DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
Microvasive Urology
Ms. Janet A. McGrath
Senior Regulatory Affairs Specialist, Urology
One Boston Scientific Place
Natick, MA 01760-1537

JUL 27 2015

Re: K030956
Trade/Device Name: Ureteral Access Sheath Set II
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KOD, FED
Dated (Date on orig SE ltr): May 2, 2003
Received (Date on orig SE ltr): May 5, 2003

Dear Ms. McGrath,

This letter corrects our substantially equivalent letter of May 23, 2003.

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 contact 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. 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K030956

Device Name: UASS II

Indications for Use:

Indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract via antegrade and/or retrograde access.

(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**
(Optional Format 1-2-96)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030956

Summary of Safety and Effectiveness

510(k) Summary: UASS II

MAY 23 2003

SPONSOR:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
CONTACT PERSON:	Janet A. McGrath Senior Regulatory Affairs Specialist Or Lorraine M. Hanley Director Regulatory Affairs
DEVICE:	Ureteral Access Sheath Set II
TRADE NAME:	Navigator™ Access Sheath Set
COMMON NAME:	Ureteral Access Sheath Set
CLASSIFICATION:	Class II; 876.1500, Endoscope and Accessories Class II; 876.5130, Urological Catheter and Accessories
PREDICATE DEVICE:	Ureteral Access Sheath Set
DESCRIPTION:	The UASS II is designed to create a conduit for urological procedural instruments. This set consists of two components: an inner tapered semi-rigid dilator and an outer more flexible sheath. The outer flexible sheath fits over the semi-rigid inner dilator and it may be locked into place. These components are radiopaque and have a lubricous hydrophilic coating. The device is offered in two French sizes, 11/13 Fr, and 13/15 Fr. in lengths up to 46cm. The UASS II may be placed retrograde and/or antegrade. To guide the access sheath into the body orifice the dilator is advanced over up to a .038" guidewire. The device can be visualized under x-ray (fluoroscopy) during placement to confirm location. The proposed device can accept other urological instrumentation with OD's compatible with the sheath's working channel of 11 and 13 Fr, respectively. The proposed device is provided sterile single use. The packaging materials used for the proposed UASS are commonly used materials for packaging medical devices and similar to the predicate device. The device will be packaged in a labeled, single

polyfilm/tyvek peel pouch double sealed, which will be placed in a labeled, paperboard shelf carton.

INTENDED USE: The UASS II is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract antegrade and/or retrograde access.

TECHNOLOGICAL CHARACTERISTICS: The proposed device is substantially equivalent in design and materials to previously cleared devices. The proposed device has hydrophilic coating to facilitate device placement and withdrawal.

PERFORMANCE DATA: 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 devices previously cleared via the 510(k) path in terms of technology, principles of operation, intended use, and materials.