MAR 1 7 2003

510 (k) SUMMARY

K030503

SPONSOR:

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

CONTACT PERSON:

Donna M. Gardner
Senior Regulatory Affairs Specialist

Or

Lorraine M. Hanley
Director Regulatory Affairs

DEVICE:

Trade Name: To Be Determined
Common Name: Ureteral Stent
Classification: Class II, per 21 CFR Part 876.4620

PREDICATE DEVICE: Contour Polaris Ureteral Stent (K010002)

DESCRIPTION: The Loop Tail Ureteral Stent is a dual durometer ureteral stent with a renal pigtail and a bladder loop configuration. A "long" and "short" loop version will be available, in sizes 5, 6, 7, and 8 Fr., and lengths ranging from 10cm to 30cm.

INTENDED USE: The Loop Tail Ureteral Stent is intended to facilitate drainage from the kidney to the bladder.

TECHNOLOGICAL CHARACTERISTICS: The intended use and the materials are identical to the predicate device. The proposed device is designed with a bladder loop configuration, whereas the predicate device has a bladder pigtail.

PERFORMANCE DATA: FDA's "Guidance for the Content of Premarket Notifications for Ureteral Stents", and the results of physical comparison and functional testing support a determination of substantial equivalence for the proposed device when compared to the predicate device. The proposed device is substantially equivalent to currently marketed ureteral stent devices in terms of performance characteristics, biocompatibility, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Donna M. Gardner
Senior Regulatory Affairs Specialist
Microvasive Urology
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

MAR 17 2003

Re: K030503
Trade/Device Name: Contour Polaris Ureteral Stent
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: 78 FAD
Dated: February 14, 2003
Received: February 19, 2003

Dear Ms. Gardner:

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

INDICATIONS FOR USE STATEMENT K030503

510(k) Number	~~To be determined~~ K030503
Device Name	To be determined (Ureteral Stent)
Indications For Use	The Loop Tail Ureteral Stent is intended to facilitate drainage from the kidney to the bladder.

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)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030503