NOV - 5 2010

510(k) Summary for Imager ™ II Urology Torque Catheter

A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Daniel Hoar
Specialist, Regulatory Affairs
508-683-4156
or
Nichole Riek
Manager, Regulatory Affairs
508-683-4175

C. Device Name

Trade name: Imager ™ II Urology Torque Catheter
Common/usual name: Catheter, Urological
Classification Name: KOD – Urological catheter and accessories.
21 CFR 876.5130, Class II

D. Predicate Device

Trade name: Imager ™ II Urology Torque Catheter
Common/usual name: Catheter, Urological
Classification Name: KOD – Urological catheter and accessories.
21 CFR 876.5130, Class II
Premarket Notification: Boston Scientific Corporation, K011965

E. Device Description

The Imager ™ II Urology Torque Catheter is single lumen, torqueable catheter that is offered with one of a variety of tip configurations, each uniquely designed to facilitate access to the urinary tract.

This device is made of a biocompatible polymer reinforced with a stainless steel braided wire with one hole at the distal tip and a luer lock hub is attached to the proximal end. The catheter may be used with a guidewire up to .038 in. diameter.

F. 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. The Imager™ II Urology Torque Catheter is also indicated for the infusion of gels, such as BackStop™, intended for use in the urinary tract.

G. Technological Characteristics

The proposed Imager ™ II Urology Torque Catheter has the same technological characteristics (i.e. connector, strain relief, catheter shaft, catheter distal segment and coating) as the predicate device.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" a direct comparison of key characteristics demonstrates that the proposed urology catheter is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics tested. The proposed Imager ™ II Urology Torque Catheter is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

Mr. Daniel Hoar
Regulatory Affairs Specialist
Urology and Gynecology
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

NOV - 5 2010

Re: K102527
Trade/Device Name: Imager™ II Urology Torque Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KOD
Dated: October 27, 2010
Received: October 28, 2010

Dear Mr. Hoar:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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510(k) Number (if Known): K102527

Device Name: Imager ™ II Urology Torque Catheter

Indications For Use:

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Prescription Use __X____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102527