November 23, 2021

STERIS Corporation
Caroll Martin
Director, Regulatory Affairs
5976 Heisley Road
Mentor, Ohio 44060

Re: K211347
Trade/Device Name: Ureterol Ureteroscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: II
Product Code: FGB
Dated: October 25, 2021
Received: October 27, 2021

Dear Caroll Martin:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211347

Device Name
Uretero1™ Ureteroscope System

Indications for Use *(Describe)*
The single use Uretero1™ 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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STERIS®

510(k) Summary for the Uretero1™ Ureteroscope System

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Carroll Martin
Regulatory Affairs Director
Tel: 440-358-6259
Email: Carroll_Martin@steris.com

Submission Date: April 30, 2021

1. Device Name

Trade Name:	Uretero1™ Ureteroscope System
Device Class:	Class II
Regulation Name:	Endoscope and Accessories
Common/usual Name:	Ureteroscope
Regulation Number:	21 CFR 876.1500
Product Code:	FGB

2. Predicate Device

LithoVue System, K153049

3. Device Description

The Uretero1™ Ureteroscope System contains an all-in-one camera control unit (CCU) for image processing and display. The CCU operates at 110 V - 230V ~ 50 - 60 Hz and has a simple graphical user interface that prompts the clinician through actions to get a live view via the Ureteroscope. After unpackaging the sterile, single-use ureteroscope, the user is required to plug in the single-use ureteroscope device via a 16-pin male connector inserted to the CCU to obtain a live image. There is a process of authentication, in which the CCU recognizes the firmware of the inserted product, and the image from the ureteroscope is displayed on live view. The Uretero1™ CCU software platform is based on i.MX8MQ processor from NXP and LATTICE ECP5 FPGA. The ECP5 provides the camera interface plus ISP functionality. The CCU software is based on Linux board support package provided by NXP. The board support package and Linux distribution are configured and built using YOCTO. The main functionality of the system is to capture the video from an external camera and display it to an external display. Graphical user interface is developed using QT5. Video pipeline is implemented through g-streamer.

The ureteroscope is disposable and can be utilized for up to 4 hours. The ureteroscope possesses a 4-hour countdown timer and after 4 hours of usage, the ureteroscope will no longer produce a live image and a use notification message will be displayed on the screen informing the user that the ureteroscope usage time has expired. The ureteroscope has 3 use notification messages. One occurs at 60 minutes left on the timer and appears on the side menu bar of the display screen on the CCU. A second occurs with 30 minutes left on the timer and also appears on the side menu bar. The final notification message appears with 5 minutes of time remaining on the ureteroscope and it is in the middle of the screen and requires user interaction to acknowledge the use notification message by pressing OK. When the duration of time has elapsed, the ureteroscope will no longer produce a live image and the user will be directed to a screen that states the ureteroscope no longer has any usable time remaining and to insert new ureteroscope.

Once the flexible shaft is inserted into the patient, the distal tip is steered via the articulation lever on the ureteroscope handle. The flexible shaft allows for passive secondary deflection while accessing the patient's urinary tract. The flexible shaft contains a working channel to allow surgical accessories and procedural solutions to be delivered through the distal tip to the surgical field. The handle button allows the user to take photos, record video and zoom in and out. In addition to the articulation lever and the handle button, the handle contains an

accessory access port and a connection port for procedural solutions. An irrigation system (irrigation tubing and an irrigation source) can be attached to one port and the biopsy port cover can be attached to the other port. In this way, the user can use endoscopic instruments through the biopsy port cover and irrigate at the same time. The Uretero1TM Single-Use Digital Flexible Ureteroscope must be used in conjunction with the Vision1™ Imaging Console and Display System (CCU).

In addition to image processing, the CCU supports video connectivity in two additional ways. The user is allowed to mirror image from the CCU to an external display which produces the same image the user sees on the CCU screen on any other compatible display system that accepts HDMI input. In addition, the CCU can accept an HDMI input signal from an external HDMI output and the CCU can act as a dummy display panel for the external HDMI imaging source. There are two USB data ports to provide data export (photos and video taken during procedure) or allow connection of selected accessories (printer). No data, including Electronic Protected Health Information (ePHI) data is stored on this device (e.g., last name, SSN, DOB, MRN) and there is no ethernet, Wi-Fi or Blue Tooth capability.

The ureteroscope will be offered in two different models: Uretero1TM Ureteroscope (Standard Deflection) and Uretero1TM Ureteroscope (Reverse Deflection). To save procedural photo or video, a proprietary system encrypted USB drive is provided to Customers with the purchase of the CCU. The Vision1™ Imaging Console and Display System communicate with the encrypted USB drive, the Uretero1TM Single-Use Digital Flexible Ureteroscope, and the external printer.

4. Indications for Use

The single use Uretero1™ 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.

5. Technological Characteristics Comparison Table

A comparison of technical characteristics between the proposed and predicate devices is summarized in **Table 1**.

Table 1. Technological Characteristics Comparison Table

Features	LithoVue System Predicate Device K153049	Uretero1™ Ureteroscope System (Proposed Device)	Comparison
Intended Use	The LithoVue 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.	The single use Uretero1™ 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.	Identical
Ureteroscope Construction/Components	Handle Articulation Lever Accessory Port Irrigation Port Connector Cable Connector Cable Plug Flexible Shaft Articulation Section Distal Tip (camera, illumination optics, and the working channel, video signal cables, articulation wires and light fiber) Instrument Channel Light (illumination fiber) Camera	Handle Articulation Lever Handle Button Accessory Port Irrigation Port Connector Cable Connector Cable Plug Flexible Shaft Articulation Section Distal Tip (camera, illumination optics, and the working channel, video signal cables, articulation wires and light fiber) Instrument Channel Light (illumination fiber) Camera	Similar. The predicate device does not have a handle button to allow the user to take photos, record video or zoom in/out. This does not affect safety and effectiveness in that this feature in the proposed device gives the user options to capture data.
Monitor Components	Frame Touchscreen Scope Connector AD/DC Power Cable DVI Input	Frame Touchscreen with Antiglare USB Ports Scope Connector Power Button HDMI In HDMI Out USB Type B Port AD/DC Power Cable	Similar. The DVI Digital Visual Interface of the predicate is similar to the HDMI Output of Uretero1 as they both allow transfer of video signal to an external display. The HDMI input allows a user to display image from an external display

Features	LithoVue System Predicate Device K153049	Uretero1™ Ureteroscope System (Proposed Device)	Comparison
			on the Vision1. The USB ports allow the user to be able to transfer data to approved devices.
Sterile/Non-sterile	Sterile	Sterile	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Sterilization Assurance Level	10^{-6}	10^{-6}	Identical
Usage	Single use, disposable	Single use, disposable	Identical
Functionality	Irrigation capability through irrigation port Ability to use endoscopic tools through instrument port.	Irrigation capability through irrigation port Ability to use endoscopic tools through instrument port Ability to record images (picture and video) Ability to record to external media (USB flash) Audio (notifications to the user)	Similar. The listed differences between the proposed and predicate devices do not impact safety/effectiveness of the device in that the additional functionality of the proposed device is a convenience to the user.
Ureteroscope Working Distance	2mm – 50mm	2mm – 50mm	Identical
Dimensions	Max. Width of Insertion Portion (Distal Face): ≤2.6 mm Max. Width of Insertion Portion: ≤3.23 mm Working Length: 680 ± 2 mm Minimum Instrument Channel Width: ≥1.12 mm	Max. Width of Insertion Portion (Distal Tip): ≤2.6 mm Max. Width of Insertion Portion: ≤3.23 mm Working Length: 680 ± 2 mm Minimum Instrument Channel Width: ≥1.12 mm	Identical.
Ureteroscope Tip Deflection	270° in both directions	270° in both directions	Identical
Target Population	Patients undergoing a urological endoscopic procedure	Patients undergoing a urological endoscopic procedure	Identical
Energy Used/Delivered	None	None	Identical
Accessories Provided	None	Accessory port cover	Different. The proposed device offers an accessory port cover for the convenience of the user. The cover facilitates the passage of instruments during a procedure.
Method of Application	Manual	Manual	Identical

6. Summary of Non-Clinical Performance Testing

Non-clinical testing consisted of the following:

Testing	Results
Width of Insertion Portion (Distal Face)	Pass
Maximum Width of Insertion Portion (Overall Shaft Diameter and Size)	Pass
Working Length	Pass
Working Channel Length	Pass
Deflection Direction Marking (Visual test)	Pass
Printing Legibility (Visual test)	Pass
Ink Integrity (Handle Print Adhesion/Legibility – Visual test)	Pass
Surface and Edges (Visual test)	Pass
Maximum Angle of Deflection	Pass
Bend Radius	Pass
Direction of View	Pass
Image Orientation	Pass
Image Latency	Pass
Lumen Output	Pass
Lever Deflection Force	Pass
Working Channel Freedom from Leakage	Pass
Aspiration Flow/Working Channel Collapse	Pass
Working Channel Freedom from Leakage (Scope and Accessory Cap (accessory port cover))	Pass
Aspiration Flow/Working Channel Collapse (Scope and Accessory Cap (accessory port cover))	Pass
Working Channel Freedom from Leakage (Scope and Accessory Cap (accessory port cover))	Pass
Button Resistance after Conditioning	Pass
Minimum Working Distance after Conditioning	Pass
Image Latency after Conditioning	Pass
Lumen Output after Conditioning	Pass
Lever Deflection Force after Conditioning	Pass
Working Channel Freedom from Leakage (Scope and Accessory) after Conditioning	Pass
Torsional Resistance at Tip	Pass
Tip Column Strength	Pass
Shaft to Handle Tensile Strength	Pass
Umbilicus to Handle Tensile Strength	Pass
Umbilicus to Connector Tensile Strength	Pass
Tip to Shaft Tensile Strength	Pass
Critical Shaft Bend Radius	Pass
3-Point Bend (Shaft Flexural Resistance)	Pass
Single Use Device Handle Temp. During Procedure	Pass
Control Body must be able to change the axis of tip deflection	Pass
Single Use Device Use Time Tracking/ Single Use Device Remaining Use Time	Pass
Button Functions	Pass
Laser Aiming Beam/Laser Lithotripsy Compatibility	Pass

Testing	Results
Maximum Width of Insertion Portion (Overall Shaft Diameter and Size) – Testing conducted after 3-month accelerated aging	Pass
Image Latency - Testing conducted after 3-month accelerated aging	Pass
Lumen Output - Testing conducted after 3-month accelerated aging	Pass
Maximum Angle of Deflection - Testing conducted after 3-month accelerated aging	Pass
Bend Radius - Testing conducted after 3-month accelerated aging	Pass
Lever Deflection Force - Testing conducted after 3-month accelerated aging	Pass
SUD Working Channel Freedom from Leakage (Scope and Accessory Cap) - Testing conducted after 3-month accelerated aging	Pass
Shaft to Handle Tensile Strength - Testing conducted after 3-month accelerated aging	Pass
Umbilicus to Handle Tensile Strength - Testing conducted after 3-month accelerated aging	Pass
Umbilicus to Connector Tensile Strength - Testing conducted after 3-month accelerated aging	Pass
Connector Retention Strength - Testing conducted after 3-month accelerated aging	Pass
Tip to Shaft Tensile Strength - Testing conducted after 3-month accelerated aging	Pass
Shaft Leakage conducted after 3-month accelerated aging	Pass
Radiopacity Testing	Pass
Luer Testing	Pass
Accessory Channel Minimum Width Assessment	Pass
Handle to Active Deflection Torque Angle at Break	Pass
Packaging Age Testing (Integrity and Seal Strength)	Pass
Software verification and validation	Pass
Radiopacity Testing	Pass
Working Channel Connection Compatibility	Pass
Packaging Integrity	Pass
Package Seal Strength	Pass
Software verification and validation	Pass

Biocompatibility of the Uretero1 Ureteroscope was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "Surface – Mucosal Membrane" with a contact duration of "Limited (< 24 hours)". The following tests were performed: Cytotoxicity, Irritation, Sensitization, and USP Physiochemical <661>. All evaluation acceptance criteria were met.

Electrical safety testing of the System was evaluated in accordance with IEC 60601-1 (2005) Edition 3.1, IEC 60601-1-2 (2014) Edition 4, IEC 60601-1-6 (2010), Edition 3.1 and IEC 60601-2-18:2009 Edition 3. All evaluation acceptance criteria were met.

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well or better than the legally marketed predicate device (K153049), Class II (21 CFR 876.1500), product code FGB.