

K122649

SECTION 5

510K SUMMARY

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

DEC 12 2012

A. Sponsor

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

B. Contact

Huda Yusuf
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508-683-4216
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or

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

C. Device Name

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

D. Predicate Device

Trade name: Navigator™ Ureteral Access Sheath Set
Common/usual name: Ureteral Access Sheath Set
Classification Name: KOD – Catheter, Urological
21 CFR 876.5130, Class II
Premarket Notification: Boston Scientific, K022135 (9/13/2002) and K030956
(5/23/2003)

E. 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.

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

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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.

The proposed device is provided sterile single use. The packaging materials used for the proposed Navigator™ HD 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, which will be placed in a labeled, paperboard shelf carton.

F. 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.

G. Technological Characteristics

The proposed device is substantially equivalent in design and materials to previously cleared devices. Like the predicate device, the proposed device has a hydrophilic coating to facilitate device placement and withdrawal.

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 Navigator™ HD UASS is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics. The Navigator™ HD is as safe, as effective, and performs as well as the predicate devices.

I. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with samples aged at T=0 and T=25 months accelerated aging in support of Navigator™ HD's design change and additional size configurations. The following testing was completed to evaluate the effects of the design change and sizes:

- Working Length
- Sheath & Dilator Outer Diameter
- Sheath & Dilator Stiffness
- Dilator Tip Stiffness
- Sheath & Dilator Tensile Strength
- Sheath & Dilator Hub to Shaft Integrity
- Dilator Tip to Shaft Integrity
- Latch Holding Force & Durability
- Dilator Luer (Compliance with ISO 594-2)
- Dilator Hub Leak Resistance
- Dilator/Guidewire Trackability
- Transition Force of Dilator and Sheath Tips
- Sheath Circular Profile
- Dilator Slideability from Sheath
- Sheath Internal Passage Resistance/Friction
- Sheath Internal Passage Durability

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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.



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

December 12, 2012

Boston Scientific Corporation
Urology/Women's Health
% Ms. Huda Yusuf, MSc
Specialist II, Regulatory Affairs
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K122649
Trade/Device Name: Navigator™ HD Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: November 20, 2012
Received: November 21, 2012

Dear Ms. Yusuf:

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.

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" (21 CFR 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

K122649

SECTION 4

INDICATIONS FOR USE

Indications for Use Statement

**510(k)
Number**

To be determined. K122649

Device Name

Navigator™ HD Ureteral Access Sheath

**Indications
For Use**

The UASS 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
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K122649