Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

K974541 p1of1

SECTION VIII
510)K) SUMMARY

FEB -9 1998

510 (k) Summary Of Safety And Effectiveness

Sponsor:	Boston Scientific Corporation One Scientific Place Natick, MA 01760-1537
Contact Person:	Lorraine M. Hanley Manager, Regulatory Affairs or Terry Myers Regulatory Affairs Associate
Submission Date:	November 26, 1997
Common/Usual Names:	Modified Ureteral Stent
Trade/Proprietary Name:	To Be Determined
Device Classification and Name:	According to CFR 21 Part 876, Section 4620 the Ureteral Stent is a Class II device. Product Code: 78FAD
Substantial Equivalence:	The proposed modified device is *Substantially Equivalent* to devices previously cleared by the FDA via the 510(k) Notification process and indicated for use as a Ureteral Catheter to provide drainage from the kidney to the bladder.
Performance:	The proposed modified device is *Substantially Equivalent* to the predicate devices in terms of performance characteristics tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1998

Ms Terry Myers
Regulatory Affairs
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K974541
Modified Ureteral Stents
Dated: January 22, 1998
Received: January 26, 1998
Regulatory class: II
21 CFR §876.4620/Product code 78 FAD

Dear Ms. Myers:

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

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

SECTION I
INDICATIONS FOR USE

510(k) Number (if known): K974541

Device Name:

Modified Ureteral Indwelling Catheter/Stent

Indications For Use:

The Modified Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement transurethrally, percutaneously, or via open surgery by a trained physician.

(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)

Robert D. Falkenberg
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974541

(Optional Format 1-2-96)