March 13, 2025

Boston Scientific Corporation
Timilehin Adenekan
Regulatory Affairs Specialist
100 Boston Scientific Way – Urology Division
Marlborough, Massachusetts 01752

Re: K250517
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 21, 2025
Received: February 21, 2025

Dear Timilehin Adenekan:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K250517

Device Name

Navigator™ HD Ureteral Access Sheath Set

Indications for Use *(Describe)*

The Navigator HD Ureteral Access Sheath 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# K250517 510(k) Summary for Navigator™ HD Ureteral Access Sheath Sets

**Date Prepared: March 13, 2025**

## A. Submitter

Boston Scientific Corporation
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100 Boston Scientific Way
Marlborough, MA 01752

## B. Contacts

Timilehin Adenekan
Regulatory Affairs Specialist
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## C. Device Name

| | |
|---|---|
| Trade Names: | Navigator™ HD Ureteral Access Sheath Set |
| Common Name: | Ureteral Access Sheath Set |
| Regulation Number: | 21 CFR §876.1500 |
| Regulation Name: | Endoscopic Access Overtube, Gastroenterology - Urology |
| Classification: | Class II |
| Product Code: | FED |

## D. Predicate Devices

For the purposes of establishing substantial equivalence, the designs and technological characteristics of the proposed Navigator™ HD Ureteral Access Sheath Sets were compared to the following 510(k)-cleared device.

**Table 11-1: Predicate Device for Establishing Substantial Equivalence**

| Characteristics | Predicate Device |
|---|---|
| **Device Trade Name** | Navigator™ HD Ureteral Access Sheath Sets |
| **Regulation Name** | Endoscopic Access Overtube, Gastroenterology - Urology |
| **Regulation Number** | 21 CFR §876.1500 |
| **Classification** | Class II |
| **Product Code** | FED |
| **510(k) Submitter/Holder** | Boston Scientific Corporation, Marlborough, MA |
| **510(k) Clearance Number & Date** | K140323 Cleared 07-March-2014 |

## E. Device Description

Navigator™ HD Ureteral Access Sheath Set consists of a semi-rigid outer sheath and a semi-rigid inner dilator with interlocking hub. The set permits utilization of a guidewire to assist in device placement.

***Sheath***

The Navigator™ HD Sheath has a sheath hub which is over-molded onto the sheath. The sheath shaft has three layers:

- Outer Pebax layer
- Reinforced stainless steel coil enhancing torqueability and maneuverability
- Inner PTFE liner

The sheath outer layer contains Barium Sulphate as a radiopacifier. In addition to the stainless-steel coil, a radiopaque marker band is sandwiched between the Pebax and PTFE layers. The radiopaque marker band is located at the sheath tip and, along with the radiopacifier added to the sheath outer layer, enhances fluoroscopic visualization of sheath placement during the procedure. A hydrophilic coating is applied to the entire length of the shaft to reduce friction and facilitate placement of the device.

***Dilator***

The Navigator™ HD dilator has a hub with a standard luer lock at the proximal end. The tab on the dilator hub allows it to lock into the sheath hub. The dilator shaft is made of extruded tube Pellethane to allow for dimensional stability, low moisture absorption, and chemical resistance. The dilator tip is made of a softer grade of Pellethane to improve tip flexibility to assist in atraumatic placement. Both the dilator shaft and tip contain Barium Sulfate as a radiopacifier, enhancing visualization under fluoroscopy during the procedure. A hydrophilic coating is applied to the entire length of the dilator to reduce friction and facilitate placement of the device, either when assembled with the sheath or when used separately as a dilatation device.

## F. Intended Use/Indication for Use

The Navigator HD Ureteral Access Sheath 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. Operating Principle

The operating principle for the Navigator™ HD Ureteral Access Sheath Sets (submitted under K140323) remains unchanged.

For the duration of the access procedure, a 0.89 mm (0.035 in.) or 0.97 mm (0.038 in.) guidewire is inserted through the urethra into the urinary tract. The dilator and sheath are secured together and then advanced over the guidewire to the target anatomy. Once positioned, the dilator is removed by grasping the luer and the tab, and the sheath is maintained in place for the duration of the procedure. To perform a retrograde pyelogram, the dilator should be re-inserted into the sheath, and the contrast injected through the luer fitting of the dilator.

## H. Comparison of Key Technological/Performance Characteristics

The proposed Navigator™ HD Ureteral Access Sheath Sets have the same technological characteristics and fundamental design as the predicate Navigator™ HD Ureteral Access Sheath Sets (K140323).

**Table 11-2: Navigator™ HD Device Comparison and Substantial Equivalence**

| Characteristics | Predicate Navigator™ HD Ureteral Access Sheath Sets (K140323) | Proposed Navigator™ HD Ureteral Access Sheath Sets (K250517) | Similarities / Differences |
|---|---|---|---|
| Indication for Use | Navigator HD 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. | Navigator HD 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. | Identical |
| Reusability | Single Use | Single Use | Identical |
| Nav HD is Supplied | Sterile | Sterile | Identical |
| Sterilization | Ethylene Oxide (EO) | Ethylene Oxide (EO) | Identical |
| Packaging | Tyvek/Poly pouch | Tyvek/Poly pouch | Identical |
| Hydrophilic Coating | Lubricent UV460 | Lubricent UV540 | Similar |
| **Dilator & Sheath Mechanical Specifications** | | | |
| Sizes Offered | 11/13 F<br>12/14 F<br>13/15 F | 11/13 F<br>12/14 F<br>13/15 F | Identical |
| Length (cm) | 28, 36 & 46 | 28, 36 & 46 | Identical |

## I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the proposed Navigator™ HD Ureteral Access Sheath Sets are substantially equivalent to the predicate Navigator™ HD Ureteral Access

Sheath Sets (K140323) in terms of intended use, technological characteristics, and performance characteristics. The proposed Navigator™ HD Ureteral Access Sheath Sets is as safe, as effective, and performs as well as the predicate devices (K140323).

**J. Performance Testing**

To evaluate the hydrophilic coating change introduced with the proposed Navigator™ HD Ureteral Access Sheath Sets, a Design Verification and Summative Usability was executed to support the safe and effective use of the proposed Navigator™ HD Ureteral Access Sheath Sets. Additional Design Verification testing was executed to verify that the proposed change had no impact to the shelf-life.

From a biocompatibility standpoint, the contact classification of the proposed Navigator™ HD Ureteral Access Sheath Sets is identical to the predicate Navigator™ HD Ureteral Access Sheath Sets (cleared under K140323). A biological evaluation assessment for the proposed Navigator™ HD Ureteral Access Sheath Sets was conducted and it was concluded there is no biocompatibility risks associated to the proposed Navigator™ HD Ureteral Access Sheath Sets.

**K. Conclusion**

Based on the intended use/indications for use, comparison of key technological characteristics, and performance testing presented in this premarket submission, it is concluded that the proposed Navigator™ HD Ureteral Access Sheath Sets are substantially equivalent to the predicate Navigator™ HD Ureteral Access Sheath Sets (cleared under K140323).