July 12, 2024

Guangzhou Red Pine Medical Instrument Co., Ltd.
Weihua Yang
Regulatory Affairs Director
12 F, No.87 Luoxuan Avenue, Guangzhou International
Bioisland, Huangpu District
Guangzhou, Guangdong 510000
CHINA

Re: K241500
Trade/Device Name: Endoscopic Video Image Processor (RP-IPD-V2000EF);
Single-Use Video Flexible Cysto-Nephroscope
(RP-U-C01F, RP-U-C01FS)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: May 27, 2024
Received: May 28, 2024

Dear Weihua 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.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241500

Device Name

Endoscopic Video Image Processor (RP-IPD-V2000EF);
Single-Use Video Flexible Cysto-Nephroscope (RP-U-C01F, RP-U-C01FS)

Indications for Use *(Describe)*

Endoscopic Video Image Processor
This device is used in conjunction with the video endoscopes produced by our company to process the images collected by the video endoscopes and send them to the display, and provide power for the endoscope.

Single-Use Video Flexible Cysto-Nephroscope
This product shall be used in conjunction with the Endoscopic Video Image Processor and other peripheral equipment for observation, diagnosis, photography and treatment within the bladder, urethra, and kidney.
The device is suitable for professional healthcare facility environments such as hospitals and clinics.
This product shall not be used for other purposes.

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 on: 2024-05-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Guangzhou Red Pine Medical Instrument Co., Ltd.
Applicant Address	12 F, No.87 Luoxuan Avenue, Guangzhou International Bioisland, Huangpu District Guangzhou Guangdong 510000 China
Applicant Contact Telephone	+86 13902971205
Applicant Contact	Mr. Weihua Yang
Applicant Contact Email	regulation@gzredpine.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Endoscopic Video Image Processor (RP-IPD-V2000EF); Single-Use Video Flexible Cysto-Nephroscope (RP-U-C01F, RP-U-C01FS)
Common Name	Cystoscope And Accessories, Flexible/Rigid
Classification Name	Endoscope and accessories
Regulation Number	876.1500
Product Code(s)	FAJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K133538	EVIS EXERA II 180 System	NWB

Device Description Summary

21 CFR 807.92(a)(4)

The proposed device, Cysto-Nephroscope System, which includes a Single-Use Video Flexible Cysto-Nephroscope and an Endoscopic Video Image Processor is intended for observation, diagnosis, photography and treatment within the bladder, urethra, and kidney.

The Single-Use Video Flexible Cysto-Nephroscope is available in two models with the different position of "U" and "D" mark on the handle and different deflection direction, RP-U-C01F, RP-U-C01FS. The Endoscopic Video Image Processor has only one model, RP-IPD-V2000EF.

The Single-Use Video Flexible Cysto-Nephroscope is sterile and single-patient-use device. The Endoscopic Video Image Processor is non-sterile and multi-patient-use device, and it will be cleaned and disinfected before first use and after each use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Endoscopic Video Image Processor
This device is used in conjunction with the video endoscopes produced by our company to process the images collected by the video endoscopes and send them to the display, and provide power for the endoscope.

Single-Use Video Flexible Cysto-Nephroscope
This product shall be used in conjunction with the Endoscopic Video Image Processor and other peripheral equipment for observation, diagnosis, photography and treatment within the bladder, urethra, and kidney.
The device is suitable for professional healthcare facility environments such as hospitals and clinics.

This product shall not be used for other purposes.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indication for use of the proposed device and the predicate device is similar.
The indication for use of proposed device is covered in the scope of the predicate device. For the target location, the proposed device is not intended to used in ureter, so the ureter is not included in the indications for use of the proposed device.
The difference will not affect the safety and effectiveness of the proposed device.

Technological Comparison 21 CFR 807.92(a)(6)

The principles of operation, color tone adjustment, image enhancement, working length, field of view of and direction of view of the proposed device are same as the predicate device. Minimum instrument channel width of the proposed device is also extremely close to the predicate device.

The main configuration, single use or reuse, sterile, dimension and weight, video signal output, white balance, zoom, insertion tube width, maximum insertion portion width, bending angle and depth of field of the proposed device are different from or similar as the predicate device. These differences will not raise new question on safety and effectiveness of the proposed device based on the comparative test report of the proposed device and predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

1. Performance testing
The performance testing was conducted on the proposed Cysto-Nephroscope System, the performance testing includes optical performance and mechanical performance. The performance testing includes ISO 8600 test, and the ISO 8600 test results demonstrated that the proposed system complies with the standard requirements.

The optical performance testing includes direction of view, field of view, depth of field, resolution, signal-to-noise ratio, geometric distortion, image intensity uniformity, dynamic range and color performance.

The mechanical performance testing includes basic size, surface and edges, water delivery system, bending control system, sealing performance, compatibility with accessories, fatigue test of rocker and bending section, tensile strength of insertion portion, performance of cable connector, comprehensive performance of luer connector.

2. Performance comparative testing
The performance comparative testing was conducted on the proposed Cysto-Nephroscope system and predicate system, the performance testing includes optical performance and mechanical performance.
The performance comparative testing includes ISO 8600 test, and the ISO 8600 test results demonstrated that the proposed system complies with the standard requirements.

The optical performance testing includes direction of view, field of view, depth of field, resolution, signal-to-noise ratio, geometric distortion, image intensity uniformity, dynamic range and color performance.

The mechanical performance testing includes basic size, surface and edges, water delivery system, bending control system, sealing performance, fatigue test of rocker and bending section, tensile strength of insertion portion and performance of cable connector. And the image quality evaluation is performed.

The test results demonstrate that the optical performance and mechanical performance of the proposed system is similar as those of the predicate device.

3. Performance Testing-Image Frame Frequency and System Delay
The Image Frame Frequency and System Delay testing was conducted on the proposed Cysto-Nephroscope System and aged proposed Cysto-Nephroscope System.

4. Performance Testing- Photobiological Safety Test
The primary components of the proposed Cysto-Nephroscope System, includes a Single-Use Video Flexible Cysto-Nephroscope and an Endoscopic Video Image Processor, are tested per the following standard, to evaluate their photobiological safety. The test results demonstrated that the proposed system complies with the standard requirements of IEC 62471:2006 Photobiological Safety of lamps and lamp systems.

The Performance Comparative Testing and Performance Testing was completed and the results proved that the proposed device and the predicate device have same or similar design features and performance specifications (both of optical performance and mechanical performance). Although there are some differences on the mechanical parameters between the subject device and predicate device,

such differences will not affect the effectiveness and safety of the proposed device.
Therefore, the tests demonstrate that the proposed device is as safe, as effective, and performs as well as the predicate device.