December 13, 2024

UroViu Corporation
Thomas Lawson, Ph.D.
Director, Regulatory Affairs
4546 El Camino Real, Suite 214
Los Altos, CA 94022

Re: K243196
Trade/Device Name: Uro-G HD Flexible Cystoscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: September 25, 2024
Received: October 1, 2024

Dear Thomas Lawson:

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 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

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)*
K243196

Device Name
Uro-G HD Flexible Cystoscope

Indications for Use *(Describe)*

The Uro-G HD Flexible Cystoscope is intended for endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra.

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

General Information

Submitter	UroViu Corporation
Address	UroViu Corporation 4546 El Camino Real Suite 214 Los Altos, CA 94022
FDA Registration Number	3015042209
Correspondence Person	Thomas Lawson, PhD
Contact Information	Email: thom@uroviu.com Phone: 510-206-1794
Date Prepared	12 December 2024

Subject Device

Trade Name	Uro-G HD Flexible Cystoscope
Common Name	Uro-G HD
Regulation Number and Classification Name	21 CFR§876.1500, Endoscope and Accessories
Product Code	FAJ
Regulatory Class	II
Note: This is the second submission for this model 4500 handle that is part of the Uro-G HD Flexible Cystoscope System.	

Predicate Device

Trade Name	Uro-G HD Flexible Cystoscope
Common Name	Uro-G HD
Premarket Notification	K232837
Regulation Number and Classification Name	21 CFR§876.1500, Endoscope and Accessories
Product Code	FAJ
Regulatory Class	II
Note: The predicate device has not been subject to a design-related recall.	

Device Description

This Special 510(k) discloses the modifications to the steps to carry out surface disinfection of the model 4500 handle that was reviewed and cleared in K232837. The Uro-G HD Flexible Cystoscope is a handheld, battery- operated portable cystoscope consisting of a disposable steerable endoscopic

cannula with a 2.2 mm channel for fluid infusion and instrument advancement, and a reusable handle with a video monitor. When fully assembled, the Uro-G HD Flexible Cystoscope— cannula and handle—has an overall length of 630 mm (approximately 25 inches). The disposable cannula's working length is 380.2 mm (approx. 15 inches) and a total length of 406 mm, from tip to connector. The cannula's maximum width is 5.6 mm and it has a connector for attaching and detaching to the handle.

Indications for Use

The indications for use statement for the Uro-G HD Flexible Cystoscope is:

> The Uro-G HD Flexible Cystoscope is intended for endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra.

Comparison of Technological Characteristics with the Predicate Device

The focus of this Special 510(k) are the steps to follow to complete surface sterilization of the reusable handle component of the Uro-G HD Flexible Cystoscope. UroViu Corp. has identified the Uro-G HD Flexible Cystoscope (K232837, UroViu Corp.) as the predicate device. The Uro-G HD Flexible Cystoscope is substantially equivalent to the predicate device based upon the following similarities:

1. The intended use of both devices is exactly the same.
2. The indications for use of both the predicate device and the subject device are exactly the same: symptomatic voiding dysfunction, hematuria, bladder tumor surveillance, recurrent lower urinary tract infection, and pelvic pain syndromes;
3. Both devices are introduced into the body via the urethra and then advanced to the bladder under visualization (that is, not a blind advancement);
4. Both devices have illumination and optic components to permit visualization of the urethra and bladder;
5. Both devices have the capability to view the urethra and bladder via the video monitor mounted on the handle of the device;
6. Both devices have a working channel to allow infusion of fluids and introduction of instruments; and

7. Both devices are made from biocompatible materials.

The specific topic of this Special 510(k) are the steps to take when surface disinfecting the model 4500 handle of the Uro-G HD Flexible Cystoscope. There are no changes to intended use, materials used in construction, software, biocompatibility of materials, EMC and electrical safety, or performance. The only change is in one paragraph in the instructions for use (IFU) concerning surface disinfection of the reusable handle.

Table 1. Summary of Indications for Use, Technological Characteristics, Mechanisms of Action, Anatomical Sites of Use, Performance Testing, Manufacturing and Software of the Subject Device Compared to the Predicate Device.

	Subject Device Uro-G HD Flexible Cystoscope (UroViu Corp.) (K243196)	Predicate Device Uro-G HD Flexible Cystoscope (UroViu Corp.) (K232837)	Changed or Not Changed
Device Overview			
Device Class	II	II	Not Changed
FDA Product Code	FAJ	FAJ	Not Changed
Product Classification	21 CFR 876.1500	21 CFR 876.1500	Not Changed
Indication for Use	The Uro-G HD Flexible Cystoscope is intended for endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra	The Uro-G HD Flexible Cystoscope is intended for endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra	Not Changed

Intended use	Endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra	Endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra	Not Changed
Contraindications	• Evidence of ongoing UTI • Overwhelming coagulopathy • Impassable urethral structures	• Evidence of ongoing UTI • Overwhelming coagulopathy • Impassable urethral structures	Not Changed
Anatomical Site of Use	Lower urinary tract—urethra & bladder	Lower urinary tract—urethra & bladder	Not Changed
Route of Advancement	Advanced to the bladder via the urethra	Advanced to the bladder via the urethra	Not Changed
Components	Reusable Handle with a video screen integrated into handle's body Disposable Cannula with a working channel and an illumination source and camera at its tip	Reusable Handle with a video screen integrated into the handle's body Disposable Cannula with a working channel and an illumination source and camera at its tip	Not Changed Not Changed
Technical Characteristics			
Cannula			
Device Identity	Uro-G HD Flexible Cystoscope	Uro-G HD Flexible Cystoscope	Not Changed
Cannula working length	380.2 mm	380.2 mm	Not Changed
Total length (tip to connector)	406 mm	406 mm	Not Changed
Number of ports	2	2	Not Changed

Working channel minimum width	2.2 mm	2.2 mm	Not Changed
Maximum insertion width of the cannula	5.6 mm	5.6 mm	Not Changed
Tip OD	4 mm	4 mm	Not Changed
Camera			
CMOS module	0.7 million pixels	0.7 million pixels	Not Changed
Focal length	5 mm to 50 mm	5 mm to 50 mm	Not Changed
Field of view (in air)	100 º ± 5 º	100 º ± 5 º	Not Changed
Direction of view from center axis	0 º (Forward Viewing)	0 º (Forward Viewing)	Not Changed
Image resolution	3 lp/mm on the 1551 USAF test chart in air	3 lp/mm on the 1551 USAF test chart in air	Not Changed
Image distortion	< 15% at x and y direction	< 15% at x and y direction	Not Changed
Sensor on the CMOS camera	1280 x 720 pixels	1280 x 720 pixels	Not Changed
Tip angulation range	Up 210 º ± 5 º Down 130 º ± 5 º	Up 210 º ± 5 º Down 130 º ± 5 º	Not Changed
Tip angulation radius	Up less than 15 mm Down less than 20 mm	Up less than 15 mm Down less than 20 mm	Not Changed
Lever force for angulation	< 2.2 lbs	< 2.2 lbs	Not Changed
Rotation torque	< 3.5 inch-lb	< 3.5 inch-lb	Not Changed
Rotation angle	Cannula torques when rotate clockwise and counter-clockwise less than 90 º	Cannula torques when rotate clockwise and counter-clockwise less than 90 º	Not Changed
Fluid lumen cross-section	4.84 mm^2	4.84 mm^2	Not Changed

Distension flow through the working channel	>120 mL/min	>120 mL/min	Not Changed
Light source	LED Luminous flux at 25 mm focal length: 520 lumens	LED Luminous flux at 25 mm focal length: 520 lumens	Not Changed
Tip temperature when LEDs are on	< 41º C	< 41º C	Not Changed
Power rating of source	90 mW	90 mW	Not Changed
Provided Sterile	Yes	Yes	Not Changed
Sterilization method	Ethylene oxide	Ethylene oxide	Not Changed
Sterility Assurance Level of the Cannula	10^{-6}	10^{-6}	Not Changed
Biocompatibility of Materials	Meets ISO 10993 requirements for external communicating device with < 24 hours of tissue contact	Meets ISO 10993 requirements for external communicating device with < 24 hours of tissue contact	Not Changed
Single Use	Yes	Yes	Not Changed
Packaging	Tyvek pouch	Tyvek pouch	Not Changed
Handle			
Device Identity	4500	4500	N/A
Length	176 mm	176 mm	Not Changed
Diameter	36 mm	36 mm	Not Changed
Weight	264 g	264 g	Not Changed

Video Monitor	Screen: 4.3 inches diagonal Horizontal: 122.2 mm Vertical: 73.9 mm	Screen: 4.3 inches diagonal Horizontal: 122.2 mm Vertical: 73.9 mm	Not Changed
Input format	RGB	RGB	Not Changed
Effective pixels	1280 x 720	1280 x 720	Not Changed
LCD resolution	800 x 480	800 x 480	Not Changed
LCD display resolution	0.4 million pixels	0.4 million pixels	Not Changed
Power supply	18650 Lithium Ion rechargeable	18650 Lithium Ion rechargeable	Not Changed
Voltage of fully charged battery	3.7 V	3.7 V	Not Changed
Operating time after fully charged	2 hours	2 hours	Not Changed
Battery capacity	3100 mA	3100 mA	Not Changed
Biocompatibility	N/A Does not contact the patient & the user wears gloves while using the device	N/A Does not contact the patient & the user wears gloves while using the device	Not Changed
Operational Characteristics			
Electrical Safety	IEC 60601-2-18 compliant	IEC 60601-2-18 compliant	Not Changed
EMC	IEC 60601-1-2 compliant	IEC 60601-1-2 compliant	Not Changed
Adjust brightness of illumination of the LEDs	Adjust by depressing a button on the handle to change settings	Adjust by depressing a button on the handle to change settings	Not Changed
Images or video capture	Capture still images (photo) or video during a procedure by depressing the camera button on the handle	Capture still images (photo) or video during a procedure by depressing the camera button on the handle	Not Changed

Cleaning, disinfecting and sterilization	The handle is not sterile. The handle is cleaned and disinfected following directions in the instructions for use (IFU): • Wipe the surface with a Super Sani-Cloth or CaviWipe towelette • Surface to remain visibly wet for 3 minutes • After 3 minutes allow the handle to air dry for 5 minutes	The handle is not sterile. The handle is cleaned and disinfected following directions in the instructions for use (IFU): • Wipe the surface with a CaviWipe towelette • Surface to remain visibly wet for 6 minutes • After 6 minutes allow the handle to air dry for 20 minutes	Equivalent The use of a Super Sani-Cloth is an option in addition to use of a CaviWipe in disinfecting the surface. Testing found that 3 minutes contact with the disinfecting agent on the wipes was sufficient for log reductions of ≥ 3 and ≥ 6 of tested pathogens. The air dry time was reduced from 20 minutes to 5 minutes
	Wet a sterile pad with sterile water and wipe all exposed surfaces of the handle	Wet a sterile pad with sterile water and wipe all exposed surfaces of the handle	Not Changed
	The disposable cannula is provided sterile and is for single use. It is deposed after the procedure	The disposable cannula is provided sterile and is for single use. It is deposed after the procedure	Not Changed
Frequency of use	Handle is reusable Cannula is single use	Handle is reusable Cannula is single use	Not Changed
Duration of use	< 24 hours	< 24 hours	Not Changed

Site of Use	Hospitals and physician offices	Hospitals and physician offices	Not Changed
Mechanism of Action			
Operational Principles	Handle: Rather than run a cable from the cystoscope to a separate video monitor as is required of all other cystoscopes, an LCD display is integrated into the handle of UroViu cystoscopes so that the user can see images of the tissue and anatomical structures directly and in real time as the cystoscope is being advanced to and while within the bladder. Cannula: the light at the tip illuminates the field so that the camera can transmit images back to the LCD display on the handle. It is a flexible shaft that the user can manipulate to view the urethra bladder by rotating the cannula or by modifying the angle of the tip manually.	Handle: Rather than run a cable from the cystoscope to a separate video monitor as is required of all other cystoscopes, an LCD display is integrated into the handle of UroViu cystoscopes so that the user can see images of the tissue and anatomical structures directly and in real time as the cystoscope is being advanced to and while within the bladder. Cannula: the light at the tip illuminates the field so that the camera can transmit images back to the LCD display on the handle. It is a flexible shaft that the user can manipulate to view the urethra bladder by rotating the cannula or by modifying the angle of the tip manually.	Not Changed Not Changed

Performance Testing			
	Testing for: • Tip angulation • Tip angulation radius • Lever force for tip angulation • Rotation torque • Rotation angles • Distention flow rate • Cannula leaking • Tip temperature • Field of view • Direction of view • Image quality	Testing for: • Tip angulation • Tip angulation radius • Lever force for tip angulation • Rotation torque • Rotation angles • Distention flow rate • Cannula leaking • Tip temperature • Field of view • Direction of view • Image quality	Not Changed
Manufacturing			
	Manufactured at a contract manufacturer with design control at UroViu Corp	Manufactured at a contract manufacturer with design control at UroViu Corp	Not Changed
Software			
SW version	4.1	4.1	Not Changed
Level of Concern	Moderate	Moderate	Not Changed
General Functions of the Software	• Initialize and setup video processing hardware • Initialize LCD display control • Initialize user interface (menus, touch screen) • Initializes recording, storage, and playback of video and still images	• Initialize and setup video processing hardware • Initialize LCD display control • Initialize user interface (menus, touch screen) • Initializes recording, storage, and playback of video and still images	Not Changed

Performance Data

Performance tests reviewed in K232837 were not repeated for this submission since the minor change in the surface disinfection process of the handle does not affect device performance. The device continues to meet the compliance requirements for electrical safety as specified in ISO 60601-1 including provisions for EMC safety in ISO 60601-1-2 and IEC 60601-2- 18 Medical electrical equipment — Part 2-18: *Particular requirements for the basic safety and essential performance of endoscopic equipment*.

Animal Testing

No preclinical testing of the subject device for this minor modification to the disinfection process was necessary; the microbiology testing was sufficient to determine the performance of the device.

Clinical Studies

No clinical testing of the subject device was necessary.

Conclusion

The Uro-G HD Flexible Cystoscope (subject device) and Uro-G HD Flexible Cystoscope (predicate device) have the same intended use, the same indications for use, and the same technological characteristics. The minor difference in the surface disinfection process of the model 4500 handle proposed in this submission do not raise any new issues of safety or effectiveness.

Therefore, the Uro-G HD Flexible Cystoscope is substantially equivalent to the identified predicate device.