July 1, 2024

HUGER Medical Instrument Co., Ltd.
Shen Junjie
RA Specialist
Building 26A, No. 3825, Xinzhuan Highway, Dongjing Town,
Songjiang District
Shanghai, 201619
CHINA

Re: K241639
Trade/Device Name: Single-use Video Ureterorenoscope (SVU-220US)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Received: June 7, 2024

Dear Shen Junjie:

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.

The FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is

consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241639

Device Name
Single-use Video Ureterorenoscope (SVU-220US)

Indications for Use *(Describe)*
Single-use Video Ureterorenoscope is intended to connect with Medical Video Processor to provide video imaging.

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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HUGER
ENDOSCOPY SYSTEM

Section 2: 510 (k) Summary

SVU-220US
Single-use Video Ureterorenoscope

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. **Date of Preparation:** 02/16/2023

2. **Submitter Identification**

HUGER Medical Instrument Co., Ltd.
Building 26A, No. 3825, Xinzhuan Highway, Dongjing Town, Songjiang District, 201619, Shanghai, China.

Establishment Registration Number: Not yet registered.

Contact Person: Shen Junjie
Position: RA Specialist
Tel: +86-021-67626235
Fax: +86-021-67691721
Email: junjie.shen@huger.cn

3. **Identification of Proposed Device**

Trade Name/ Common Name: Single-use Video Ureterorenoscope

Classification Name: Ureteroscope and Accessories, Flexible/rigid
Classification: II
Product Code: FGB
Regulation Number: 21CFR 876.1500
Review Panel: Gastroenterology/Urology

Intended use/ Indications for Use:
Single-use Video Ureterorenoscope is intended to connect with Medical Video Processor to provide video imaging.

Device Description:
The Single-use Video Ureterorenoscope (SVU-220US) is intended to be used with the HUGER'S Medical Video Processor (cleared in K230475). The Single-use Video Ureterorenoscope is a single use device. The Single-use Video Ureterorenoscope is consist of distal end, bending section, insertion portion, operational portion and connection portion. The Single-use Video Ureterorenoscope is a single-channel endoscope. Only one instrument channel is in the distal end

of the endoscope.

The Single-use Urology Videoscope is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of three years.

4. Identification of Predicate Device

510(k) Number: K230475

Product Name: Medical Video Endoscope system

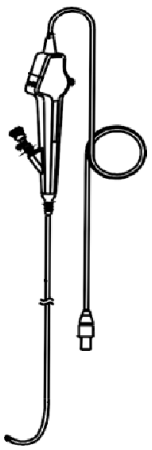
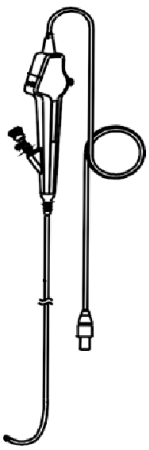
Information on Legally Marketed Predicate Device:

Predicate#	Predicate Trade Name	Product Code
K230475	Single-use Video Ureterorenoscope (model: SVU-220)	FGB

Differences between the subject device and predicate device

The subject and predicate devices have the same fundamental technology, optical and physical characteristics, materials, structure, sterilization methods and components. The only difference is the deflection at the distal end. A comparison between the proposed device and predicate devices is included in the table below:

Comparison Table: Subject vs. Predicate Device (SVU-220US vs. SVU-220)

ITEM	**Subject Device Single-use Video Ureterorenoscope (model: SVU-220US)**	**Predicate Device Single-use Video Ureterorenoscope (model: SVU-220)**	**Remark**
Product Code	FGB	FGB	Same
Regulation No.	876.1500	876.1500	Same
Class	II	II	Same
Structure and components			Same
Indications for Use	Single-use Video Ureterorenoscope is intended to connect with Medical Video	Medical Video Endoscope System has been designed to be used with endo-therapy	Similar, refer to difference analysis ①

	Processor to provide video imaging	accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney. Medical Video Processor is intended to be used in conjunction with the endoscopes to enhance and display the image of the field of view of the endoscope on the monitor, and also provides functional supply for the endoscope. Single-use Video Ureterorenoscope is intended to connect with Medical Video Processor to provide video imaging.	below
Single use/ Reuse	Single use	Single use	Same
Sterile	Yes	Yes	Same
Anatomical Site	Urinary tract and interior of the kidney	Urinary tract and interior of the kidney	Same
Where used	Hospital	Hospital	Same
Label/Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Performance of Single-use Video Ureterorenoscope			
Scope type	Flexible	Flexible	Same
Field of view	120°	120°	Same
Direction of view	0°	0°	Same
Depth of field	2-100mm	2-100mm	Same
Sensor type	CMOS	CMOS	Same
Max. outer diameter of insertion section	2.9mm	2.9mm	Same
Up/down deflection	Up:270° Down: 270°	Up:270° Down: 270°	Same
Work length	700mm	700mm	Same
Minimum instrument channel width	1.2mm	1.2mm	Same
Product Performance	Comply with ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 8600-7	Comply with ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 8600-7	Same
Deflection	Refer to figure 1 below	Refer to figure 2 below	Different,

			refer to difference analysis ② below
Patient-contact component and material			
Bending section	Thermoplastic Polyurethane (TPU)	Thermoplastic Polyurethane (TPU)	Same
Insertion section	Thermoplastic Polyurethane (TPU)	Thermoplastic Polyurethane (TPU)	
Distal End Section	Polycarbonate (PC)	Polycarbonate (PC)	
CMOS Front End	Glass	Glass	
Instrument channel	Pebax and Barium sulfate	Pebax and Barium sulfate	
Tuohy Borst Valve Assembly	Polycarbonate (PC) and Polyethylene copolymer	Polycarbonate (PC) and Polyethylene copolymer	
UV Glue	Epoxy resin	Epoxy resin	
Biocompatibility	Cytotoxicity: ISO 10993-5	Cytotoxicity: ISO 10993-5	Same
	Sensitization: ISO 10993-10	Sensitization: ISO 10993-10	
	Irritation: ISO 10993-10	Irritation: ISO 10993-10	
Sterilization method			
Method	EO sterilization	EO sterilization	Same
SAL	10^{-6}	10^{-6}	Same

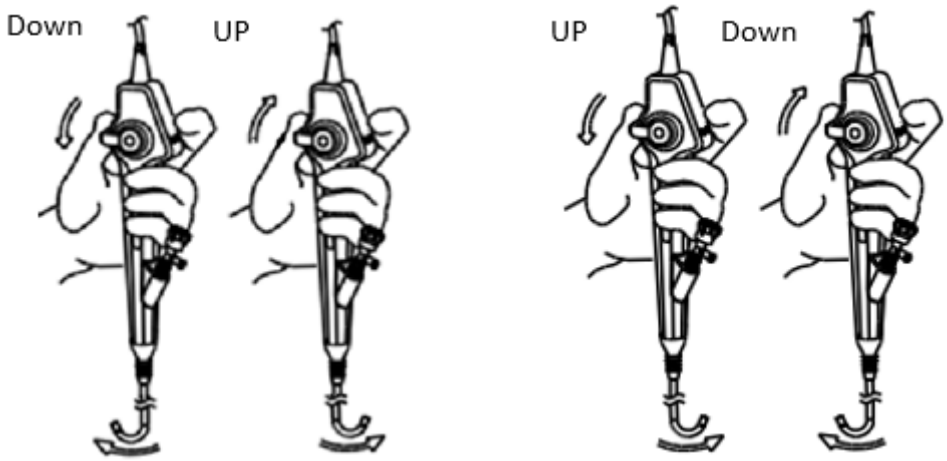
Difference analysis:

① For the difference on Indications of use, since the predicate device includes indications of use of medical video endoscope System, medical video processor and Single-use Video Ureterorenoscope, only the indications of use of single-use Video Ureterorenoscope of the predicate device has been adopted for the subject device SVU-220US. In conclusion, the indications of use of subject device is identical with that of single-use video Ureterorenoscope SVU-220 of predicate device.

② The only difference between the subject device and predicate device is deflection at the distal end. For SVU-220US, the direction of the clockwise rotation is marked “up”, and that of the counterclockwise rotation is marked as “down”. For SVU-220, the direction of the clockwise rotation is marked “down”, and that of the counterclockwise rotation is marked as “up”.

Figure 1. Deflection of subject device (SVU-220US)

Figure 2. Deflection of predicate device (SVU-220)



5. Non-Clinical Test Conclusion

Since the subject device is exactly the same as the predicate device in terms of fundamental technology, optical and physical characteristics, materials, structure, sterilization methods and components, the only difference between these models is deflection at their distal end, and through a risk analysis was completed to identify the risks associated with assembly process in production, but not in product design. HUGER Medical believed that the verification testing of Predicate device (SVU-220) can be fully covered with subject device (SVU-220US).

Therefore, the subject device also complies with the following standards:

- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ISO 8600-1:2015 Endoscopes-Medical endoscopes and endotherapy devices - Part 1: General requirements
- ISO 8600-3:1997/Amd1:2003 Optics and optical instruments -Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics
- ISO 8600-4:2014 Endoscopes - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance, including the US National Differences
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic disturbances -

Requirements and tests

- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 14971:2019 Medical Devices - Application of risk management to medical devices
- IEC 62471:2006 Photobiological safety of lamps and lamp systems

Biocompatibility testing

Since the raw materials of the subject device is exactly the same as that of predicate device The contact level of the subject device is mucosal membrane, and the contact duration is limited contact (<24 hours). Therefore, the biocompatibility testing results of the predicate device apply to the subject device. The results of the biocompatibility testing as following showed that there are no negative impacts from the materials that are used in the predicate device.

- Cytotoxicity,
- Sensitization,
- Intracutaneous,

Bench performance testing

Optical performance testing

- Photobiological safety test was performed according to IEC 62471: 2006 on predicate device;

Physical/functional performance testing

- Irrigation valve leakage test was performed on the predicate device.

Endoscope and video processor use-life testing

The optical performance comparison test was conducted on the un-aged Single-use Video Ureterorenoscope (SVU-220) and aged Single-use Video Ureterorenoscope (SVU-220). The test results demonstrate that the optical performance of the aged endoscope is similar as those of the un-aged endoscope.

6. Clinical Test Conclusion

No Clinical study is included in this submission

7. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Single-use Video Ureterorenoscope (Model: SVU-220US) is substantially equivalent to the predicate devices.