SECTION 6 **510K SUMMARY**

MAR - 7 2014

510(k) Summary for Navigator™ HD Ureteral Access Sheath

A. Date Prepared

February 07, 2014

B. Sponsor

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

C. Contact

Nichole Riek
Regulatory Affairs Manager
508-683-4175
riekn@bsci.com

D. Device Name

Trade name:	Navigator™ HD Ureteral Access Sheath Set
Common/usual name:	Ureteral Access Sheath Set
Classification Name:	FED – Endoscopic Access Overtube, Gastroenterology-Urology 21 CFR 876.1500, Class II

E. Predicate Device

Trade name:	Navigator™ HD Ureteral Access Sheath Set
Common/usual name:	Ureteral Access Sheath Set
Classification Name:	FED – Endoscopic Access Overtube, Gastroenterology-Urology 21 CFR 876.1500, Class II
Premarket Notification:	Boston Scientific, K122649 (12/12/2012)

F. Device Description

The Navigator ™ HD Ureteral Access Sheath Set is designed to provide the physician with reliable access to the urinary tract, the ability to inject fluids, and act as a conduit for device exchanges. Like all ureteral access sheath sets, Navigator™ HD also protects the ureter during device exchanges, thus helping reduce tissue trauma. This set consists of two components: an inner tapered semi-rigid dilator and an outer semi-rigid sheath. The outer sheath fits over the inner dilator, and the design of the hub allows the dilator to lock into the sheath. Both the dilator and sheath are radiopaque and have a lubricous hydrophilic coating. The device is offered in three French sizes, 11/13 Fr, 12/14 Fr and 13/15 Fr, in lengths up to 46cm. The Navigator ™ HD Ureteral Access Sheath Set is intended for single use only.

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 OD of 11, 14 and 13 Fr.

G. Intended Use

The Navigator™ HD Ureteral Access Sheath Set 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.

H. Technological Characteristics

The proposed device is substantially equivalent in design and materials to the predicate Navigator HD Ureteral Access Sheath Set. Like the predicate device, the proposed device has a hydrophilic coating to facilitate device placement and withdrawal.

I. 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 Navigator™ HD UASS is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics.

J. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with samples aged at T=0 to support the addition of a flexural durability specification to Navigator™ HD. There are no changes to the device design or device materials, packaging materials, sterilization method, intended use or contraindications proposed in this 510(k) Premarket Notification that would impact aging. See Section 14 for further discussion. The following testing was completed to evaluate the effects of the design change and sizes:

- Dilator Tip Weld / Shaft Integrity
- Flexible Tip Weld Integrity (Durability)

The results of the performance testing demonstrate equivalence of the Navigator™ HD to the predicate Ureteral Access Sheath Set. The Navigator™ HD UASS are considered safe and effective for their intended use.

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

March 7, 2014

Boston Scientific Corporation
Urology/Women's Health
Nichole Riek
Regulatory Affairs Manager
100 Boston Scientific Way
Marlborough, MA 01752

Re: K140323
Trade/Device Name: Navigator™ HD Ureteral Access Sheath Set
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: February 7, 2014
Received: February 10, 2014

Dear Nichole Riek,

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,

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

SECTION 5 INDICATIONS FOR USE

Indications for Use Statement

510(k) Number	K140323
Device Name	Navigator™ HD Ureteral Access Sheath Set
Indications For Use	The Navigator™ HD Ureteral Access Sheath Set 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.

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)

Benjamin R. Fisher -S
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