U.S. FOOD & DRUG ADMINISTRATION

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August 26, 2025

Seplou (ZHUHAI) Co., Ltd.
% Jie Yang
Consultant
Chonconn Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong
CHINA

Re: K250049
Trade/Device Name: Medical Video Endoscope [Standard Deflection] (URS3005);
Medical Video Endoscope [Reverse Deflection] (URS3005E);
Medical Video Endoscope [Standard Deflection] (URS3006);
Medical Video Endoscope [Reverse Deflection] (URS3006E);
Medical Video Endoscope [Standard Deflection] (URS3016);
Medical Video Endoscope [Reverse Deflection] (URS3016E);
Image processor (DIS8000)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: July 21, 2025
Received: July 21, 2025

Dear Jie Yang:

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 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
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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.

Submission Number *(if known)*

K250049

Device Name

Medical Video Endoscope [Standard Deflection] (URS3005);
Medical Video Endoscope [Reverse Deflection] (URS3005E);
Medical Video Endoscope [Standard Deflection] (URS3006);
Medical Video Endoscope [Reverse Deflection] (URS3006E);
Medical Video Endoscope [Standard Deflection] (URS3016);
Medical Video Endoscope [Reverse Deflection] (URS3016E);
Image processor (DIS8000)

Indications for Use *(Describe)*

The Medical Video Endoscope is 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.

The image processor is used with the specified endoscope designed by SEPLOU during minimally invasive surgery.
The image processor provides power and processes the images for medical electronic endoscope.

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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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92 on August 18, 2025

1. Submission sponsor

Name: SEPLOU (ZHUHAI) CO., LTD.
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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Medical Video Endoscope [Standard Deflection] (URS3005); Medical Video Endoscope [Reverse Deflection] (URS3005E); Medical Video Endoscope [Standard Deflection] (URS3006); Medical Video Endoscope [Reverse Deflection] (URS3006E); Medical Video Endoscope [Standard Deflection] (URS3016); Medical Video Endoscope [Reverse Deflection] (URS3016E); Image processor (DIS8000)
Common Name	Endoscope and accessories
Regulatory Class	Class II
Classification	21CFR 876.1500 / Ureteroscope And Accessories, Flexible/Rigid / FGB
Submission type	Traditional 510(K)

4. Predicate Device

510(k) number: K172098
Product name: Medical Video Endoscope System
Product code: FGB

5. Device Description

The Medical Video Endoscope system is designed to provide image solution for endoscopy and endoscopic surgery, and perform procedures in the urinary tract and interior of the kidney using appropriate accessory devices (e.g. laser fibers, forceps baskets).

The Medical Video Endoscope is a sterile Medical Video Endoscope. The Image Processor for Endoscopy is a reusable monitor.

The Medical Video Endoscope is comprised of a control body with articulation controls and accessory access ports, and a flexible insertion tube with an on-tip camera module and LED lighting source. The Image Processor processes the images from the Endoscope and outputs video signals to a display.

6. Indications for use

The Medical Video Endoscope is 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.

The image processor is used with the specified endoscope designed by SEPLOU during minimally invasive surgery.

The image processor provides power and processes the images for medical electronic endoscope.

7. Comparison to the Predicate Device

Features	**Subject Device** Medical Video Endoscope: [Standard Deflection]: URS3005, URS3006, URS3016 [Reverse Deflection]: URS3005E, URS3006E, URS3016E Image Processor: DIS8000	**Predicate Device** Medical Video Endoscope System	**Comparison**
K number	K250049	K172098	/
Product Code	FGB	FGB	Same
Regulation No.	876.1500	876.1500	Same
Device trade name	Medical Video Endoscope Image Processor	Medical Video Endoscope System	/
Indication for use	The Medical Video Endoscope is designed to be used with	This instrument has been	Same

	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. The image processor is used with the specified endoscope designed by SEPLOU during minimally invasive surgery. The image processor provides power and processes the images for medical electronic endoscope.	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.	
Anatomical Site	Urinary tract and interior of the kidney	Urinary tract and interior of the kidney	Same
Target population	Adults	Adults	Same
Where used	Hospital	Hospital	Same
Medical Video Endoscope			
Scope type	Flexible	Flexible	Same
Single use/ Reuse	Single use	Single use	Same
Sterile	Yes	Yes	Same
Sterilization Method	EO sterilization	EO sterilization	Same
SAL	10^{-6}	10^{-6}	Same
Field of view	120°	120°	Same
Direction of view	0°	0°	Same
Sensor type	CMOS	CMOS	Same
Illumination source	LED	LED	Same
Max. outer diameter of insertion section	3.0mm 2.5mm 2.2mm	3.2mm	Similar
Up/down deflection	Up:275° Down: 275°	Up:270° Down: 270°	Similar
Work length	650mm	650mm	Same
Minimum instrument channel width	1.2mm	1.0mm	Similar

Product Performance	Comply with ISO 8600-1, ISO 8600-3, ISO 8600-4	Comply with ISO 8600-1, ISO 8600-3, ISO 8600-4	Same
Biocompatibility	Cytotoxicity: ISO 10993-5 Sensitization: ISO 10993-10 Irritation: ISO 10993-10 Acute Systemic Toxicity: ISO 10993-11 Material-mediated Pyrogens: ISO 10993-11	Cytotoxicity: ISO 10993-5 Sensitization: ISO 10993-10 Irritation: ISO 10993-10	Different
Image system	Image Processor DIS8000	UTV100 as the image system	Same

8. Non-clinical Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Medical Video Endoscope was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

Sterilization and shelf life testing

The Medical Video Endoscope is provided sterile and its shelf-life is 3 years.
Sterilization Process has been validated accordance with ISO 11135:2014.
EO/ECH residual test was performed according to ISO 10993-7:2008.
The shelf life is determined based on optical testing and product performance testing after accelerated aging test according to ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F1886/F1886M-16, ASTM F88/F88M-23, ASTM F1929-23.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Medical Video Endoscope system. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

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, "Content of Premarket Submissions for Device Software Functions".

Bench performance testing
The following bench tests were performed:
1. Optical performance testing according to ISO 8600 series.
2. Color performance (color reproduction), geometric distortion, optical performance (resolution, depth of field and image intensity uniformity), Noise and dynamic range compared with the predicate device.
3. Mechanical testing including use-life of bending section and control knob, connection strength, peak tensile force and corrosion resistance etc.

9. Clinical study
Not applicable.

10. Conclusion
Performance testing and compliance with voluntary standards demonstrate that the proposed Medical Video Endoscope system is substantially equivalent to the predicate device.