June 7, 2024

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

Re: K232837
Trade/Device Name: Uro-G HD Flexible Cystoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: September 10, 2023
Received: September 14, 2023

Dear Thom 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.

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
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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)*
K232837

Device Name
Uro-G HD Flexible Cystoscope

Indications for Use *(Describe)*
The Uro-G HD Flexible Cystoscope is intended for endoscopic diagnosis and infusion of irrigating fluids 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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SECTION 5.

510(k) SUMMARY

General Information

Submitter	UroViu Corporation
Address	UroViu Corporation 4546 El Camino Real Suite 214 Los Altos, CA 94022
FDA Registration Number	3015042209
Correspondence Person	Thomas Lawson, PhD
Contact Information	Email: thom@uroviu.com Phone: 510-206-1794
Date Prepared	7 September 2023

Proposed Device

Trade Name	Uro-G HD Flexible Cystoscope
Common Name	Uro-G HD
Regulation Number and Classification Name	21 CFR§876.1500, Endoscope and Accessories
Product Code	FAJ
Regulatory Class	II
Note: This is the first submission for this model of UroViu cystoscope.	

Predicate Device

Trade Name	Uro-G Flexible Cystoscope
Common Name	Uro-G
Premarket Notification	K202921
Regulation Number and Classification Name	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.	

Device Description

This Special 510(k) discloses the modifications made to the Uro-G Flexible Cystoscope System (K202921) so that the user has an option for a flexible cystoscope with high-definition imaging. 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. The fully assembled Uro-G HD Cystoscope System—cannula and handle—has an overall length of 630 mm (approximately 25 inches). The disposable cannula's working length is 380.2 mm (approx. 15 inches) and a total length of 406 mm, from tip to connector. The cannula's maximum width is 5.6 mm and it has a connector for attaching and detaching to the handle.

Indications for Use

The indications for use statement for the Uro-G HD Flexible Cystoscope is:

> The Uro-G HD Flexible cystoscope has been designed for endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra

Comparison of Technological Characteristics with the Predicate Device

UroViu Corp. has identified the Uro-G Cystoscope (K202921, UroViu Corp.) as the predicate device. The Uro-G HD Flexible Cystoscope is substantially equivalent to the predicate device based upon the following similarities:

1. The intended use of both devices is exactly the same.
2. The indications for use of both the predicate device and the Uro-G HD cystoscope are exactly the same: symptomatic voiding dysfunction, hematuria, bladder tumor surveillance, recurrent lower urinary tract infection, and pelvic pain syndromes;
3. Both devices are introduced into the body via the urethra and then advanced to the bladder under visualization (that is, not a blind advancement);
4. Both devices have illumination and optic components to permit visualization of the urethra and bladder;
5. Both devices have the capability to view the urethra and bladder via the video monitor mounted on the handle of the device;

6. Both devices have a working channel to allow infusion of fluids and introduction of instruments; and
7. Both devices are made from biocompatible materials.

The specific modifications of Uro-G cannula and 3500 model handle to become the Uro-G HD cannula and 4500 model handle are:

1. The cannula of the modified device is 0.1 mm wider than the predicate device—5.6 mm v. 5.5 mm—to accommodate the slightly larger cable that carries image information from the camera at the tip of the cannula to the handle's LCD monitor. 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 CMOS module has a higher resolution – 0.7 million pixels—for HD imaging than the current module at 0.3 million pixels to facilitate HD imaging.
3. The sensor on the CMOS camera has higher resolution – 1280 x 720 pixels – than the camera on the Uro-G cannula (640 x 480) to facilitate HD imaging.
4. The field of view is 20º smaller—100º in the Uro-G HD v. 120º in the Uro-G cystoscope, but within the range of endoscopes and other cystoscopes.
5. The LCD monitor on the handle is slightly larger at 4.5 inches (diagonal) versus 3.5 inches of the 3500 handle. This larger monitor added 44 g/1.6 oz to the weight of the handle.
6. The effective pixels and resolution of the LCD monitor on the handle are higher in order to accommodate HD imaging.
7. The steps for surface disinfecting of the handle has been modified from allowing the handle to air dry for 20 minutes to an unspecified time by saying "Allow the handle to air dry." This does not affect the efficiency of the disinfection process.
8. The instructions for use (IFU) and packaging labeling have been updated for changes in product parameters related to displaying an HD image.
9. The software has been updated to perform the following:
    - Updated the startup logo that is displayed on the screen.
    - Updated the image parameters for Uro-G HD v. standard definition.
    - Play files in reverse order.
    - During recording, if the signal is interrupted, the file will be saved, and the system will return to live view.
    - Added zoom in / zoom out functionality.
    - Changed the replay file list to display in reverse order (latest files at the top).

Table 1. Summary of Indications for Use, Technological Characteristics, Mechanisms of Action, Anatomical Sites of Use, Performance Testing, Manufacturing and Software of the Subject Device Compared to the Predicate Device.

	Predicate Device Uro-G (UroViu Corp.) K202921	Subject Device Uro-G HD (UroViu Corp.) This Submission	Changed or Not Changed
Device Overview			
Device Class	II	II	Not Changed
FDA Product Code	FAJ	FAJ	Not Changed
Product Classification	21 CFR 876.1500	21 CFR 876.1500	Not Changed
Indication for Use	Generally recognized indications for cystoscopy include: • Symptomatic voiding dysfunction • Hematuria • Bladder tumor surveillance • Recurrent lower urinary tract infections • Pelvic pain syndromes	Generally recognized indications for cystoscopy include: • Symptomatic voiding dysfunction • Hematuria • Bladder tumor surveillance • Recurrent lower urinary tract infections • Pelvic pain syndromes	Not Changed
Intended use	Endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra	Endoscopic diagnosis and infusion of irrigating fluids within the bladder and urethra	Not Changed
Contraindications	• Evidence of ongoing UTI	• Evidence of ongoing UTI	

	• Overwhelming coagulopathy • Impassable urethral structures	• Overwhelming coagulopathy • Impassable urethral structures	Not Changed
Anatomical Site of Use	Lower urinary tract—urethra & bladder	Lower urinary tract—urethra & bladder	Not Changed
Route of Advancement	Advanced to the bladder via the urethra	Advanced to the bladder via the urethra	Not Changed
Components of the System	Reusable Handle with a video screen integrated in its body Attachable Cannula with a working channel and an illumination source and camera at its tip	Reusable Handle with a video screen integrated in its body Attachable Cannula with a working channel and an illumination source and camera at its tip	Not Changed Not Changed
Technical Characteristics			
Cannula			
Device Identity	Uro-G	Uro-G HD	N/A
Cannula working length	380.2 mm	380.2 mm	Not Changed
Total length (tip to connector)	406 mm	406 mm	Not Changed
Number of ports	2	2	Not Changed
Working channel minimum width	2.2 mm	2.2 mm	Not Changed
Maximum insertion width of the cannula	5.5 mm	5.6 mm	Equivalent The extra 0.1 mm in width does not introduce a new risk to use of the cannula
Tip OD	4 mm	4 mm	Not Changed
Camera			
CMOS module	0.3 million pixels	0.7 million pixels	Equivalent The higher number of pixels results in an HD image, but HD does not introduce any new risk from the

			SD image provided by the predicate
Focal length	5 mm to 50 mm	5 mm to 50 mm	Not Changed
Field of view (in air)	120 ° ± 5 °	100 ° ± 5 °	Equivalent With HD imaging, the field of view can be more narrow in order to capture details in the confined spaces within the urinary tract
Direction of view from center axis	0 ° (Forward Viewing)	0 ° (Forward Viewing)	Not Changed
Image resolution	3 lp/mm on the 1551 USAF test chart in air	3 lp/mm on the 1551 USAF test chart in air	Not Changed
Image distortion	< 15% at x and y direction	< 15% at x and y direction	Not Changed
Sensor on the CMOS camera	640 x 480 pixels	1280 x 720	Equivalent The higher numbers are the basis for the imaging being HD but an HD image does not introduce a new risk nor increase an established risk
Tip angulation range	Up 210 ° ± 5 ° Down 130 ° ± 5 °	Up 210 ° ± 5 ° Down 130 ° ± 5 °	Not Changed
Tip angulation radius	Up less than 15 mm Down less than 20 mm	Up less than 15 mm Down less than 20 mm	Not Changed
Lever force for angulation	< 2.2 lbs	< 2.2 lbs	Not Changed
Rotation torque	< 3.5 inch-lb	< 3.5 inch-lb	Not Changed
Rotation angle	Cannula torques when rotate clockwise and counter-clockwise less than 90 °	Cannula torques when rotate clockwise and counter-clockwise less than 90 °	Not Changed
Fluid lumen cross-section	4.84 mm^2	4.84 mm^2	Not Changed
Distension flow through the working channel	>120 mL/min	>120 mL/min	Not Changed

Light source	LED Luminous flux at 25 mm focal length: 520 lumens	LED Luminous flux at 25 mm focal length: 520 lumens	Not Changed
Tip temperature when LEDs are on	< 41º C	< 41º C	Not Changed
Power rating of source	90 mW	90 mW	Not Changed
Provided Sterile	Yes	Yes	Not Changed
Sterilization method	Ethylene oxide	Ethylene oxide	Not Changed
Sterility Assurance Level	10^{-6}	10^{-6}	Not Changed
Biocompatibility of Materials	Meets ISO 10993 requirements for external communicating device with < 24 hours of tissue contact	Meets ISO 10993 requirements for external communicating device with < 24 hours of tissue contact	Not Changed
Single Use	Yes	Yes	Not Changed
Packaging	Tyvek pouch	Tyvek pouch	Not Changed
Handle			
Device Identity	3500	4500	N/A
Length	135 mm	176 mm	Equivalent The extra length does not affect performance of the system.
Diameter	37 mm	36 mm	Equivalent The 1 mm reduction in the diameter of the handle has not impact on risk or performance of the system.
Weight	220 g	264 g	Equivalent The additional 44 g / 1.6 oz in the subject device does not introduce a new risk nor affect usability,

			and for most users will be imperceptible
Video Monitor	Screen: 3.5 inches diagonal Horizontal: 103 mm Vertical: 72 mm	Screen: 4.3 inches diagonal Horizontal: 122.2 mm Vertical: 73.9 mm	Equivalent The larger size of the monitor makes it easier for the user to view the image as the device is being used and does not introduce a new risk or increase an established risk
Input format	RGB	RGB	Not Changed
Effective pixels	640 x 480	1280 x 720	Equivalent The higher numbers are the basis for the imaging being HD but an HD image does not introduce a new risk nor increase an established risk
LCD resolution	480 x 320	800 x 480	Equivalent The higher numbers are the basis for the imaging being HD but an HD image does not introduce a new risk nor increase an established risk
LCD display resolution	0.15 million pixels	0.4 million pixels	Equivalent The higher resolution is what makes the subject device HD; however, this does not introduce a new risk to the Uro-G cystoscope. Rather it provides a sharper image to the user during the procedure, which allows the user to perform diagnostic surveillance safely
Power supply	18650 Lithium Ion rechargeable	18650 Lithium Ion rechargeable	Not Changed

Voltage of fully charged battery	3.7 V	3.7 V	Not Changed
Operating time after fully charged	2 hours	2 hours	Not Changed
Battery capacity	3100 mA	3100 mA	Not Changed
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	Not Changed
Operational Characteristics			
Electrical Safety	IEC 60601-2-18 compliant	IEC 60601-2-18 compliant	Not Changed
EMC	IEC 60601-1-2 compliant	IEC 60601-1-2 compliant	Not Changed
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	Not Changed
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	Not Changed
Cleaning, disinfecting and sterilization	The handle is not sterile. The handle is cleaned and disinfected following instructions in the instructions for use (IFU) The disposable cannula is provided sterile and is for single use. It is deposed after the procedure	The handle is not sterile. The handle is cleaned and disinfected following instructions in the instructions for use (IFU) The disposable cannula is provided sterile and is for single use. It is deposed after the procedure	Equivalent Disinfection instructions have been modified as to a statement to not use until the handle is dry, without the specific time period of 20 minutes. Not Changed

	following the institution's procedures	following the institution's procedures	
Frequency of use	Handle is reusable Cannula is single use	Handle is reusable Cannula is single use	Not Changed
Duration of use	< 24 hours	< 24 hours	Not Changed
Site of Use	Hospitals and physician offices	Hospitals and physician offices	Not Changed
Mechanism of Action			
Operational Principles	Handle: Rather than run a cable from the cystoscope to a separate video monitor as is required of all other cystoscopes, an LCD display is integrated into the handle of UroViu cystoscopes 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 while within 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 flexible shaft that the user can manipulate to	Handle: Rather than run a cable from the cystoscope to a separate video monitor as is required of all other cystoscopes, an LCD display is integrated into the handle of UroViu cystoscopes 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 while within 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 flexible shaft that the user can manipulate to	Not Changed Not Changed

	view the urethra bladder by rotating the cannula or by modifying the angle of the tip manually.	view the urethra bladder by rotating the cannula or by modifying the angle of the tip manually.	
Performance Testing			
	Testing for: • Tip angulation • Tip angulation radius • Lever force for tip angulation • Rotation torque • Rotation angles • Distention flow rate • Cannula leaking • Tip temperature • Field of view • Direction of view • Image quality	Testing for: • Tip angulation • Tip angulation radius • Lever force for tip angulation • Rotation torque • Rotation angles • Distention flow rate • Cannula leaking • Tip temperature • Field of view • Direction of view • Image quality	Not Changed
Manufacturing			
	Manufactured at a contract manufacturer with design control at UroViu Corp	Manufactured at a contract manufacturer with design control at UroViu Corp	Not Changed
Software			
SW version	2.0	4.1	N/A
Level of Concern	Moderate	Moderate	Not Changed
General Functions of the Software	• Initialize and setup video processing hardware • Initialize LCD display control • Initialize user interface (menus, touch screen) • Initializes recording,	• Initialize and setup video processing hardware • Initialize LCD display control • Initialize user interface (menus, touch screen) Initializes recording, storage,	Not Changed

	storage, and playback of video and still images	and playback of video and still images	
General Parameters of Action	The transfer of sensor data (MIPI) to ISP for image processing into digital data (RGB) and then transfer to the LCD module for visual display	The transfer of sensor data (MIPI) to ISP for image processing into digital data (RGB) and then transfer to the LCD module for visual display	Not Changed
Block Diagram (in text)	The Main Board performs imaging functionality. The sensor in the Cannula is a digital camera. This signal is passed down in the Main Board to the DSP processor, which is the main processor. The MIPI sensor data (serial) is converted to parallel data through STMIPI. The parallel data is then fed to the DSP via FPGA1. The output image data from DSP is formatted into serial RGB666 signal and transferred to FPGA2 which converts the signal to parallel RGB666 format to be displayed on the LCD Monitor. Physically overlaid on the monitor is a touch screen. The touch screen data is conveyed back to	The Main Board performs imaging functionality. The sensor in the Cannula is a digital camera. This signal is passed down in the Main Board to the DSP processor, which is the main processor. The MIPI sensor data (serial) is converted to parallel data through STMIPI. The parallel data is then fed to the DSP via FPGA1. The output image data from DSP is formatted into serial RGB666 signal and transferred to FPGA2 which converts the signal to parallel RGB666 format to be displayed on the LCD Monitor. Physically overlaid on the monitor is a touch screen. The touch screen data is conveyed back to	Equivalent The block diagram is the same except that the Sensor in the 3500 handle is CI362 and the Sensor in the 4500 handle is CI1310.

	the DSP processor over an I2C bus. On the Main Board, the DSP processor is attached to DDR RAM memory. The Main Board also has the power electronics (Battery Charger, voltage converter/regulator, and power switch). There is also flash memory for holding image data.	the DSP processor over an I2C bus. On the Main Board, the DSP processor is attached to DDR RAM memory. The Main Board also has the power electronics (Battery Charger, voltage converter/regulator, and power switch). There is also flash memory for holding image data.	
Specific Parameters of Action for the Software Version	v2.0 is an update to the original v1.1 that was completed under internal documentation (*i.e.*, Letter to File) 1. New added "no connection warning" to be displayed as necessary. 2. When exiting preview, the LED will turn off. When entering preview, the LED will first turn on, and then after a 200ms delay, the sensor will be initialized. 3. Optimized the I2C read-write protocol to reduce the probability of freezing. 4. Optimized battery level display, increasing	All of the parameters listed for v2.0 with the following added: 1. Updated the startup logo. 2. Updated the image parameters for Uro-G HD. 3. Play files in reverse order. 4. During recording, if the signal is interrupted, the file will be saved, and the system will return to live view. 5. Added zoom in / zoom out functionality. 6. Changed the replay file list to display in reverse order (latest files at the top).	Equivalent The updates from v2.0 to v4.1 do not introduce a new risk to operation of the Uro-G HD system

	the refresh rate of the battery icon. 5. Changed to a 2-second-long press for power-off, and when clicking the power button, a 'beep' sound prompt will occur. 6. Fixed the bug on the replay page where the video was not displaying the recording time. 7. Modified the 'No Connection' warning message to allow input of Case ID without a connected scope. 8. Added hot-swapping functionality. 9. Modified the startup screen to feature a dual-logo new startup screen. 10. Added the Hysterovue logo to the home page on the monitor.		

Performance Data

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

- Measurement of outer diameter of the cannula;
- Image quality against the 1951 USAF test chart;

- Image distortion against an Image Distortion Target chart;
- Specification review and analysis of CMOS camera;
- Field of view;
- Resolution of the LCD monitor;
- Disinfection procedure;
- Software verification testing.
- 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.

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).

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-G HD Flexible Cystoscopes have the same intended use, the same

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

Therefore, the Uro-G HD Flexible Cystoscope is substantially equivalent to the identified predicate device.