January 30, 2018

UroViu Corporation
Thomas Lawson, Ph.D.
Vice President, Regulatory Affairs
5337 - 14th Place SE
Bellevue, WA 98006

Re: K171500
Trade/Device Name: Uro-V Cystoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: December 21, 2017
Received: December 22, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Division Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K171500

Device Name
Uro-V Cystoscope

Indications for Use *(Describe)*

The Uro-V 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITER:

UroViu Corporation
5337 14th Place SE
Bellevue, WA 98006
Phone: 650 397 5174
Fax: 888 388 1420

Contact Person: Thomas Lawson, PhD

Phone: 510 206 1794
eMail: thom@urosee.com

Submission Date: May 11, 2017

II. DEVICE

Device Name: Uro-V Cystoscope
Common Name: Cystoscope
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: II
Product Code: FAJ
Classification Panel: 78

III. PREDICATE DEVICE

VISCERA Cystovideoscope Type CYF V, Olympus American, Inc. K021074

IV. DEVICE DESCRIPTION

The UroViu Uro-V cystoscope is a handheld, battery-operated portable cystoscope. It includes a sterile, single-use disposable cannula and a reusable handle. 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 a video of the procedure, a video processor, a display unit (LCD display), a rechargeable battery, management electronics, microcontrollers, and firmware.

V. INDICATIONS FOR USE

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

VI. SUBSTANTIAL EQUIVALENCE

The Uro-V device is substantially equivalent to the VISCERA cystovideoscope Type CYF V manufactured by Olympus America, Inc. (K021074) in terms of indications for use, route the devices are introduced and advanced within the body, capability to view the urethra and bladder, having a working channel to allow instillation of fluids and introduction of endourological tools, and being made from biocompatible materials.

Table I. Comparison of the Uro-V cystoscope to the predicate device, the Olympus VISCERA Cystovideoscope Type CYF V.

	Subject device Uro-V cystoscope (this submission)	Predicate device VISCERA Cystovideoscope Type CYF V Olympus America, Inc. (K021074)
Indication for use	For endoscopic diagnosis and infusion of fluids within the bladder and urethra.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder and urethra.
Intended Use	The Uro-V cystoscope has been designed for endoscopic diagnosis and infusion of irrigating fluid within the bladder and urethra.	The cystovideoscope is used for endoscopic diagnosis and treatment within the bladder and urethra.
Route of Advancement	Advanced to the bladder via the urethra	Advanced to the bladder via the urethra

Site of use	Hospitals and physician offices	Hospitals and physician offices
Device Features		
Components	Reusable handle with video screen Attachable cannula with a working channel along its length and an illumination source and camera at its tip	Optic component with an insertion tube that has one working channel Additional components necessary for the visualization of the procedure are a light source, video system center, and display monitor, which are provided separately from the cystovideoscope itself
Cannula / Insertion Tube Outer Diameter	4.2 mm	5.5 mm
Working length	254 mm	380 mm
Working channel internal diameter	2.8 mm	2.2 mm
Illumination light source	LEDs	Xenon short-arc lamp
Image transmission	Image transmitted from a video camera at the tip of the cannula to a video monitor on the handle	Either the physician will view by looking through the cystoscope's eyepiece or by attaching a coupling lens to the eyepiece of the scope and sending that image to a video monitor in the procedure room
LCD display size	3.5 inches (diagonal) on the handle	26 inches (diagonal) on the system tower
Field of View	140 degrees	120 degrees
Focal Length	5 to 25 mm	3 to 50 mm
Direction of View from Center Axis	30 degrees	0 degrees (forward viewing)
Adjust brightness of illumination	Adjust by depressing a button on the handle to change settings	Adjust by changing settings on the ancillary light source equipment

Capture still images or video images during the procedure	Capture still images or video during procedure by depressing a camera button on the handle	Capture still images or video during procedure by use of an ancillary video system center equipment
Duration of use	≤ 24 hours	≤ 24 hours
Sterilization	The handle is not provided sterile. The handle is cleaned, disinfected, or sterilized following company instructions. The disposable cannula is provided sterile following exposure to ethylene oxide (EO) and is single use; it is disposed after the procedure following the institution's procedures.	Cystovideoscope is not provided sterile. The device is cleaned, disinfected, or sterilized following company instructions.
Frequency of use	Handle is reusable. Cannula is single patient use.	Cystovideoscope is reusable.
Tissue contact materials	Compliant with ISO 10993	Compliant with ISO 10993

Any differences between the Uro-V cystoscope and the predicate device do not alter the intended use of the Uro-V cystoscope.

VII. PERFORMANCE DATA

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

- Design verification and validation studies;
- Packaging and shelf-life studies;
- Transit testing;
- Biocompatibility testing;
- Sterilization procedure validation;
- Software verification and validation;
- Surface and edges evaluation;
- Cannula dimensions (maximum insertion portion width, minimum instrument channel width);
- Electrical safety, electromagnetic compatibility, and laser safety testing;
- Temperature testing of the surface of the insertion portion of the device; and
- Optical tests
    - Field of view accuracy

- Direction of view accuracy
- Optical resolution.

Testing was conducted on the device to verify that it is compliant with biocompatibility requirements for a short duration indwelling device, as specified in ISO 10993 — Part 1. 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.

VIII. CONCLUSION

The Uro-V cystoscope and the VISCERA Cystovideoscope Type CYF V have the same intended use and indications for use and have equivalent technological characteristics. The minor differences between the Uro-V cystoscope and the predicate device do not raise any new issues of safety or effectiveness. Therefore, the Uro-V cystoscope is substantially equivalent to the identified predicate device.