September 11, 2025

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

Re: K250797
Trade/Device Name: UV5000 Handle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: March 14, 2025
Received: July 30, 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: 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 R. Kreitz -S

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*

K250797

Device Name
UV5000

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D)  [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# 510(k) SUMMARY

## General Information

| | |
|---|---|
| Submitter | UroViu Corporation |
| Address | 4546 El Camino Real<br>Suite 214<br>Los Altos, CA 94022 |
| Correspondence Person | Thomas Lawson, PhD<br>Director, Regulatory Affairs |
| Contact Information | Email: thom@uroviu.com<br>Phone: 510-206-1794 |
| Date Prepared | September 9, 2025 |

## Proposed Device

| | |
|---|---|
| Trade Name | UV5000 Handle |
| Common Name | Endoscope and accessories |
| Regulation Number and Classification Name | 21 CFR§876.1500<br>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 | Uro-G HD Flexible Cystoscope |
| Common Name | Endoscope and accessories |
| Premarket Notification | K232837 |
| Regulation Number and Classification Name | 21 CFR§876.1500<br>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 Uro-G Cystoscope System is comprised of a cannula and handle 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 handle of the Uro-G HD Cystoscope System (K232837), UV5000 Handle. The Uro-G HD Flexible Cystoscope System 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.

**Indications for Use**

The indication for use for the UV5000 Handle is:

> 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.

**Comparison to the Predicate Device**

The focus of this Traditional 510(k) is the handle component of the Uro-G HD Flexible Cystoscope, which was reviewed in K232837 as the 4500 Handle. The UV5000 Handle is substantially equivalent to the U4500 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 via the video monitor that is integrated into the body of the handle.

Table 1 shows the comparison of the UV5000 Handle (the subject of this submission) to the predicate device, the 4500 Handle of the Uro-G HD Flexible Cystoscope. The similarities between the two devices satisfy the criteria for a 510(k) notice.

Table 1. Comparison of the UV5000 Handle to the predicate device, the 4500 Handle of the Uro-G HD Flexible Cystoscope.

| | **Subject Device**<br><br>**UV5000 Handle**<br>UroViu Corp.<br><br>(This submission) | **Predicate Device**<br><br>**Uro-G HD Flexible Cystoscope**<br>UroViu Corp.<br><br>K232837 | **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 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 | The Uro-G HD Flexible Cystoscope is intended for endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra | Same |

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| | for the purpose of performing diagnostics. | | |
| Contraindications | As described in each UroViu cannula instructions for use | As described in each UroViu cannula instructions for use | Same |
| | | | |
| **Technical Characteristics** | | | |
| Device Identity | UV5000 | Uro-G HD Flexible Cystoscope (4500 handle) | N/A |
| Components | • 1 piece handle<br>• 1 piece charging cradle<br>• 1 piece USB cable | • 1 piece handle<br>• 1 piece charging cradle<br>1 piece USB cable | Same |
| Length | 178 mm | 176 mm | Equivalent<br>The 2 mm difference in length does not introduce any new risk |
| Diameter | 38 mm | 36 mm | Equivalent<br>The 2 mm increase in diameter is to accommodate a different size battery but this does not introduce any new risk |
| Weight | 345 g | 264 g | Equivalent<br>The extra weight is mainly due to the increased size of the monitor and the larger capacity |

| | | | |
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| | | | battery and does not introduce any new risk |
| Monitor | 5 inches diagonal<br>125.4 mm horizontal<br>91.4 mm vertical | 4.3 inches diagonal<br>122.2 mm horizontal<br>73.9 mm vertical | Equivalent<br>The slight larger monitor makes it easier for the user to view the image and does not introduce any new risk |
| Input format | RGB | RGB | Same |
| Effective pixels | 1280 x 720 | 1280 x 720 | Same |
| LCD resolution | 1024 x 768 | 800 x 480 | Equivalent<br>Increased resolution does not introduce any new risk |
| LCD display resolution | 0.8 million pixels | 0.4 million pixels | Equivalent<br>Increased resolution does not introduce any new risk |
| Power supply | 21700 Lithium Ion rechargeable battery | 18650 Lithium Ion rechargeable battery | Equivalent<br>The higher power supply necessary for the increased power consumption but it does not introduce any new risk in that it is compliant with IEC 60601-1 & 60601-2-18 |
| Voltage of fully | 4.2 V | 3.7 V | Equivalent |

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| charged battery | | | The 0.5 V increase in power supply is necessary for the increased power consumption but it does not introduce any new risk in that it is compliant with IEC 60601-1 & 60601-2-18 |
| Time to obtain full charge | 4 hours | 4 hours | Same |
| Operating time after fully charged | 2 hours | 2 hours | Same |
| Battery capacity | 5000 mA | 3100 mA | Equivalent The higher capacity is necessary for the increased power consumption but it does not introduce any new risk in that it is compliant with IEC 60601-1 & IEC 60601-2-18 |
| 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- | IEC 60601-1 & | Same |

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| | 2-18 compliant | IEC 60601-2-18 compliant | |
| 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.<br><br>The handle is cleaned and disinfected following directions in the instructions for use (IFU):<br>• Wipe the surface with a Super Sani-Cloth or CaviWipe towelette<br>• Surface to remain visibly wet for 3 minutes<br>• After 3 minutes, allow the handle to air dry for 5 minutes<br><br>Wet a sterile pad with sterile water and wipe all exposed surfaces of the handle. | The handle is not sterile.<br><br>The handle is cleaned and disinfected following directions in the instructions for use (IFU):<br>• Wipe the surface with a Super Sani-Cloth or CaviWipe towelette<br>• Surface to remain visibly wet for 3 minutes<br>• After 3 minutes, allow the handle to air dry for 5 minutes<br><br>Wet a sterile pad with sterile water and wipe all | Same<br><br>Same<br><br>Same |

| | | | |
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| | | exposed surfaces of the handle. | |
| 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 | 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 system 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 within the bladder. | 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 system 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 within the bladder. | Same |
| **Performance Testing** | | | |
| Bench testing for Image Quality | Pass | Pass | Same |
| Battery change and discharge test | Pass | Pass | Same |
| 3 Year service life | Pass | Pass | Same |
| **Software (SW)** | | | |
| SW version | 1.0 | 4.1 | This SW version was developed separately but it used version 4.1 |

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| | | | for the 4500 Handle as reference. |
| Level of Concern | Moderate | Moderate | Same |
| General functions of the software | • Initialize and setup video processing software<br>• Initialize LCD display control<br>• Initialize user interface (menus, touch screen)<br>• Initialize recording, storage, and playback of video and still images | • Initialize and setup video processing software<br>• Initialize LCD display control<br>• Initialize user interface (menus, touch screen)<br>• Initialize recording, storage, and playback of video and still images | Same |

**Performance Data**

All necessary performance testing as conducted:

- Field of view accuracy
- Direction of view
- Depth of Field
- Noise and Dynamic Range
- Image distortion
- Image resolution
- Image uniformity
- Color performance
- 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.

**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 UV5000 Handle and the predicate raise no new questions of safety and effectiveness. Therefore, the UV5000 Handle is substantially equivalent to the identified predicate device.