD-3 Catheters** is as follows:

Sponsor:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760-1537
Contact Person:	Linda S. Pollitz Senior Regulatory Affairs Specialist or Lorraine M. Hanley Manager, Regulatory Affairs
Submission Date:	February 24, 1998
Common/Usual Names:	Urological Balloon Dilatation Catheter
Trade/Proprietary Name:	To Be Determined
Device Classification and Name:	According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards Product Code: 78 EZN and 78 KOE
Substantial Equivalence:	The proposed modified devices are *Substantially Equivalent* to devices previously cleared by the FDA via the 510(k) Notification process and indicated for dilatation of the urinary tract.
Performance:	The proposed modified device is *Substantially Equivalent* to the predicate devices in terms of performance characteristics tested.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 1998

Ms. Linda S. Pollitz
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K980795
BD-3 Urological Balloon Dilatation Catheters
Dated: February 27, 1998
Received: March 2, 1998
Regulatory class: II
21 CFR §876.5470/Product code 78 EZN
21 CFR §876.5520/Product code 78 KOE

Dear Ms. Pollitz:

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) 594-4613. 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,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980795 ~~New Application~~

Device Name: To Be Determined

Indications For Use:

BD-3 Catheters are intended for urological dilatation; ureteral and urethral.

(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)

Robert D Nathing
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980795