May 4, 2021

UroViu Corporation
Thomas Lawson, Ph.D.
Vice President, Regulatory Affairs
5337 - 145th Place SE
Bellevue, WA 98006

Re: K202921
Trade/Device Name: Uro-G Cystoscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: April 1, 2021
Received: April 2, 2021

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 (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,

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202921

Device Name
Uro-G Cystoscope

Indications for Use *(Describe)*
The Uro-G flexible cystoscope has been designed for endoscopic diagnosis and infusion of irrigating fluid 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 5337 145th Place SE Bellevue, WA 98006
FDA Registration Number	Not assigned yet
Correspondence Person	Thomas Lawson, PhD
Contact Information	Email: thom@uroviu.com
Date Prepared	16 November 2020

Proposed Device

Trade Name	Uro-G Cystoscope
Common Name	Uro-G
Regulation Number and Classification Name	21 CFR§876.1500, Endoscope and Accessories
Product Code	FAJ
Regulatory Class	II

Predicate Device

Trade Name	Uro-V Cystoscope
Common Name	Uro-V
Premarket Notification	K171500
Regulation Number and Classification	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.	

Reference Device

Trade Name	U-Scope 8000 System with HSC+EMB Cannula
Common Name	U-Scope 8000
Premarket Notification	K132384

Regulation Number and Classification	21 CFR§884.1690, Hysteroscope and accessories
Product Code	HIH
Regulatory Class	II
Note: The reference device has not been subject to a design-related recall.	

Device Description

The Uro-G cystoscope is a handheld, battery-operated portable cystoscope consisting of a sterile, disposable steerable endoscopic cannula and a reusable handle with a video monitor. The disposable cannula contains a miniature CMOS camera and a light-emitting diode (LED) illumination module at its tip and one channel for infusion of irrigating fluid. The handle is lightweight and ergonomically designed. It has a connector and locking mechanism for attaching and detaching the disposable cannula. The handle contains the remaining electronics, including a power on/off button, a button to adjust the brightness of the LED, a button to allow capture of single images or to start/stop video of the procedure, a video processor, a display unit (LCD display), a rechargeable battery, management electronics, microcontrollers, and firmware.

Indications for Use

The indications for use for the Uro-G Cystoscope is:

The Uro-G flexible cystoscope has been designed for endoscopic diagnosis and infusion of irrigating fluid within the bladder and urethra.

Comparison of Technological Characteristics with the Predicate Device

UroViu Corp. has identified the Uro-V Cystoscope (K171500, UroViu Corp.) as the predicate device. The Uro-V disposable cystoscope is substantially equivalent to the predicate device based upon the following similarities:

1. The indications for use of both the predicate device and the Uro-G cystoscope are exactly the same: symptomatic voiding dysfunction, hematuria, bladder tumor surveillance, recurrent lower urinary tract infection, and pelvic pain syndromes;

2. Both devices are introduced into the body via the urethra and then advanced to the bladder under visualization (that is, not a blind advancement);
3. Both devices have illumination and optic components to permit visualization of the urethra and bladder;
4. Both devices have the capability to view the urethra and bladder via video monitors;
5. Both devices have a working channel to allow infusion of fluids; and
6. Both devices are made from biocompatible materials.

These similarities are not surprising in that the subject and predicate devices are manufactured for UroViu Corporation by the same contract manufacturer and both use the same handle with an integrated video screen.

The U-Scope 8000 is a reference device since the same handle is used in the Uro-G cystoscope and so the electrical safety and EM compatibility testing performed in its review—K132384—is applicable for the handle of the Uro-G cystoscope. This is the only part of the submission applicable, so the U-Scope 8000 is not present in the SE comparison table.

Comparison of the Uro-G Cystoscope to the predicate device, the Uro-V Cystoscope.

	Subject Device Uro-G Cystoscope (UroViu Corp.) This Submission	Predicate Device Uro-V Cystoscope (UroViu Corp.) K171500
Device Class	II	II
FDA Product Code	FAJ	SAME
Product Classification	876.1500	SAME
Intended Use	The Uro-G Cystoscope has been designed for endoscopic diagnosis and infusion of irrigating fluid within the bladder and urethra.	The Uro-V cystoscope has been designed for endoscopic diagnosis and infusion of irrigating fluid within the bladder and urethra.

Indications for Use	Symptomatic voiding dysfunction Hematuria Bladder tumor surveillance Recurrent lower urinary tract infection Pelvic pain syndromes	SAME
Route of Advancement	Advanced to the bladder via the urethra.	SAME
Site of Use	Hospitals and physician offices	SAME
Technical Characteristics		
Components of the Set	Reusable handle with video screen Attachable cannula with a working channel and an illumination source and camera at its tip	SAME SAME
Outer Diameter (OD) of Cannula	5.5 mm	4.2 mm
Working Length of the Cannula	380 mm	254 mm
Image Transmission	Image transmitted from a video camera at the tip of the cannula to a video monitor on the handle	SAME
LCD Display Size	3.5 inches (diagonal) on the handle	SAME
Field of View	140 degrees	SAME
Focal Length	5 to 50 mm	3 to 50 mm
Direction of View from Center Axis	0 degrees (forward viewing)	SAME
Operational Characteristics		
Adjust Brightness of Illumination	Adjust by depressing a button on the handle to change settings.	SAME

Images or Video	Capture still images or video during a procedure by depressing a camera button on the handle	SAME
Cleaning, Disinfecting, and Sterilization	The handle is not provided sterile. The handle is cleaned and disinfected following instructions in the user manual (IFU). The disposable cannula is provided sterile following exposure to ethylene oxide (EO) and is for single use. It is disposed after the procedure following the institution's procedures.	SAME SAME
Frequency of Use	Handle is reusable Cannula is single patient use	SAME SAME
Duration of Use	< 24 hours	SAME
Tissue Contact Materials	Compliant with ISO 10993	SAME

These devices are further noted to be substantially equivalent by their indications for use following such determinations outlined in 21 CFR 807(f):

	Uro-V Cystoscope (predicate device)	Uro-G Cystoscope (subject device)
Intended Use	Endoscopic diagnosis and infusion of irrigating fluid within the bladder and urethra	EXACTLY THE SAME.
Indications for Use	Symptomatic voiding dysfunction Hematuria Bladder tumor surveillance Recurrent lower urinary tract infection Pelvic pain syndromes	EXACTLY THE SAME

Method of introduction into the body	Advance through the external urethral orifice, up the urethra, and into the bladder	EXACTLY THE SAME
Characteristics of equivalence of indications for use defined in 21 CFR 807(f)		
Materials	Handle: not patient contact but the outer shell is plastic Cannula: Lens – Zeonex F52R Lens coating – WR-110/N Camera housing – SS 304 Camera tip – Polycarbonate Fluid channel – Teflon (PTFE) Fluid hub - Polycarbonate Cannula shaft – Nylon Adhesives – Loctite 3211 & 3218 The cannula materials passed all applicable biocompatibility tests.	Handle: Exactly the same handle as is used with the Uro-V cannula. Cannula: Lens – Zeonix F53R Lens coating – WR-110/N Camera housing – SS 304 Camera tip – Polycarbonate Fluid channel – Teflon (PTFE) Fluid hub - Polycarbonate Cannula shaft – Thermoplastic polyurethane Distal section of cannula – Fluororubber TP Adhesives – Loctite 3211 & 3218 The cannula materials passed all applicable biocompatibility tests.
Design	Handle: contains the electronics, a video processor, a rechargeable battery, and an LCD display. The handle is curve slightly so that the user can hold it easily in one hand. Cannula: 1. Contains a miniature CMOS camera and LED illumination at its tip. 2. Contains a working channel for fluid infusion. 3. The tip can be deflected manually prior to use and rotated during a procedure. 4. Connects to the handle. 5. Provided sterile.	Handle: Exactly the same handle as is used with the Uro-V cannula. Cannula: 1. Contains a miniature CMOS camera and LED illumination module at its tip. 2. Contains a working channel for fluid infusion. 3. The tip can be deflected and rotated during a procedure 4. Connects to the handle. 5. Provided sterile.
Energy Used	Handle: powered by a 3.7 V rechargeable battery Cannula: while the tip of the cannula contains both a camera and light, the handle provides all the energy.	Handle: Exactly the same handle as is used with the Uro-V cannula. Cannula: while the tip of the cannula contains both a camera and light, the handle provides all the energy.

Operational Principles	Handle: Rather than run a cable from the cystoscope to a separate video monitor that is required of all other cystoscopes, an LCD display is integrated into the handle of UroViu cystoscopes so that the user can see directly images of the tissue and anatomical structures as the cystoscope is being advanced to 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 semi-rigid shaft with a tip angle originating by the company, so the user either navigates the urethra and looks within the bladder by rotating the cannula or can modify the angle of the tip manually before inserting the cannula into the uretheral orifice.	Handle: Exactly the same handle as is used with the Uro-V cannula. Cannula: the light at the tip illuminates the field so that the camera can transmit images back to the LCD display on the handle. The angle of the tip can be modified by moving a deflection lever on the proximal portion of the cannula, so that the user can navigate the urethra and look within the bladder by changing the tip angle after inserting the cannula into the urethral orifice.

The changes to the design of the Uro-G cystoscope centers on the cannula for this model; the handle has not changed from what it was in the Uro-V cystoscope submission (K171500). Cytoscopes are available in rigid, semi-rigid, or flexible configurations. Rigid cystoscopes typically are constructed of stainless steel and the shaft/cannula is not intended to bend or deflect. Their use requires that the physician force the non-flexible shaft up, down or to the side in order to navigate anatomic structures and obstructions within the urethra and bladder. The Uro-V cystoscope is considered a semi-rigid cystoscope in that its cannula comes out of the pouch in a pre-curved angle of 25º but the user has the ability to change the angle of the cannula before or during the procedure by manually bending the shaft of the cannula to a desired angle. As the Uro-V cystoscope is being advanced, the user can negotiate structures and obstructions my turning the cannula so that the tip advances away from structures/obstructions as it makes its way to the bladder. The Uro-G cystoscope builds on this by providing the user with the ability to change the angle of the cannula's tip by moving a deflection control lever on the proximal portion of the cannula. This capability to manipulate the cannula's tip during use improves ease of use for the physician but does not introduce a reduction in safety since the user can monitor the deflection with continual imaging so that structures can either be avoided or targeted directly if that was the purpose of the procedure.

The specific modifications with the Uro-G cannula are:

1. The outer diameter (OD) was increased to 5.5 mm. The OD of the Uro-G cystoscope was increased in order to permit an increase in the ID of the working channel to 2.2 mm. Since the urethral diameter of males ranges from 8 to 9 mm and the diameter in females averages 6 mm, this OD does not increase any risk to the device's use. This risk is further reduced since it is standard practice to infuse fluid as a cystoscope is advanced so that the urethra dilates ahead of the tip's position.
2. The working length was increased to 380 mm, which is about 5 inches longer than the Uro-V model. In clinical work, the length of the Uro-V cystoscope is adequate, but in some patients does not always allow the tip to extend to the distal bladder wall in some male patients. This increase in 5 inches permits tip access to all parts of the bladder and is comparable to the lengths of other cystocopes, which range from 370 to 400 mm.
3. The working channel has an ID of 2.2 mm.
4. The flexible tip can deflect up to 210 degrees up and 130 degrees down from a straight, non-deflected orientation. Deflection wires embedded into the wall of the cannula that compress or extend based upon movement of the deflection control lever accomplish this. Active tip deflection is a standard feature of some cystoscopes.
5. The focal length of the camera is 5 to 50 mm. It is important to maintain focus of an area of interest or surrounding tissue as a cystoscope is being advanced or when targeting a specific anatomical area. This focal length is equivalent to that of the Uro-V cystoscope and also to those of cystoscopes marketed by Storz and Olympus.

Performance Data

All necessary performance testing was conducted with bench testing and included:

- Design verification and validation studies;
- Packaging and shelf-life studies;
- Biocompatibility testing;
- Sterilization procedure validation;
- Software verification and validation; and
- Electrical safety and electromagnetic compatibility testing.

The device was found 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*, including thermal safety . Mechanical characteristics were also tested, with successful results. Due to the cannula being labeled as sterile, the cannula underwent sterilization validation and shelf life testing to confirm the label shelf life complies with the following standards.

- ISO 11135-1 *Sterilization of health care products -- Ethylene oxide -Part 1: Requirements for development, validation and routine control of a sterilization process for medical device*;
- ISO 11607 *Packaging for Terminally Sterilized Medical Devices*;
- AAMI TIR12:2010 — *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*; and
- AAMI TIR30:2011 — *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*.

Biocompatibility testing

Testing was conducted on the cannula of the Uro-G cystoscope to verify that it is compliant with biocompatibility requirements for a short duration (< 24 hours) indwelling device, as specified in ISO 10993 — Part 1, for the following tests:

- Cytotoxicity,
- Irritation,
- Sensitization, and
- Systemic Toxicity (acute).

The device passed all tests.

Animal Testing

No preclinical testing of the subject device was necessary; the bench top testing was sufficient to determine the performance of the device.

Clinical Studies

No clinical testing of the subject device was necessary; the bench top testing was sufficient to determine the performance of the device.

Conclusion

The Uro-G and Uro-V cystoscopes have the same intended use, the exact same indications for use, and have equivalent technological characteristics. The minor differences between the Uro-V and the Uro-G cystoscopes do not raise any new issues of safety or effectiveness.

Therefore, the Uro-G cystoscope is substantially equivalent to the identified predicate device.