



February 17, 2023

STERIS Corporation
Carroll L. Martin
Regulatory Affairs Director
5976 Heisley Road
Mentor, OH 44060

Re: K223466
Trade/Device Name: Uretero1™ Ureteroscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: January 13, 2023
Received: January 19, 2023

Dear Carroll L. 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 -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

510(k) Number (if known)
K223466

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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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: February 6, 2023

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**

Uretero1 Ureteroscope System, K211347
Class II (21 CFR 876.1500), product code FGB

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 into 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 Uretero1™ 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: Uretero1™ Ureteroscope (Standard Deflection) and Uretero1™ 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 Uretero1™ Single-Use Digital Flexible Ureteroscope, and the external printer.

The Uretero1 Ureteroscope System comes packaged with single-use, disposable accessory port cover. The accessory port cover is adjustable and is intended to resist the backflow of fluid around an instrument inserted through the working channel of the ureteroscope. It is designed to facilitate the passage of instruments during a procedure. It has a cap feature to allow instruments to be inserted and secured. A clicking mechanism is used to facilitate the open, semi-closed and closed position of the valve. It also has a side arm y-port with a luer cap to allow for irrigation or other procedural solutions, if needed. This accessory attaches to the instrument port of the Uretero1 Ureteroscope via a distal luer connection.

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. Comparison of Technological Characteristics with the Predicate Device

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

Table 1. Technological Characteristics Comparison Table

Features	Uretero1™ Ureteroscope System K211347	Uretero1™ Ureteroscope System (Modified Device)	Comparison
Intended 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.	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 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	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	Identical
Monitor Components	Frame Touchscreen with Antiglare USB Ports Scope Connector Power Button HDMI In HDMI Out USB Type B Port AD/DC Power Cable	Frame Touchscreen with Antiglare USB Ports Scope Connector Power Button HDMI In HDMI Out USB Type B Port AD/DC Power Cable	Identical
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

Features	Uretero1™ Ureteroscope System K211347	Uretero1™ Ureteroscope System (Modified Device)	Comparison
Functionality	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)	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)	Identical
Ureteroscope Working Distance	2mm – 50mm	2mm – 50mm	Identical
Dimensions	Tip Diameter: 6.6F (2.2mm) Outer Diameter: 9.5F (3.2mm) Instrument Channel internal diameter: 3.6F (1.2mm)	Tip Diameter: 6.6F (2.2mm) Outer Diameter: 9.5F (3.2mm) Instrument Channel internal diameter: 3.6F (1.2mm)	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	Accessory port cover	Accessory port cover	Identical
Method of Application	Manual	Manual	Identical
Software System	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 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.	Identical

Features	Uretero1™ Ureteroscope System K211347	Uretero1™ Ureteroscope System (Modified Device)	Comparison
Software Update: Allow unlimited addresses for scope detection.	Has finite number of addresses for scope detection.	Has unlimited addresses for scope detection.	Similar. No impact on safety, effectiveness or how the device is used. This software change is a convenience feature for the user.
Software Update: Synchronization check on incoming video frame.	Synchronization check not performed on incoming video.	Synchronization check performed on incoming video.	Similar. No impact on safety, effectiveness or how the device is used by the user. Change is intended to increase manufacturability.
Software Update: Modification in Image Signal Processing (ISP)	Image Signal Processing (ISP) utilizes an external clock source as a root clock.	Image Signal Processing (ISP) utilizes an internal clock source as a root clock	Similar. No impact on safety, effectiveness or how the device is used by the user. Change is intended to increase manufacturability.
Software Update: Modification in behavior of HDMI output to external monitors	Use of an incompatible monitor causes a “stutter” effect.	Use of an incompatible monitor results in no video from the ureteroscope.	Different. No impact on safety, effectiveness or how the device is used by the user. The Uretero1 System allows a user to connect a monitor other than the Vision1. The change is for the convenience of the user.
Software Update: Turn off scope LED drive when the scope is not connected.	LED drive remains on when scope is disconnected.	LED drive is turned off when the scope is disconnected.	Different. No impact on safety, effectiveness or how the device is used by the user. This change is to extend the life of the LED driver chip.
Software Update: Update initialization for Hardware Chip	Error checks performed only at boot up	Additional error checks performed at boot up and screen transitions.	Similar. No impact on safety, effectiveness or how the device is used by the user. This change improves the boot up performance of the system.
Software Update: Remove dormant software class objects from memory	Dormant software class objects remain in memory.	Dormant software class objects removed from memory.	Different. No impact on safety, effectiveness or how the device is used by the user. This change improves memory usage of the system.
Software Update: Update the Uretero1 System application to eliminate the digital artifact	Sensor registers are not monitored once they are set.	Sensor registers are constantly monitored once they are set.	Different. No impact on safety, effectiveness or how the device is used by the user. This change returns the device to its original specifications.

Features	Uretero1™ Ureteroscope System K211347	Uretero1™ Ureteroscope System (Modified Device)	Comparison
Software Update: Provide the user the ability to disable the scope buttons in the Settings menu of the console.	Scope button is always enabled.	Option given to the user to disable the scope button.	Different. This change does not impact safety or effectiveness. This change is for the convenience of the user.
Software Update: Implement on-screen annotation of Left vs. Right kidney.	No ability to annotate left and right kidney.	Ability for user to annotate left and right kidney.	Different. This change does not impact safety or effectiveness. This change is to aid the user
Software Update: Change email address listed in HELP menu from vision1@steris.com to urology@steris.com.	Email address is vision1@steris.com	Email address is urology@steris.com	Different. This change does not impact safety, effectiveness or how the device is used. The change is for the convenience of the user
Software Update: Remove the red static text “Insert Thumb drive to take photos or videos” in the patient data box.	Red static text remains regardless of whether or not the thumb drive has been inserted.	The red static text is removed.	Different. This change does not impact safety, effectiveness or how the device is used. The change is for the convenience of the user.
Software Update: Make the pop-up message “Photo or video not saved, insert USB drive” disappear after 5 seconds, without requiring user intervention.	User intervention is required to remove the pop-up message.	User intervention is not required to remove the pop-up message.	Different. This change does not impact safety, effectiveness or how the device is used. The change is for the convenience of the user.
Software Update: Grey out all languages except English.	All languages appear available.	Only English appears available.	Different. This change does not impact safety, effectiveness or how the device is used. The change is for the convenience of the user.
Software Update: Refactor device power board software code and GUI software code.	Unoptimized code structure and memory usage.	Improved code structure and memory usage.	Different. This change does not impact safety, effectiveness or how the device is used.

Features	Uretero1™ Ureteroscope System K211347	Uretero1™ Ureteroscope System (Modified Device)	Comparison
Software Update: Lock the HDMI output resolution to 1080p/60.	HDMI output capable of 720p and 1080p	HDMI output capable of 1080p/60	Different. This change does not impact safety, effectiveness or how the device is used. This change is to ensure monitor compatibility.
Software Update: Provide a selection button on the monitor that allows the user to print a snapshot of the live view during a procedure to a printer.	No printer functionality available.	Printer functionality available.	Different. This change does not impact safety or effectiveness, but does have an impact on how the device is used. The new button is an added feature. It's for the convenience of the user
Debug port	Closed	Open	Different. This change does not impact safety, effectiveness or how the device is used. This change is for the convenience of STERIS technicians.
Connector on the console (Gumby) main board	Present	Present	Identical. This change does not impact safety, effectiveness or how the device is used. The original connector is being replaced by an alternative supplier's connector that is identical in form, fit and function.
Ureteroscope camera sensor	Present	Present	Similar. Replacement of the original camera sensor with a similar one due to obsolescence.
Ureteroscope tip adhesive	Loctite 4902	Loctite 4311	Similar. This change does not impact safety, effectiveness or how the device is used. Change is intended to increase manufacturability

Features	Uretero1™ Ureteroscope System K211347	Uretero1™ Ureteroscope System (Modified Device)	Comparison
Distal end of ureteroscope adhesive.	No adhesive in the gap at the distal end	Adhesive (Dymax) added to gap at distal end.	Different. This change does not impact safety, effectiveness or how the device is used. This change is for aesthetics only.
Insertion Tube to Handle Adhesive	Loctite 4902	Loctite 4311	Similar. This change does not impact safety, effectiveness or how the device is used. Change is intended to increase manufacturability
Instrument Channel to Luer Adhesive	Loctite 4902	Loctite 4311	Similar. This change does not impact safety, effectiveness or how the device is used. Change is intended to increase manufacturability
Light Fiber and Light Fiber Bracket Adhesive	Loctite 4902	Loctite 3321	Similar. This change does not impact safety, effectiveness or how the device is used. Change is intended to increase manufacturability
Tip to Shaft (Backbone) Adhesive	Loctite EA 9017	Loctite EA M-31 CL	Similar. This change does not impact safety, effectiveness or how the device is used. Change is intended to increase manufacturability.

Features	Uretero1™ Ureteroscope System K211347	Uretero1™ Ureteroscope System (Modified Device)	Comparison
T-Luer Dimensions	Tubing Pocket outside diameter: 1.17mm Minimum inside diameter of the T- Luer: 1.49mm	Tubing Pocket outside diameter: 1.19mm Minimum inside diameter of the T-Luer: 1.59mm	Similar. These changes do not impact safety, effectiveness or how the device is used. This change addresses the possibility that a user could encounter difficulties in passing instruments through the channel.
Light bracket hole dimension	0.51mm	0.58mm	Similar. This change does not impact safety, effectiveness or how the device is used. Change is intended to increase manufacturability
Shaft retention bracket dimension	11mm	8mm	Similar. This change does not impact safety, effectiveness or how the device is used. Change is intended to increase manufacturability
Power cord length dimension	3.5 feet	10 feet	Similar. This change does not impact safety, effectiveness or how the device is used. Change is for the convenience of the user.
Labeling Changes	“Manufactured for” not present on the device labels	“Manufactured for” present on device labels.	Different. This change does not impact safety, effectiveness or how the device is used.
	Insertion tube outer diameter nominal dimensions: 9.5FR (3.23mm)	Insertion tube outer diameter nominal dimensions: 8.9FR (2.98mm)	Different. This change does not impact safety, effectiveness or how the device is used. It is information for the user.
	Information not present.	Provide the following information directly on the label. • Maximum Insertion Portion Diameter: 3.23mm • Angle of Deflection: - 275° - +275° • Working length: 680mm	Different. This change does not impact safety, effectiveness or how the device is used. It is information for the user.
	Information not present.	Added a description of the screen icons for the Multifunction Scope Function button and for Kidney Location (for annotating “left” or “right” kidney). Also, added instruction for annotating “left” or “right” on the monitor screen and any saved images or video	Different. This change does not impact safety, effectiveness or how the device is used. It is information for the user.
Expiration dating	3 months	3 years	Different. This change does not impact safety, effectiveness or how the device is used.

6. Summary of Non-Clinical Performance Testing

Non-clinical testing consisted of the following:

Change Type	Testing Type	Results	Standard	FDA Guidance
Software	Functional and Regression Testing	Pass	IEC 62304:2006/A1:2016	Not applicable
Hardware Changes	Optical Color Performance Testing	Pass	Not applicable	Not applicable
	White Balance Testing	Pass	Not applicable	Not applicable
	Optical Performance Testing	Pass	ISO 8600-3:2019 ISO 8600-5:2020 ISO 12233:2017 ISO 9039:2008 ISO 15739:2017	Not applicable
	Review of Prior Testing	Pass	Not applicable	Not applicable
	Software Regression Testing	Pass	IEC 62304:2006/A1:2016	Not applicable
Material Change (Adhesive)	Workmanship, functionality and performance	Pass	Not applicable	Not applicable
	Biocompatibility	Pass	ISO 10993-1:2018	Not applicable
Dimensional Changes	Device passage, lumen output and tensile testing	Pass	Not applicable	Not applicable
	Electrical Testing	Pass	IEC 60601-1:2012	Not applicable
Labeling Changes	Labeling Review	Pass	ISO 15223-1:	Not applicable
Extension of Expiration Date	Functional/performance testing	Pass	Not applicable	Not applicable
	Packaging testing	Pass	ASTM F1886 ASTM F2096 ASTM F88	Not applicable

*Please note that all prior implemented changes were evaluated for their 510(k) implication in accordance with FDA guidance “Deciding When to Submit a 510(k) for a Change to an Existing Device” and “Deciding When to Submit a 510(k) for a Software Change to an Existing Device”

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe and effective as and substantially equivalent to the legally marketed predicate device (K211347).