November 3, 2023

HUGER Medical Instrument Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K230475
Trade/Device Name: Medical Video Endoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: September 26, 2023
Received: September 27, 2023

Dear Diana Hong:

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,
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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)*

K230475

Device Name
Medical Video Endoscope System

Indications for Use *(Describe)*

Medical Video Endoscope System has been designed to be used with endo-therapy 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.

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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Tab #6 510(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. Sponsor Identification

HUGER Medical Instrument Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

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Tel: +86-21-22815850,
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4. Identification of Proposed Device

Trade Name: Medical Video Endoscope System;
Common Name: Flexible Urology Endoscope System

Regulation Name: Endoscope and Accessories
Classification: II
Product Code: FGB
Regulation Number: 21CFR 876.1500
Review Panel: Gastroenterology/Urology

Indications for Use:
Medical Video Endoscope System has been designed to be used with endo-therapy 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.

Device Description:
Medical Video Endoscope System is consist of a Single-use Video Ureterorenoscope and a Medical Video Processor. The proposed device has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.

Table 1 Product Model

System	Component	Model
Medical Video Endoscope System	Single-use Video Ureterorenoscope	SVU-220
	Medical Video Processor	VEP-220

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.

The Medical Video Processor is a reusable device. The Medical Video Processor is composed of a power circuit, an image processing circuit and software.

5. Identification of Predicate Device

510(k) Number: K172098
Product Name: Medical Video Endoscope system

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device 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

The contact level of the proposed device is mucosal membrane, and the contact duration is limited contact (<24 hours). The proposed endoscope was evaluated for the following tests. The results of the biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device.

- Cytotoxicity,
- Sensitization,
- Intracutaneous irritation,

Software verification and validation testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Bench performance testing

Optical performance testing

- Photobiological safety test according to IEC 62471: 2006;
- Color reproduction, Resolution, Depth of Field, Field of view, Noise, Geometric distortion, Intensity uniformity, Image frame frequency and system delay testing compared with the predicate device (K172098). The test results show that the performance of the proposed device is similar to the predicate device.

Physical/functional performance testing

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

Endoscope and video processor use-life testing

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

A use-life verification was conducted to determine the image system's use life. After accelerating aging and running, the qualitative was conducted on the video processor. The test results demonstrate that the performance of the proposed system doesn't reduced after accelerating aging and running, and the use-life statement of six years are accepted. In addition, the quantitative optical performance comparison testing was conducted on the new image processor and the image processor after accelerating aged and

running. The test results demonstrate that the optical performance of the image process after accelerating aged and running is similar as those of the new one.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 SE Comparison

ITEM	Proposed Device	Predicate Device K172098	Remark
Product Code	FGB	FGB	Same
Regulation No.	876.1500	876.1500	Same
Class	II	II	Same
Indication for Use	Medical Video Endoscope System has been designed to be used with endo-therapy 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.	The instrument has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.	Similar
Single use/ Reuse	Endoscope: Single use	Endoscope: Single use	Same

	Video Processor: Reuse	Image Processor: Reuse		
Sterile	Yes for disposable endoscope	Yes for disposable endoscope		Same
Anatomical Site	Urinary tract and interior of the kidney	Urinary tract and interior of the kidney		Same
Where used	Hospital	Hospital		Same
Main Configuration	Single-use Video Ureterorenoscope	Uscope (single-use endoscope)		Similar
	Medical Video Processor	Eview (touch PC with data processing center)		
Label/Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801		Same
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	3-50mm		Different
Sensor type	CMOS	CMOS		Same
Max. outer diameter of insertion section	2.9mm	3.2mm		Similar
Up/down deflection	Up:270° Down: 270°	Up:270° Down: 270°		Same
Work length	700mm	650mm		Similar
Minimum instrument channel width	1.2mm	1.0mm		Similar
Product Performance	Comply with ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 8600-7	Comply with ISO 8600-1		Different
Patient-contact component and material				
Bending section	Thermoplastic Polyurethane (TPU)	Sheath	SUS 304 and PEBAX	Different
Insertion section	Thermoplastic Polyurethane (TPU)	Controllable portion	SUS 304, covered with silicone rubber	
Distal End Section	Polycarbonate (PC)	Distal tip	ABS	
CMOS Front End	Glass	Working channel	Fluorinated ethylene propylene	
Instrument channel	Pebax and Barium sulfate	/		
Tuohy Borst Valve	Polycarbonate (PC) and			

Assembly	Polyethylene copolymer		
UV Glue	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	EO sterilization	EO sterilization	Same
SAL	10^{-6}	10^{-6}	Same
Medical Video Processor			
Illumination source	LED	LED	Same
Power supply	AC: 100-240V±10% 50/60 Hz	AC: 100-240V 50/60 Hz	Same
Dimension	320(W)×96(H)×370(D) mm	315(W)×187(H)×308 (D) mm	Different
Weight	9Kg	4.3 Kg	
Input power	50VA	Unknown	Different
Video signal output	DVI	HDMI	Different
Auto white balance	Automatically adjusted	Automatically adjusted	Same
Communication with endoscope	Provided	Provided	Same
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Particular requirements	Comply with IEC 60601-2-18	Comply with IEC 60601-2-18	Same

Similar Analysis 1-Indication for Use

The indication for use of the proposed device is different from that of the predicate device in expression. The indications for use of the proposed device are provided in the form of system's indications for use, video processor's indications for use and disposable endoscope's indications for use. The predicate device only provides the whole system's indications for use. The expression of the indications for use of the proposed device provides the indications for use of video processor and disposable endoscope. Many cleared endoscope systems adopted this expression form of indications for use. Both devices are used for endoscopic diagnosis and therapies within the urinary system. Based on above analysis, the indication for use of the proposed device and the predicate device is only different in expression. Therefore, the difference will not affect the new safety and effectiveness of the proposed device.

Similar Analysis 2- Main Configuration

The main configuration of the proposed device is different with the predicate device. However, it's just the different name. The Single-use Video Ureterorenoscope of the proposed device and the Uscope of the predicate device have the same function and the Medical Video Processor of the proposed device and the view of the predicate device have the same function. Therefore, the

difference will not affect the safety and effectiveness of the proposed device.

Different Analysis 3 - Depth of Field

The proposed device has a wider range of depth of field than the predicate device to give physicians more options for diagnosis and treatment based on the patient's condition. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Similar Analysis 4- Max. outer diameter of insertion section

The max. outer diameter of insertion section of the proposed device is similar to that of the predicate device. The out diameter of the proposed device is 2.9mm, and the out diameter of the predicate device is 3.2mm. The proposed device was complied with the requirements of ISO 8600 series standards. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Similar Analysis 5- Work length

The work length of the proposed device is similar as that of the predicate device. The work length of the proposed device is 700mm, and the work length of the predicate device is 650mm. The proposed device was complied with the requirements of ISO 8600 series standards. Therefore, this difference does not raise new problems on safety and effectiveness of proposed device.

Similar Analysis 6- Min. inner diameter instrument channel

The minimum instrument channel width of the proposed device is similar to that of the predicate device. The instrument channel inner diameter of the proposed device is 1.2mm, and the instrument channel inner diameter of the predicate device is 1.0mm. The device was tested per ISO 8600 standard, which can prove that the performance of the proposed endoscope is comply with ISO 8600 standards. Endoscopes with different sizes can be applied to different size of surgical instruments. This difference on minimum instrument channel width between the proposed device and predicate devices does not affect the safety and effectiveness of the proposed device.

Different Analysis 7- Product Performance

The performance tests of the proposed device follow more standards than those of the predicate device, ISO 8600-3, ISO 8600-4 and ISO 8600-7. And the performance test result of the proposed device meets the requirements of ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 8600-7. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different Analysis 8- Patient-contact component and material

The patient-conduct component and material of the proposed device is different with the predicate device. However, the biocompatibility tests were conducted on the proposed device and the test result showed that the proposed device does not raise the adverse effect on the material. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different Analysis 9-Dimension and weight

The dimension and weight for the proposed image processor is different from predicate image processor. However, the dimension and weight difference is just in physical specification and this difference will not raise new issues in safety and effectiveness.

Different Analysis 10- Input power

The input power for the predicate image processor is unknown. However, the input power of proposed image processor complies with IEC 60601-1 standard, the difference in input power is just the difference in device design. Therefore, this difference on input power is considered not affect the safety and effectiveness of the proposed device.

Different Analysis 11-Video Signal Output

The types of video signal output are different between proposed image processor and predicate image processor. The proposed device has DVI interface, the predicate device has HDMI interface. The image quality of DVI output and HDMI output of the proposed device and predicative device have been tested in the quantitative image quality testing. The test results demonstrate that there is no difference in image quality between the two products. Therefore, the difference on video signal output will not affect the safety and effectiveness of the proposed device.

9. Substantially Equivalent (SE) Conclusion

The proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K172098.