July 2, 2019

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

Re: K182876
Trade/Device Name: Uro-N Cystoscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ, FBK
Dated: June 4, 2019
Received: June 5, 2019

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,

Glenn B. Bell, Ph.D.
Assistant Division 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)*
K182876

Device Name

Uro-N Cystoscope

Indications for Use *(Describe)*

The Uro-N Cystoscope is intended for directed injection of therapeutic agents and solutions into target areas of the bladder and the lower urinary tract via a cystoscope.

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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SECTION 5. 510(k) Summary

General Information

Submitter	UroViu Corporation
Address	5337 – 145th Place SE Bellevue, WA 98006
FDA Registration Number	3007498664
Correspondence Person	Thomas Lawson, PhD Vice President, Clinical & Regulatory Affairs UroViu Corp.
Contact Information	Email: thom@uroviu.com Phone: 510-206-1794
Date Prepared	1 July 2019

Proposed Device

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

Predicate Device

Trade Name	Williams Cystoscopic Injection Needle
Common Name	Williams injection needle
Premarket Notification	K171602
Regulation Number and Classification Name	21 CFR§876.1500, Endoscope and Accessories
Product Code	FBK
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Predicate Device

Trade Name	Uro-V Cystoscope
Common Name	Uro-V cystoscope
Premarket Notification	K171500
Regulation Number and Classification Name	21 CFR§876.1500, Endoscope and Accessories

Product Code	FAJ
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Device Description

The UroViu Uro-N Cystoscope System consists of (1) a hand-held, battery operated portable endoscope contained within a reusable handle and (2) a disposable cannula with an injection needle. The fully assembled Uro-N system has overall length of 522 mm (~21 inches). The disposable cannula working length is 269 mm (~11 inches) and total length is 388 mm (~15 inches). The injection needle is 23 Ga (OD 0.635mm, ID 0.318mm). The combined handle and cannula weigh less than 1 pound. The reusable handle has a connector and locking mechanism for attaching and detaching the cannula. The catheter is sterilized by electron beam and is intended for single use only.

The Uro-N cystoscope's injection needle and cannula are in contact with patient tissue for less than 24 hours and are made of materials that are biocompatible.

This Traditional 510(k) builds on the Uro-V cystoscope cleared in K171500 (predicate device), with the added component of an injection needle, which is equivalent to the intended use of the Williams injection needle (K171602), the other predicate device.

Intended Use

The Uro-N Cystoscope is intended for directed injection of therapeutic agents and solutions into target areas of the bladder and the lower urinary tract via a cystoscope.

Both the subject device and the predicate device have the same intended use.

Comparison of Technological Characteristics with the Predicate Devices

The Uro-N Cystoscope System builds on the Uro-V cystoscope (K171500), which is a predicate device in this submission. The Williams Cystoscopic Injection Needle (K171602) is another predicate device for the injection needle component of the system that is supplied with the disposable cannula of the Uro-N cystoscope. The Williams Cystoscopic Injection Needle is used for cystoscopic-directed injection of medications and solutions into the urethra, bladder neck, and bladder wall, as is the needle component of the Uro-N cystoscope's disposable cannula.

Both the Uro-N system's injection needle component of the cannula and the Williams Cystoscopic Injection Needle are designed to inject medications and solutions into tissue

within the lower urinary system. Both devices are introduced into the urinary system through the working channel of a cystoscope that visualizes the target area for the injection and guides the needle into the target tissue. The needles for both devices are pushed into the tissue and then medication and solution are injected using a syringe that is attached to the luer lock hub at the proximal end of the needle.

The imaging component of the Uro-N cystoscope system is the same as that of the predicate device, the Uro-V cystoscope. When the cannula of the system is attached to the handle, it forms a fully functional cystoscope that provides images on a screen that the user can reference as the device is being advanced within the urinary tract. As with the Uro-V cystoscope system, the Uro-N cystoscope system's cannula has a camera at its tip that transmits images to the viewing screen on the device's handle. In this way, the user can navigate the urinary tract with minimal contact or injury to the walls of the urethra and then permit the examination of the bladder and direct injection of therapeutic agents and solutions as needed.

The imaging capability of the cannula of the Uro-N system is the same as that of the predicate device, the Uro-V system, and it is this imaging that permits directed injection of agents and solutions via the needle component that is housed in the working channel of the Uro-N system. Similarly, the second predicate device, the Williams cystoscopic injection needle, is advanced via the working channel of a cystoscope and using the images generated by the cystoscope, the Williams needle can be directed to the place within the bladder or urinary tract that is to receive the injection.

Comparison of the Uro-N Cystoscope System to the two predicate devices, the Williams Cystoscopic Injection Needle, and the Uro-V Cystoscope.

	Subject Device Uro-N Cystoscope system with injection cannula (UroViu Corp.) (This Submission)	Predicate Device Williams Cystoscopic Injection Needle (Cook Medical) K171602	Predicate Device Uro-V Cystoscope with diagnostic cannula (UroViu Corp.) K171500
Indication for Use	The Uro-N cystoscope is indicated for injection of	The Williams Cystoscopic Injection Needle is	The Uro-V cystoscope is indicated for diagnostic

	indicated for injection of therapeutic agents in the bladder and lower urinary tract for neurogenic bladder, overactive bladder syndrome, increased frequency and urgency of urination, scarring of the bladder neck, and Hunner's ulcer.	indicated for injection of therapeutic agents in the bladder and lower urinary tract.	cystoscopy of symptomatic voiding dysfunction, hematuria, bladder tumor surveillance, recurrent lower urinary tract infections, and pelvic pain syndromes.
Intended use	Directed injection of therapeutic agents and solutions into target areas of the bladder and the lower urinary tract via a cystoscope	Directed injection of therapeutic agents into the urethra, bladder neck, and bladder wall via a cystoscope	Endoscopic diagnosis and infusion of irrigating fluid within the bladder and urethra
Route of Advancement	The cannula of the cystoscope is advanced to the bladder via the urethra, with the injection needle advanced to the bladder via a working channel of the cystoscope	The injection needle is advanced to the bladder via the working channel of a cystoscope	The cannula of the cystoscope is advanced to the bladder via the urethra
Site of Use	Hospitals and physician offices	Same	Same
Device Features			
Components of the System	Reusable handle with a video screen that acts as an endoscope Attachable cannula with an injection needle, a working channel along its	Injection Needle with a hub	Reusable handle with a video screen that acts as an endoscope Attachable cannula with a working channel along its length and an

	length, and an illumination source and camera at its tip		illumination source and camera at its tip
Imaging Transmission	Image transmitted from a video camera at the tip of the cannula to a video monitor on the handle	No imaging component	Image transmitted from a video camera at the tip of the cannula to a video monitor on the handle
Illumination Light Source	LEDs	N/A	LEDs
LCD Monitor Display Size	3.5 inches (diagonal) on the handle	N/A	3.5 inches (diagonal) on the handle
Field of View	140 degrees	N/A	140 degrees
Focal Length	5 to 50 mm	N/A	5 to 25 mm
Direction of View from Center Axis	15 degrees	N/A	30 degrees
Electrical Safety	Class I, Type CF, defibrillation proof IEC 60601-1	N/A	Class I, Type CF, defibrillation proof IEC 60601-1
Electromagnetic compatibility	IEC 60601-1-2	N/A	IEC 60601-1-2
Software Level of Concern	Moderate	N/A	Moderate
Sterilization method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Sterility Assurance Level	10^{-6}	Same	Same
Biocompatibility of Materials	Meets ISO 10993 requirements	Same	Same
Operational Characteristics			
Length of cannula	269 mm	N/A	254 mm
Working Channel Inner Diameter	2.6 mm	N/A	2.8 mm
Needle Gauge	23 gauge	23 gauge	N/A
Needle Tip Length	12 mm	8 mm	N/A
Needle Bevel Type	Standard	Standard	N/A
Needle Material	Stainless Steel	Stainless Steel	N/A
Length of Needle Assembly	35 cm	35 cm	N/A

Procedure Site	Hospitals, clinics, and physician offices	Same	Same
Anatomical Site of Use	Bladder and lower urinary tract	Same	Same
Duration of Use	< 24 hours	Same	Same
Provided Sterile?	Yes	Yes	Yes
Sterilization Method	Disposable cannula and needle are sterile following exposure to ethylene oxide (EO) The handle is not provided sterile. The handle is cleaned and disinfected following company instructions.	Disposable needle is sterile following exposure to ethylene oxide (EO)	Disposable cannula is sterile following exposure to ethylene oxide (EO) The handle is not provided sterile. The handle is cleaned and disinfected following company instructions.
Single-use	Yes, for the cannula and the needle	Yes	Yes, for the cannula

Performance Data

The performance testing conducted establishes that the Uro-N Cystoscope and cannula do not raise new questions of the safety and effectiveness from those noted for the Uro-V Cystoscope cleared under K171500.

Biocompatibility testing

The Uro-N Cystoscope and cannula are manufactured from materials reviewed in K171500. The only new material is a stainless steel needle, which passed cytotoxicity testing.

Electrical safety and electromagnetic compatibility (EMC)

The predicate and subject devices comply with IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC, which was reviewed and cleared in K171500.

Software Verification and Validation Testing

There was no change to the software for the subject device from the predicate device reviewed and cleared in K171500.

Mechanical Testing

The mechanical testing of the subject device included:

- Simulated use testing;
- Mechanical testing (bending, pulling, torque, and presence of leaks);
- Temperature at the surface of the tip testing;
- Field of view testing;
- Direction of view testing; and
- Image quality testing.

Animal Testing

No animal testing of the subject device was necessary.

Clinical Studies

No clinical testing of the subject device was necessary.

Conclusion

The information submitted in this premarket notification confirms that the Uro-N Cystosope raises no new questions of safety and effectiveness and that it is substantially equivalent to the predicate devices.