



October 16, 2025

UroViu Corporation
Thomas Lawson
Director, Regulatory Affairs
4546 El Camino Real
Suite 214
Los Altos, California 94022

Re: K253226
Trade/Device Name: UV5000W Handle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: September 29, 2025
Received: September 29, 2025

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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

Indications for Use

Submission Number (if known)

K253226

Device Name

UV5000W Handle

Indications for Use (Describe)

The UV5000W Handle is to be used with UroViu Cannula Uro-G HD, Uro-G, Uro-V, Uro-N, and Hystero-V and is intended to be used to permit viewing of the urethra and bladder or cervical canal and uterine cavity for the purpose of performing diagnostics.

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

General Information

Submitter	UroViu Corporation
Address	4546 El Camino Real Suite 214 Los Altos, CA 94022
Correspondence Person	Thomas Lawson, PhD Director, Regulatory Affairs
Contact Information	Email: thom@uroviu.com Phone: 510-206-1794
Date Prepared	October 15, 2025

Proposed Device

Trade Name	UV5000W Handle
Common Name	Endoscope and accessories
Regulation Number and Classification Name	21 CFR§876.1500 Cystoscope and Accessories, Flexible/Rigid
Product Code	FAJ
Regulatory Class	II
Note: This is the first 510(k) submission for this device.	

Predicate Device

Trade Name	UV5000 Handle
Common Name	Endoscope and accessories
Premarket Notification	K250797
Regulation Number and Classification Name	21 CFR§876.1500 Cystoscope and Accessories, Flexible/Rigid
Product Code	FAJ
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Device Description

The UV5000W Handle is a component of UroViu cystoscope and hysteroscope systems. The UroViu Cannula Uro-G HD, Uro-G, Uro-V, Uro-N, and Hystero-V connect to the UV5000W Handle to become an endoscopic system that is intended to allow visualization of the urethra, bladder, cervical canal, and uterine cavity for the purpose of performing diagnostics. This 510(k) discloses the modifications

made to the UV5000 Handle (K250797) with the capability of transmitting the images captured wirelessly to an external monitor.

Indications for Use

The indication for use for the UV5000W Handle is:

The UV5000W Handle is to be used with UroViu Cannula Uro-G HD, Uro-G, Uro-V, Uro-N, and Hystero-V and is intended to be used to permit viewing of the urethra and bladder or cervical canal and uterine cavity for the purpose of performing diagnostics.

Comparison to the Predicate Device

The focus of this Traditional 510(k) is the Handle component of the UroViu cystoscope and hysteroscope systems that were reviewed in previous 510(k) submissions. The UV5000W Handle is substantially equivalent to the UV5000 Handle based upon the following equivalences:

1. The intended use of both devices is the same.
2. Both devices provide the means for the physician to view the urethra and bladder or cervical canal and uterine cavity via the video monitor that is integrated into the body of the handle.

Table 1 shows the comparison of the UV5000W Handle (the subject of this submission) to the predicate device, the UV5000 Handle. The similarities between the two devices satisfy the criteria for a 510(k) notice.

Table 1. Comparison of the UV5000W Handle to the predicate device, the UV5000 Handle.

	Subject Device UV5000W Handle UroViu Corp. (This submission)	Predicate Device UV5000 Handle UroViu Corp. K250797	Equivalence
Device Overview			
Device Class	II	II	Same
FDA Product Code	FAJ	FAJ	Same
Product Classification	21 CFR 876.1500	21 CFR 876.1500	Same
Intended Use	Used to permit viewing of the urethra and bladder or cervical canal and uterine cavity for the purpose of performing diagnostics	Used to permit viewing of the urethra and bladder or cervical canal and uterine cavity for the purpose of performing diagnostics	Same
Indication for Use	The UV5000W Handle is to be used with UroViu Cannula Uro-G HD, Uro-G, Uro-V, Uro-N, and Hystero-V and is intended to be used to permit viewing of the urethra and bladder or cervical canal and uterine cavity for the purpose of performing diagnostics.	The UV5000 Handle is to be used with UroViu Cannula Uro-G HD, Uro-G, Uro-V, Uro-N, and Hystero-V and is intended to be used to permit viewing of the urethra and bladder or cervical canal and uterine cavity for the purpose of performing diagnostics.	Same
Contraindications	As described in each UroViu cannula's instructions for use	As described in each UroViu cannula's instructions for use	Same

Technical Characteristics			
Device Identity	UV5000W	UV5000	N/A
Components	<ul style="list-style-type: none"> • 1 piece handle • 1 piece charging cradle • 1 piece USB cable • 1 Wireless Relay 	<ul style="list-style-type: none"> • 1 piece handle • 1 piece charging cradle • 1 piece USB cable 	<p>Equivalent</p> <p>The wireless relay does not affect the intended use of the UV5000W Handle</p>
Length	178 mm	178 mm	Same
Diameter	38 mm	38 mm	Same
Weight	345 g	345 g	Same

Monitor	5 inches diagonal 125.4 mm horizontal 91.4 mm vertical	5 inches diagonal 125.4 mm horizontal 91.4 mm vertical	Same
Input format	RGB	RGB	Same
Effective pixels	1280 x 720	1280 x 720	Same
LCD resolution	1024 x 768	1024 x 768	Same
LCD display resolution	0.8 million pixels	0.8 million pixels	Same
Power supply	21700 Lithium Ion rechargeable battery	21700 Lithium Ion rechargeable battery	Same
Voltage of fully charged battery	3.63 V	3.63 V	Same

Time to obtain full charge	4 hours	4 hours	Same
Operating time after fully charged	2 hours	2 hours	Same
Battery capacity	4900 mA	4900 mA	Same

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	Same
Operational Characteristics			
Electrical Safety	IEC 60601-1 & IEC 60601-2-18 compliant	IEC 60601-1 & IEC 60601-2-18 compliant	Same

EMC	IEC 60601-2 compliant	IEC 60601-2 compliant	Same
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	Same
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	Same

Cleaning, disinfecting, and sterilizing	The handle is not sterile.	The handle is not sterile.	Same
	<p>The handle is cleaned and disinfected following directions in the instructions for use (IFU):</p> <ul style="list-style-type: none"> • 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 	<p>The handle is cleaned and disinfected following directions in the instructions for use (IFU):</p> <ul style="list-style-type: none"> • 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 	Same
	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	Same

Frequency of use	Reuseable	Reusable	Same
Duration of use	< 24 hours	< 24 hours	Same
Location of use	Hospitals and physician offices	Hospitals and physician offices	Same

Mechanism of Action			
Operating Principles	<p>Rather than run a cable from the cystoscope to a separate video monitor as is required for all other cystoscopes, the LCD monitor is integrated into the body of the handle of the UroViu cystoscope & hysteroscope system so that the user can see images of the tissue and anatomical structures directly and in real time as the cannula is being advanced to and within the bladder or the cervical canal and uterine cavity.</p> <p>In addition, the image can be transmitted to an external monitor via WIFI with the use of a separate wireless relay device.</p>	<p>Rather than run a cable from the cystoscope to a separate video monitor as is required for all other cystoscopes, the LCD monitor is integrated into the body of the handle of the so that the user can see images of the tissue and anatomical structures directly and in real time as the cystoscope or hysteroscope is being advanced to and within the bladder or the cervical canal and uterine cavity .</p>	<p>Equivalent</p> <p>WIFI transmission of the images to an external monitor does not alter the intended use of the Handle</p>
Performance Testing			
Bench testing for Image Quality	Pass	Pass	Same
Battery change and discharge test	Pass	Pass	Same
15-month service life	Pass	Pass	Same
Software (SW)			
SW version	1.0.100	1.0	<p>Equivalent</p> <p>The UV5000W SW version was developed separately to permit wireless transmission but it used version 1.0</p>

			for the UV5000 Handle as reference.
Level of Concern	Moderate	Moderate	Same
General functions of the software	<ul style="list-style-type: none"> • Initialize and setup video processing software • Initialize LCD display control • Initialize user interface (menus, touch screen) • Initialize recording, storage, and playback of video and still images • Facilitate wireless transmission of images to an external monitor 	<ul style="list-style-type: none"> • Initialize and setup video processing software • Initialize LCD display control • Initialize user interface (menus, touch screen) • Initialize recording, storage, and playback of video and still images 	Equivalent

Performance Data

All necessary performance testing were conducted:

- Tip temperature during use
- Cybersecurity
- 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.

Preclinical (Animal) Studies

Bench testing was sufficient to demonstrate performance of the device.
No preclinical testing of the subject device was necessary.

Clinical Studies

Bench testing was sufficient to demonstrate performance of the device.
No clinical testing of the subject device was necessary.

Conclusion

The information submitted in this premarket notification confirms that the minor differences between the UV5000W Handle and the predicate raise no new questions of safety and effectiveness. Therefore, the UV5000W Handle is substantially equivalent to the identified predicate device.