Guangzhou Red Pine Medical Instrument Co., Ltd.
℅ Xiangfei Li
Regulatory Affairs
Ezisurg Medical Co., Ltd.
Rm. 103, Bldg. 2, No.1690 Cailun Rd.,
China (Shanghai) Pilot Free Trade Zone
Shanghai, 201203
China

Re: K221158
Trade/Device Name: Single-Use Video Flexible Ureterorenoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FGB
Dated: February 7, 2023
Received: February 7, 2023

Dear Xiangfei Li:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Bonhye Koo -S

For Mark Antonino
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)*
K221158

Device Name
Single-Use Video Flexible Ureterorenoscope System

Indications for Use *(Describe)*
The device has been developed to be used with endoscopic accessories such as a biopsy forceps and Endoscopic Video Image Processor for endoscopy and endoscopic surgery within urinary tract and interior of the ureter and kidney.

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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Traditional 510(k) Premarket Notification

Guangzhou Red Pine Medical Instrument Co., Ltd.

Single-Use Video Flexible Ureterorenoscope System

Applicant:
Guangzhou Red Pine Medical Instrument Co., Ltd.
Room 303, 308, No. 12, Luoxuan 3 Road, Guangzhou International Bioisland, 510200
Guangzhou City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Revision A-3
March 06, 2023

510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

1. **Date of Preparation: 03/06/2023**

2. **Sponsor Identification**

Guangzhou Red Pine Medical Instrument Co., Ltd.
Room 303, 308, No. 12, Luoxuan 3 Road, Guangzhou International Bioisland,
510200 Guangzhou City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Establishment Registration Number: 3021246306

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3. **Designated Submission Correspondent**

Mr. Xiangfei Li (Primary Contact Person)(Primary Contact Person)
Mr. Weihua Yang (Alternative Contact Person)(Alternative Contact Person)

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4. **Identification of Subject device**

Trade Name: Single-Use Video Flexible Ureterorenoscope System
Common Name: Ureteroscope and Accessories, Flexible/rigid
Model: RP-U-C12, RP-U-C0304, RP-U-C0305
Classification Name: Endoscope and accessories
Classification: II
Product Code: FGB
Regulation Number: 21 CFR 876.1500
Review Panel: Gastroenterology/Urology

Indication for Use Statement:

The device has been developed to be used with endoscopic accessories such as a biopsy forceps and Endoscopic Video Image Processor for endoscopy and endoscopic surgery within urinary tract and interior of the ureter and kidney.

Device Description:

The Single-Use Video Flexible Ureterorenoscope System consists of a sterile Single-Use Video Flexible Ureterorenoscope (consists of handle and insertion portion) and an Endoscopic Video Image Processor (the video system, touch PC) with its accessories power adapter, footswitch.The Ureterorenoscope is provided sterile (sterilized by EO) and intended to be single-use.The video system is powered by the main line.

The handle includes a deflection lever, a lever lock, and a Luer port for insertion of accessory devices and irrigation to the working channel. The insertion portion contains one working channel and wiring to transmit the image signals to the Video Image Processor. The distal bending section of the insertion portion controlled by the user via the deflection lever on the handle. The distal end of the insertion portion contains a CMOS sensor for capturing image and transmitting it to the Video Image Processor, LEDs for illumination, and the distal opening of the working channel. The video cable connects the endoscope handle to the Video Image Processor, which provides power and processes video signals from the endoscope.

Flexible Ureterorenoscope has the following physical and performance characteristics:

- Flexible insertion portion
- Camera and LED light source at the distal tip

5. Identification of Predicate Devices

Trade/Device Name: Medical Video Endoscope System
Regulation Number: 21 CFR 876.1500
Regulatory Class: Class II
Product Code: FGB
510(k) Number: K172098

6. Summary of Technological Characteristics and Comparison

The principles of operation of the subject device is similar to that of the predicate device. The following basic technological elements are the same or similar for the subject and predicate devices:

Compared items	Subject device Single-Use Video Flexible Ureterorenoscope System	Predicate Device Medical Video Endoscope system(K172098)	Comparison
Classification			
Product Code	FGB	FGB	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Classification	Class II	Class II	Same
Indications For Use			
Indications for Use	The device has been developed to be used with endoscopic accessories such as a biopsy forceps and Endoscopic Video Image Processor for endoscopy and endoscopic surgery within urinary tract and interior of the ureter and kidney.	This 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 See Note1.
anatomical site	Urinary tract and interior of the kidney	Urinary tract and interior of the kidney	Same
target population	Adults	Adults	Same
Environment of use	Hospitals	Hospitals	Same
Physical Characteristics			
Type of Scope	Flexible	Flexible	Same
Type of Imager	CMOS	CMOS	Same
Light source	LED	LED	Same
Up/down deflection(°)	Up 275 ° Down 275 °	Up 270 ° Down 270 °	Similar See Note2.
Direction of view	0 °	0 °	Same
Field of view	120 °	120 °	Same
Maximum insertion portion width (mm)	RP-U-C12: 3.2 RP-U-C0304: 3.15 RP-U-C0305: 3.18	3.2	Similar See Note2.
Working length(mm)	670	650	Similar See Note2.
Minimum instrument channel width (mm)	1.2	1.0	Similar See Note2.
Depth of field	3mm-50mm	3mm-50mm	Same

System composition	- Endoscopic Video Image Processor - Single-use video flexible ureterorenoscope and	- Eview (the video system, touch PC with data processing center) - Uscope	Same
Patient Contacting Materials			
General material type of main patient-contact part	Compliance with ISO10993-1	Compliance with ISO10993-1	Similar See Note2.
Duration and type of contact	"Surface –Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	"Surface –Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	Same
Sterilization Methods			
Number of Users	Single-Use	Single-Use	Same
Sterilization	EO Sterilized, SAL 10-6	EO Sterilized, SAL 10-6	Same
Note: 1. The indications for use statement for the subject device is similar to that of the predicate device. The differences do not alter the intended use of the device nor do they raise different questions of safety and effectiveness of the device relative to the predicate. 2. The subject and predicate device have similar principles of operation, type of scope, type of imager, light source, sterilization method, number of users and environment. The subject device differs from the predicate in deflection, maximum insertion portion width, working length, minimum instrument channel width, and patient-contacting materials, most of them are better than the predicate device in clinic use. These differences do not raise different questions of safety and effectiveness as compared to the predicate, and can be evaluated through performance testing.			

7. Non clinical testing summary

Electrical Safety and Electromagnetic Compatibility Summary

The electrical safety and EMC data included in the submission are in compliance with the following FDA recognized standards:

•IEC 60601-1:2012, and AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012
•IEC 60601-2-18:2009: Part 2-18
•IEC 60601-1-2:2014 and A1:2020

Photobiological safety
The subject device were tested according to the following FDA recognized standards:
• IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems

Bench Testing Summary
Mechanical and Optical Performance
The subject device was designed to comply with applicable parts of ISO 8600-1:2015. Optical measurements were performed according to applicable part of ISO 8600-1:2015, ISO 12233:2017 and ISO 15739:2017 standard.

The following mechanical characteristics were evaluated: water delivery, fatigue stress of rocker, stress of the bending part, tensile strength of the insertion portion, maximum insertion portion width, minimum instrument channel width deflection.
Optical performance characteristics relevant to functions as intended were tested include field of view, direction of view, resolution, depth of field, distortion, SNR, illumination, dynamic range,color performance.

Biocompatibility Summary
Biocompatibility evaluation for the Flexible Ureterorenoscope was conducted in accordance with the FDA Guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”.
The following tests were conducted based contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours):
• Cytotoxicity: ISO 10993-5:2009/(R) 2014
• Sensitization, Intracutaneous reactivity/irritation: ISO 10993-10:2010
• Material-mediated pyrogenicity: ISO 10993-11:2017
• Acute systemic toxicity: ISO 10993-11:2017

Sterilization and shelf life testing
Sterile barrier systems were evaluated in accordance with ISO 11607:2006.
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 of the Flexible Ureterorenoscope is determined based on stability study which includes ageing test according to ASTM F1980-16 and ASTM F 1980-

07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Package Validation

Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and F88/F88M-15, ASTM F 1929-15
Transport and shipping testing as per ISTA 2A :2011.

The collective results of Non-clinical testing demonstrate that the materials chosen, the manufacturing processes and design of Ureterorenoscope System meet the established specifications necessary for consistent performance during its intended use. In addition, the Bench Test results demonstrate that compared with the predicate , Ureterorenoscope System has the same or similar image quality, optical performance and mechanical performance.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

Non clinical tests demonstrated that the Single-Use Video Flexible Ureterorenoscope System is as safe and effective as the predicate. Therefore, the Single-Use Video Flexible Ureterorenoscope System is substantially equivalent to the predicate devices."