September 24, 2025

Boston Scientific Corporation
Alexandra Skinner
Senior Regulatory Affairs Specialist
Boston Scientific Corporation -Urology and
Pelvic Health Division
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K252703
Trade/Device Name: LithoVue Elite Single-Use Digital Flexible Ureteroscope – Standard with pressure monitoring (M0067940000); LithoVue Elite Single-Use Digital Flexible Ureteroscope – Reverse with pressure monitoring (M0067940500)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: August 26, 2025
Received: August 27, 2025

Dear Alexandra Skinner:

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 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)*
K252703

Device Name
LithoVue Elite Single-Use Digital Flexible Ureteroscope - Standard with pressure monitoring (M0067940000); LithoVue Elite Single-Use Digital Flexible Ureteroscope - Reverse with pressure monitoring (M0067940500)

Indications for Use *(Describe)*
The LithoVue Elite Digital Flexible Ureteroscope System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in 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.

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510(k) Summary for LithoVue™ Elite Single-Use Digital Flexible Ureteroscope
Date Prepared: August 26, 2025

A. Submitter

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

B. Contacts

Alexandra Skinner
Sr. Regulatory Affairs Specialist
508-382-9492
Alexandra.Skinner@bsci.com

C. Device Name

Trade Names:	**LithoVue™ Elite Single-Use Digital Flexible Ureteroscope – Standard with pressure monitoring (M0067940000)** **LithoVue™ Elite Single-Use Digital Flexible Ureteroscope – Reverse with pressure monitoring (M0067940500)**
Common/Usual Name:	Ureteroscope And Accessories, Flexible/Rigid
Regulation Number:	21 CFR §876.1500
Regulation Name:	Endoscope and accessories
Classification:	Class II
Product Code:	FGB

D. Predicate Devices

For the purpose of establishing 'substantial equivalence', the design and technological characteristics of the proposed LithoVue Elite Single-Use Digital Flexible Ureteroscope with Pressure Monitoring were compared to the following 510(k)-cleared device.

Predicate Devices for Establishing 'Substantial Equivalence'

	Predicate Devices
Device Trade Name(s):	LithoVue Elite Single-Use Digital Flexible Ureteroscope With Pressure Monitoring
Regulation Name:	Endoscope and accessories
Regulation Number:	21 CFR §876.1500
Classification:	Class II
Product Code:	FGB
510(k) Submitter/Holder:	Boston Scientific Corporation, Marlborough, MA

510(k) #/ Clearance Date	K241598 July 1, 2024

E. Device Description

The LithoVue Elite Digital Flexible Ureteroscope System is a software-controlled digital flexible ureteroscope system that consists of the StoneSmart™ Connect Console (cleared under K233645 on 12-DEC-2023) and the LithoVue™ Elite Single-Use Digital Flexible Ureteroscope (with and without pressure monitoring) (cleared under K241598 on 01-JUL-2024). The LithoVue Elite Digital Flexible Ureteroscope System is designed to allow the physician to access, visualize and perform procedures in the urinary tract.

The proposed device within the scope of this Special 510(k) premarket notification is LithoVue Elite Single-Use Digital Flexible Ureteroscope with Pressure Monitoring (referred hereafter as “ureteroscope” for brevity).

The proposed design changes to the ureteroscope include an updated pressure sensor assembly, along with modifications to the other device components such as the distal tip and PCBA to ensure compatibility with the new sensor assembly. The new pressure sensor is functionally equivalent to the currently used sensor assembly; however, its integration results in changes to patient-contacting materials.

F. Intended Use/Indications for Use

The LithoVue Elite Digital Flexible Ureteroscope System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

G. Operating Principle

The operating principle for the illumination and intraluminal pressure monitoring for the predicate ureteroscope with pressure monitoring (submitted under K241598) remains unchanged. Illumination is generated by an LED located in the single-use digital ureteroscope handle and transmitted to the distal tip lens via a fiber-optic illumination fiber. A digital CMOS imager located in the distal tip of the ureteroscope provides the raw image data from the surgical field. The raw image data is transferred from the CMOS imager through the ureteroscope handle, via the umbilicus, to the console for processing and output to an external display.

The console supports real-time intraluminal pressure monitoring when used with a LithoVue Elite ureteroscope with pressure monitoring capability. Like the predicate ureteroscope with pressure monitoring, the proposed ureteroscope with pressure monitoring contains a Micro-Electro-Mechanical Systems (MEMS) piezoresistive pressure sensor located at the distal tip of the ureteroscope. Pressure signals from the ureteroscope are transmitted to the console for real-time display of the pressure value

on an external display.

H. Comparison of Key Technological/Performance Characteristics

The proposed ureteroscope with pressure monitoring has the same technological characteristics and fundamental design as the predicate ureteroscope with pressure monitoring.

	Proposed ureteroscope	**Predicate ureteroscope (K241598)**	**Substantial Equivalence Discussion**
Reusability	Single Use	Single Use	Identical
Ureteroscope Type	Flexible	Flexible	Identical
Ureteroscope is Provided	Sterile	Sterile	Identical
Sterilization Agent	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Identical
Imager Type	CMOS	CMOS	Identical
Imager Location	Distal	Distal	Identical
Illumination Source	LED	LED	Identical
Ureteroscope Mechanical Specifications			
Shaft Working Length	68 cm	68 cm	Identical
Shaft OD	9.5F	9.5F	Identical
Insertion Portion Width (Distal Face)	7.7 F	7.7 F	Identical
Working Channel Size	3.6 F (1.15mm MIN ABS)	3.6 F (1.15mm MIN ABS)	Identical
Working Length	82 cm	82 cm	Identical
Deflection	Active and Passive	Active and Passive	Identical
Degree of Active Deflection	270° in both directions	270° in both directions	Identical
Optical Specifications			
Field of View (in air)	120° (diagonal)	120° (diagonal)	Identical
Working Distance	2 - 50 mm	2 - 50 mm	Identical

	Proposed ureteroscope	**Predicate ureteroscope (K241598)**	**Substantial Equivalence Discussion**
Direction of View	0° (forward viewing)	0° (forward viewing)	Identical
Resolution	Typical (5mm Distance): >9.81 lp/mm	Typical (5mm Distance): >9.81 lp/mm	Identical
Pressure Measurement (Applies to ureteroscope with pressure monitoring only)			
Pressure Measurement Accuracy (Applies to ureteroscope with pressure monitoring only)	Procedure Duration Post Initialization: **0 minutes to 60 minutes:** 0 mmHg - 100 mmHg: (+/- 10 mmHg) 100 mmHg - 300 mmHg: (+/- 5 mmHg +5 % of reading) **60 minutes to 120 minutes:** 0 mmHg - 100 mmHg: (+/- 13 mmHg) 100 mmHg - 300 mmHg: (+/- 8 mmHg +5 % of reading)	Procedure Duration Post Initialization: **0 minutes to 60 minutes:** 0 mmHg - 100 mmHg: (+/- 10 mmHg) 100 mmHg - 300 mmHg: (+/- 5 mmHg +5 % of reading) **60 minutes to 120 minutes:** 0 mmHg - 100 mmHg: (+/- 13 mmHg) 100 mmHg - 300 mmHg: (+/- 8 mmHg +5 % of reading)	Identical

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the proposed ureteroscope is substantially equivalent to the predicate ureteroscope in terms of intended use, technological characteristics, and performance characteristics. The differences between the proposed and the predicate devices do not alter suitability of the proposed devices for their intended use.

J. Performance Testing

Design changes to the proposed ureteroscope were evaluated through re-execution of a subset of the tests **-** associated with mechanical performance, pressure measurement, and durability (including pressure measurement durability testing) - along with an engineering analysis for “Image Rotation Offset” to support the safe and effective use. Additional Design Verification (DV) testing was executed to verify the proposed changes had no impact on the device labeled shelf life.

Biocompatibility of the proposed ureteroscope was evaluated in accordance with ISO 10993-1 and FDA's guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* The body contact classification of the proposed ureteroscope is identical to that of the predicate ureteroscope i.e. "Externally Communicating – Tissue/Bone/Dentin" with a contact duration of "Limited (≤24 hours)". The following tests were performed: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, and Material Mediated Pyrogenicity. Results of the Biocompatibility testing met the requirements of the respective tests and support the biocompatibility of the proposed ureteroscope.

There is no difference between the proposed and the predicate ureteroscope that could affect device sterility, or Basic Safety and EMC performance. Additionally, the ureteroscope does not contain software. So, software testing is not applicable.

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 ureteroscope is substantially equivalent to the predicate ureteroscope (cleared under K241598).