

JUL 13 2001

Special 510(k) Premarket Notification
Imager™ II Urology Torque Catheter
June 22, 2001

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

K011965
PG. 1 OF 1

Appendix C: Regulatory Submission Summary (510k Summary)

Submission Summary (per 21 CFR 808.92)

SPONSOR: Boston Scientific Corporation (BSC)
Microvasive Urology
One Scientific Place
Natick, MA 01760-1537

CONTACT PERSON: Lorraine M. Hanley, RAC
Director, Global Regulatory Affairs
Boston Scientific / Microvasive
or
Robert J. Michalik, RAC
Principal Specialist, Global Regulatory Affairs
Boston Scientific / Microvasive

SUBMISSION DATE: June 22, 2001

TRADE/PROPRIETARY NAME: Imager II™ Urology Torque Catheter

COMMON/USUAL NAMES: Urological Catheter

PROCEDURE: 78 KOD

CLASSIFICATION CODE: CFR 876.5130

CLASS NAME: Urological Catheters and Accessories, Class II

INTENDED USE: The Imager™ II Urology Torque Catheter is indicated for use in facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the infusion of radiopaque contrast material.

DESCRIPTION OF DEVICE: The Imager™ II Urology Torque Catheter is a single-lumen urological catheter comprised of a flexible tip bonded to the distal end of a reinforced, torqueable. A luer lock hub is attached to the proximal end of the shaft. The catheter is supplied in a variety of standard lengths and with an array of tip styles commonly used in urological procedures.

SUBSTANTIAL EQUIVALENCE: The proposed device is *substantially equivalent* to other urological catheters classified under 21 CFR 876.5130, more specifically with Boston Scientific Corporation's Imager Torque Catheter (K965229). The substantial equivalence determination is based upon test results that confirm the proposed device is biocompatible and substantially similar to the legally marketed predicate device in terms of material composition and performance parameters.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Robert J. Michalik, RAC
Principal Specialist, Global Regulatory Affairs
Boston Scientific Corporation
Microvasive Urology
One Boston Scientific Place
NATICK MA 01760-1537

Re: K011965
Imager™ II Urology Torque Catheter
Dated: June 22, 2001
Received: June 25, 2001
Regulatory Class: II
21 CFR §876.5130/Procode: 78 KOD

Dear Mr. Michalik:

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 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). 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 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.

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) 594-4639. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Appendix D: Indications for Use Enclosure

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510(k) Number (if known): K011965

Device Name: Microvasive®

Indications For Use:

The Microvasive® Imager™ II Urology Torque Catheter is indicated for use in facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the infusion of radiopaque contrast material.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

or

Over-The-Counter Use _____

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011965