



July 1, 2024

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

Re: K241598

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);
LithoVue Elite Single-Use Digital Flexible Ureteroscope –
Standard (without pressure monitoring) (M0067941000);
LithoVue Elite Single-Use Digital Flexible Ureteroscope –
Reverse (without pressure monitoring) (M0067941500)

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: II

Product Code: FGB

Dated: June 3, 2024

Received: June 4, 2024

Dear Matthew Minks:

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.

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

Indications for Use

Submission Number (if known)

K241598

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);
LithoVue Elite Single-Use Digital Flexible Ureteroscope -- Standard
(without pressure monitoring)
(M0067941000);
LithoVue Elite Single-Use Digital Flexible Ureteroscope -- Reverse
(without pressure monitoring)
(M0067941500)

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.

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510(k) Summary for LithoVue™ Elite Single-Use Digital Flexible Ureteroscope**Date Prepared: June 03, 2024****A. Submitter**

Boston Scientific Corporation
 Urology and Pelvic Health Division
 100 Boston Scientific Way
 Marlborough, MA 01752

B. Contacts

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 508-683-6522
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C. Device Names

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)
	LithoVue™ Elite Single-Use Digital Flexible Ureteroscope - Standard (without pressure monitoring) (M0067941000)
	LithoVue™ Elite Single-Use Digital Flexible Ureteroscope - Reverse (without pressure monitoring) (M0067941500)
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 designs and technological characteristics of the proposed LithoVue Elite Single-Use Digital Flexible Ureteroscope with pressure monitoring and LithoVue Elite Single-Use Digital Flexible Ureteroscope without pressure monitoring were compared to the following 510(k)-cleared devices device.

Predicate Device for Establishing 'Substantial Equivalence'

	Predicates	
Device Trade Name:	LithoVue Elite Single-Use Digital Flexible Ureteroscope with pressure monitoring	LithoVue Elite Single-Use Digital Flexible Ureteroscope
Regulation Name:	Endoscope and accessories	Endoscope and accessories
Regulation Number:	21 CFR §876.1500	21 CFR §876.1500
Classification:	Class II	Class II
Product Code:	FGB	FGB
510(k) Submitter/Holder:	Boston Scientific Corporation, Marlborough, MA	Boston Scientific Corporation, Marlborough, MA
510(k) #/ Clearance Date	K221515 February 2, 2023	K233645 December 12, 2023

E. Device Description

The LithoVue Elite Digital Flexible Ureteroscope System (cleared under K221515 on 02-FEB-2023 and K233645 on 12-DEC-2023) consists of the StoneSmart Connect Console, LithoVue Elite Single-Use Digital Flexible Ureteroscope with pressure monitoring, and LithoVue Elite Single-Use Digital Flexible Ureteroscope (without pressure monitoring). The proposed devices within the scope of this Special 510(k) premarket notification are the LithoVue Elite Single-Use Digital Flexible Ureteroscope with pressure monitoring and LithoVue Elite Single-Use Digital Flexible Ureteroscope (without pressure monitoring).

The proposed ureteroscope with pressure monitoring contains a redesigned distal tip to improve its durability during a ureteroscopy procedure. To maintain congruence between the two marketed configurations of the ureteroscope, the distal tip of the ureteroscope (without pressure monitoring) is also modified to match the one used in the ureteroscope with pressure monitoring, with the exception that it does not contain the specific modifications intended for pressure monitoring. Furthermore, test methods are also modified to be more representative of "challenging" working conditions as well as for better alignment with the intent of the specifications.

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 (submitted under K221515 and K233645) 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 LithoVue Elite ureteroscope with pressure monitoring contains the Micro-Electro-Mechanical Systems (MEMS) pressure sensor located at the distal tip of the ureteroscope. The 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 have the same technological characteristics and fundamental design as the predicate ureteroscopes.

	Proposed ureteroscopes	Predicate ureteroscopes (K221515 and K233645)	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

	Proposed ureteroscopes	Predicate ureteroscopes (K221515 and K233645)	Substantial Equivalence Discussion
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
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)	Same

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the proposed ureteroscopes are substantially equivalent to the predicate ureteroscopes 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

To evaluate the design changes introduced with the proposed ureteroscopes, a subset of the mechanical performance and durability testing (including pressure sensor durability testing) along with the “Image Rotation Offset” testing was executed to support the safe and effective use of the proposed ureteroscopes.

There are no differences between the proposed and the predicate ureteroscopes that could affect the shelf life or sterility; therefore, sterilization and shelf-life evaluations were not required. From a biocompatibility standpoint, the contact classification of the proposed ureteroscopes is the same as that of the predicate ureteroscopes (cleared under K221515 and K233645). A biocompatibility assessment for the proposed devices was conducted and it was concluded that no additional biocompatibility testing was required.

Basic safety and EMC compatibility were not affected by the modifications made for the proposed devices as there were no changes to the electrical components, and the mechanical updates do not introduce sharp edges or corners.

The ureteroscopes do 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 ureteroscopes are substantially equivalent to the predicate ureteroscopes (cleared under K221515 and K233645).