December 12, 2023

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

Re: K233645
Trade/Device Name: StoneSmart Connect Console, LithoVue Elite Standard Deflection, LithoVue Elite Reverse Deflection
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: November 13, 2023
Received: November 14, 2023

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.

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233645

Device Name
StoneSmart Connect Console
LithoVue Elite Standard Deflection
LithoVue Elite Reverse Deflection

Indications for Use *(Describe)*
The LithoVue Elite Digital Flexible Ureteroscope System is intended to by 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 Digital Flexible Ureteroscope System

Date Prepared: 13-NOV-2023

A. Submitter

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B. Contacts

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C. Device Names

Trade Name(s):	**StoneSmart Connect Console** **LithoVue Elite Standard Deflection** **LithoVue Elite Reverse Deflection**
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 and Reference Devices

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

Predicate Device for Establishing 'Substantial Equivalence'

	Predicate Device
Device Trade Name(s):	StoneSmart™ Connect Console and 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	K221515 February 2, 2023

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 and the Single-Use Digital Flexible Ureteroscope. 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 devices within the scope of this Special 510(k) premarket notification are the StoneSmart Connect Console and the LithoVue Elite Single-Use Digital Flexible Ureteroscope (without pressure monitoring).

Changes to the StoneSmart Connect Console (cleared under K221515 on 02-FEB-2023) include software changes to introduce a new user control feature (referred to as “Aiming Beam Mode”) that is designed to provide the physician with more options to reduce interference from high intensity laser aiming beams within the live image displayed by the LithoVue Elite ureteroscope system and implement software bug fixes and enhancements.

The proposed LithoVue Elite Single-Use Digital Flexible Ureteroscope is the same as the predicate LithoVue Elite Single-Use Digital Flexible Ureteroscope with pressure monitoring (K221515) with respect to its design, performance, intended use, operating principle, and fundamental technology, except that it does not possess the pressure monitoring capability.

F. Intended Use/Indications for Use

The indications for use of the LithoVue Elite Digital Flexible Ureteroscope System (cleared under K221515, on 02-FEB-2023) remains valid; therefore, no change to the cleared indications for use (presented below) is being proposed in the current submission.

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 of the predicate ureteroscope system (submitted under K221515) is unchanged and therefore applies to the proposed ureteroscope system. The illumination is generated by an LED located in the 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, which contains the piezoresistive MEMS absolute pressure sensor located at the distal tip. The proposed ureteroscope, submitted as part of the current application, does not have pressure measuring/monitoring capability.

H. Comparison of Key Technological/Performance Characteristics

The proposed StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope (without pressure monitoring) have the same technological characteristics and fundamental design as the predicate devices.

	Proposed StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope (without Pressure Monitoring)	**Predicate StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope (with Pressure Monitoring) (K221515)**	**Substantial Equivalence Discussion**
Reusability	Ureteroscope (without pressure monitoring): Single Use Console: Reusable	Ureteroscope (with pressure monitoring): Single Use Console: Reusable	Same
Ureteroscope Type	Flexible	Flexible	Same
Ureteroscope is Provided	Sterile	Sterile	Same
Sterilization Agent	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same
Power Input (Workstation)	100-240 VAC, 50-60 Hz	100-240 VAC, 50-60 Hz	Same
Imager Type	CMOS	CMOS	Same
Imager Location	Distal	Distal	Same
Illumination Source	LED	LED	Same
Ureteroscope supports real-time intraluminal	No	Yes	The proposed ureteroscope does not support real-

	Proposed StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope (without Pressure Monitoring)	Predicate StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope (with Pressure Monitoring) (K221515)	Substantial Equivalence Discussion
pressure monitoring			time intraluminal pressure monitoring.
Aiming Beam Mode	Yes	No	Aiming beam mode is a new feature introduced with the proposed console. It is an optional (user-activated) feature that is designed to provide the physician with more options to reduce interference from high intensity laser aiming beams within the live image displayed by the LithoVue Elite ureteroscope system.
Ureteroscope Mechanical Specifications			
Shaft Working Length	68 cm	68 cm	Same
Shaft OD	9.5F	9.5F	Same
Insertion Portion Width (Distal Face)	7.7 F	7.7 F	Same
Working Channel Size	3.6 F (1.15mm MIN ABS)	3.6 F (1.15mm MIN ABS)	Same
Working Length	82 cm	82 cm	Same
Deflection	Active and Passive	Active and Passive	Same
Degree of Active Deflection	270° in both directions	270° in both directions	Same
Optical Specifications			

	Proposed StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope (without Pressure Monitoring)	Predicate StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope (with Pressure Monitoring) (K221515)	Substantial Equivalence Discussion
Field of View (in air)	120° (diagonal)	120° (diagonal)	Same
Working Distance	2 - 50 mm	2 - 50 mm	Same
Direction of View	0° (forward viewing)	0° (forward viewing)	Same
Resolution	Typical (5mm Distance): >9.81 lp/mm	Typical (5mm Distance): >9.81 lp/mm	Same
Video Latency (Max.)	155 ms	155 ms	Same

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the proposed StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope (without pressure monitoring) are substantially equivalent to the predicate devices with respect to intended use, technological characteristics, and performance characteristics. The differences between the proposed and predicate devices do not alter the suitability of the proposed devices for their intended use.

J. Performance Testing

Design verification (bench) testing for visualization, mechanical performance, and durability, conducted by utilizing the predicate ureteroscope (K221515), remains valid for the proposed ureteroscope. Changes to the cleared console (K221515) are limited to software changes only. The existing bench testing information/data reviewed by the FDA for the predicate console (reference K221515) remains valid for the proposed console.

Software testing was completed. The software documentation stipulated in FDA guidance document, *Content of Premarket Submissions for Device Software Functions* (issued June 14, 2023) was included in this premarket submission.

The proposed ureteroscope does not introduce any new direct or indirect patient-contacting materials, as compared to the predicate ureteroscope. Furthermore, the predicate ureteroscope with its additional patient-contacting components to support its pressure monitoring capability is considered a worst-case device for biocompatibility testing purposes. Therefore, the biocompatibility test results reviewed by the FDA for the predicate ureteroscope (reference K221515) also support the proposed ureteroscope (without pressure monitoring). Thus, additional biocompatibility testing was not required for the proposed device. The console is non-patient contacting; therefore, no biocompatibility testing is required.

There are no differences between the predicate ureteroscope (with pressure monitoring) and the proposed ureteroscope (without pressure monitoring) that could affect the shelf life or sterility; therefore, sterilization and shelf-life evaluations were not required. The console is a durable medical device that will be supplied non-sterile and is not intended to be sterilized by the user. Handling and storage conditions, as described in the console user's manual, are not expected to affect the safety or effectiveness of the console. Therefore, sterilization and shelf-life testing are not required for the console.

Changes to the cleared console (K221515) are limited to software changes only and the predicate ureteroscope with active pressure monitoring circuitry is considered a worst-case device for electrical safety and EMC testing purposes. Therefore, the previously reviewed electrical safety and EMC test results for the predicate ureteroscope and console (reference K221515) also support the proposed ureteroscope and console.

K. Conclusion

Based on the intended use/indications for use, comparison of key technological characteristics, and performance testing presented in this premarket notification, it is concluded that the proposed StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope are substantially equivalent to the predicate devices (cleared under K221515).