August 4, 2026

Boston Scientific Corporation
Uma Ramnanan
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K261915
Trade/Device Name: Navigator™ Flex Ureteral Access Sheath Set
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED, FAJ, FGA
Dated: June 8, 2026
Received: June 9, 2026

Dear Uma Ramnanan:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 R. Kreitz -S

for 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.

510(k) Number *(if known)* K261915

Device Name
Navigator™ Flex Ureteral Access Sheath Set (M0062504100, M0062504110, M0062504120, M0062504200, M0062504210, M0062504220)

Indications for Use *(Describe)*
The Navigator™ Flex Ureteral Access Sheath Set is intended to be used in establishing a conduit during endoscopic urological procedures, to facilitate the passage and use of endoscopes and other instruments into the urinary tract, and to remove urinary stones through the use of suction.

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.

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Navigator™ Flex Ureteral Access Sheath Set – 510(k) Summary

1. Submission Details

Date Prepared: 24 July 2026

Sponsor: Boston Scientific Corporation Urology Division
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Uma Ramnanan
+1 (508) 382-9595
uma.ramnanan@bsci.com

Secondary Contact: Justin Kapitan
+1 (508) 683-4518
justin.kapitan@bsci.com

Proposed Device:

Premarket Notification – Traditional 510(k)	
Device Common Name	Ureteral Access Sheath
Device Trade Name	Navigator™ Flex Ureteral Access Sheath Set
Classification	Class II per 21 CFR §876.1500
Classification Name	Endoscope and accessories
Product Code	FED (Endoscopic Access Overtube, Gastroenterology-Urology) FAJ (Cystoscope and Accessories, Flexible/Rigid) FGA (Kit, Nephroscope)

Table 1: Scope of Submission

Predicate Device:

Predicate 510(k) - K161110	
Device Trade Name	ClearPetra Suction-Evacuation Sheath
Classification	Class II per 21 CFR §876.1500
Classification Name	Endoscope and accessories
Product Code	FED (Endoscopic Access Overtube, Gastroenterology-Urology) FAJ (Cystoscope and Accessories, Flexible/Rigid) FGA (Kit, Nephroscope)

Table 2: Predicate Device

Reference Device:

Reference 510(k) - K250517	
Device Trade Name	Navigator™ HD Ureteral Access Sheath
Classification	Class II per 21 CFR §876.1500
Classification Name	Endoscope and accessories
Product Code	FED (Endoscopic Access Overtube, Gastroenterology-Urology)

Table 3: Reference Device

2. Device Description

The Navigator™ Flex Ureteral Access Sheath Set consists of an inner tapered dilator and an outer navigable sheath with aspiration capabilities. The device is designed to create a conduit for retrograde (transurethral) urological procedure instruments and for the removal of urinary system stone debris using suction. The sheath can be connected to an external negative pressure (i.e., suction) source (e.g., standard operating room "wall suction", 3rd party fluid management system, pump) with standard medical-grade suction tubing.

Navigator™ Flex Ureteral Access Sheath Set includes three key components : (1) a lubricious outer sheath with a semi-rigid distal shaft, a flexible distal end, and a proximal suction control hub (a slider enables on/off control of suction); (2) a lubricious semi-rigid inner dilator, which interlocks with the sheath hub; and (3) a seal tethered to the sheath hub, used to cover the hub's proximal end after the inner dilator is removed, to maintain a vacuum and thereby enable suction when scope is inserted through seal.

This device is an example of a flexible and navigable suction (FANS) ureteral access sheath (UAS), a class of devices used during treatment and clearance of stones in the urinary collecting system (urinary calculi or urolithiasis). Navigator™ Flex Ureteral Access Sheath Set functions as a catheter by providing a pathway for fluid and debris removal and as an access sheath that, when used with a ureteroscope offers steerable access to the urinary tract and enables suction.

Navigator™ Flex Ureteral Access Sheath Set Configurations

Product Identification	Product Description
M0062504100	Navigator™ Flex Ureteral Access Sheath Set 11/13 FR x 38 CM
M0062504110	Navigator™ Flex Ureteral Access Sheath Set 11/13 FR x 46 CM
M0062504120	Navigator™ Flex Ureteral Access Sheath Set 11/13 FR x 52 CM
M0062504200	Navigator™ Flex Ureteral Access Sheath Set 12/14 FR x 38 CM
M0062504210	Navigator™ Flex Ureteral Access Sheath Set 12/14 FR x 46 CM
M0062504220	Navigator™ Flex Ureteral Access Sheath Set 12/14 FR x 52 CM

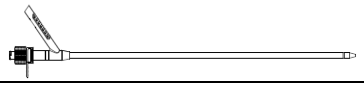
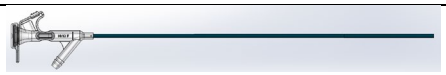
3. Intended Use/Indications for Use

Navigator™ Flex Ureteral Access Sheath Set is intended to be used in establishing a conduit during endoscopic urological procedures, to facilitate the passage and use of endoscopes and other instruments into the urinary tract, and to remove urinary stones through the use of suction.

4. Comparison to Predicate Device

The subject device Navigator™ Flex Ureteral Access Sheath Set have similar technological characteristics and fundamental design as the legally marketed predicate ClearPetra Suction-Evacuation Sheath (predicate device, K161110).

Characteristic	ClearPetra Suction-Evacuation Sheath (Predicate Device)	Navigator™ Flex Ureteral Access Sheath Set (Subject Device)	Comparison
Indications for Use	The ClearPetra Suction-Evacuation Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary	Navigator™ Flex Ureteral Access Sheath Set is intended to be used in establishing a conduit during endoscopic urological procedures, to facilitate the passage and use of endoscopes and other instruments into the urinary tract, and to remove urinary stones through the use of suction.	Similar

Characteristic	ClearPetra Suction-Evacuation Sheath (Predicate Device)	Navigator™ Flex Ureteral Access Sheath Set (Subject Device)	Comparison
	diseases during the endoscopic procedures.		
Contraindications	Coagulation disorders Acute urinary tract infection Severe cardiopulmonary insufficiency Uncorrected diabetes	Patients who are contraindicated for retrograde urological procedures. Patients who have untreated urinary tract infections or any other condition which may lead to a high viscous flow within the kidney.	Similar
Use Environment	Healthcare facility	Healthcare facility	Same
Material	Stainless Steel (SS) Polytetrafluoroethylene (PTFE) Polyethylene (PE) Nylon (PA) Polycarbonate (PC) disposable materials, with a hydrophilic coating	Stainless steel (SS) Polytetrafluropolymer (PTFE) Polyurethane (PU) Polycarbonate (PC) Nylon (PA) disposable materials, with a hydrophilic coating	Similar
Sterilization Method and Sterility	EO sterilized Sterility 10^{-6}	EO sterilized Sterility 10^{-6}	Same
Device Diagram			Similar.
Size	10/12Fr x 13cm 10/12Fr x 26cm 10/12Fr x 36cm 10/12Fr x 40cm 10/12Fr x 46cm 10/12Fr x 55cm 11/13Fr x 13cm 11/13Fr x 26cm 11/13Fr x 36cm 11/13Fr x 40cm 11/13Fr x 46cm 11/13Fr x 55cm 12/14Fr x 13cm 12/14Fr x 26cm 12/14Fr x 36cm 12/14Fr x 40cm 12/14Fr x 46cm 12/14Fr x 55cm 13/15Fr x 13cm 13/15Fr x 26cm 13/15Fr x 40cm 13/15Fr x 46cm 13/15Fr x 55cm 14/16Fr x 13cm 14/16Fr x 26cm 14/16Fr x 36cm 14/16Fr x 40cm 14/16Fr x 46cm 14/16Frx 55cm	11/13Fr x 38cm 11/13Fr x 46cm 11/13Fr x 52cm 12/14Fr x 38cm 12/14Fr x 46cm 12/14Fr x 52cm	The predicate device offers a broader range of sizes; however, the subject device falls within the range of sizes offered by the predicate. The selected subject sizes represent those that are clinically relevant and comparable for the intended use.

Characteristic	ClearPetra Suction-Evacuation Sheath (Predicate Device)	Navigator™ Flex Ureteral Access Sheath Set (Subject Device)	Comparison
Components	Sheath, Obturator, Connector, Rubber Cap	Sheath, Obturator, Connector, Rubber Cap, Slider	Similar. Navigator™ Flex Ureteral Access Sheath Set has a slider for suction control.
Single Use	Yes	Yes	Same

While the Intended Use is not identical, the subject and predicate device intended use are fundamentally the same. The Product Code, Class, Environment Use and Users are the same. The differences in technological characteristics have been assessed and do not raise any new questions of safety or effectiveness.

5. Performance Testing

The Navigator™ Flex Ureteral Access Sheath Set has undergone Performance Testing in the following ways:

- Biocompatibility Testing
  - Assessments of the safety of the patient contacting materials per:
    - ISO 10993-1 Fifth edition 2018-*08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* (FDA Recognition Number: 2-258)
    - ISO 10993-5 Third edition 2009-06-01 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* (FDA Recognition Number: 2-245)
    - ISO 10993-10 Fourth edition 2021-11 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization* (FDA Recognition Number: 2-296)
    - ISO 10993-12 Fifth edition 2021-01 *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials* (FDA Recognition Number: 2-289)
    - ISO 10993-18 Second edition 2020-01 *Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process* (FDA Recognition Number: 2-276)
    - ISO 10993-23 First edition 2021-01 *Biological evaluation of medical devices - Part 23: Tests for irritation* (FDA Recognition Number: 2-291)
- Performance Testing
  - Assessment of the Navigator™ Flex Ureteral Access Sheath Set product and packaging to demonstrate safety and effectivity over the proposed shelf-life utilizing internally developed bench test methods per
    - ASTM D4169: 2023 *Standard practice for performance testing of shipping containers and systems* (FDA Recognition Number: 14-576)
    - ASTM F1929:2023 *Standard test method for detecting seal leaks in porous medical packaging by dye penetration* (FDA Recognition Number: 14-600)
    - ASTM F2096:2011 *Standard test method for detecting gross leaks in packaging by internal pressurization (bubble test)* (FDA Recognition Number: 14-359)
    - ASTM F1980:2021 *Standard guide for accelerated aging of sterile barrier systems for medical devices* (FDA Recognition Number: 14-575)
  - Assessment of Sterile Barrier Packaging to demonstrate safety and effectivity over the proposed shelf-life per
    - ISO 11607-1 Second edition 2019-02 [Including AMD1:2023] *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)]* (FDA Recognition Number: 14-594)
  - Assessment of the overall performance of the subject device was evaluated using the following tests to demonstrate that the design requirements have been met
    - Dimensional evaluation
    - Tensile Testing
    - Aspiration Performance
    - Device Durability

- Device Insertion
- Distal End Functionality
- Frictional Force
- Radiopacity

No clinical tests/data were submitted, referenced, or relied on in this 510(k) for determination of substantial equivalence.

The testing performed concludes that the Navigator™ Flex Ureteral Access Sheath Set performs both safely and effectively per their design requirements and does not introduce new safety concerns that would impact the device's intended use or substantial equivalence.

6. Conclusion

Based on the intended use, comparison of key technological characteristics, and performance testing presented in this premarket submission, it is concluded that the subject device Navigator™ Flex Ureteral Access Sheath Set is substantially equivalent to the predicate ClearPetra Suction-Evacuation Sheath (K161110).