February 7, 2025

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

Re: K243321
Trade/Device Name: Endoscopic Video Image Processor (RP-IPD-V1000F)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Received: January 7, 2025

Dear Ping 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
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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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)*

K243321

Device Name

Endoscopic Video Image Processor (RP-IPD-V1 000F)

Indications for Use *(Describe)*

The Endoscopic Video Image Processor is used in conjunction with the Single-Use Video Flexible Cysto-Nephroscope (Models: RP-U-C01F, RP-U-C01FS) to process the images collected by the video endoscope and send them to the display, and provide power for the 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Number: K243321

I. Contact Details

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Correspondent Contact: Ms. Ping Yang

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Date prepared: January 22, 2025

II. Subject Device

Device Trade Name: Endoscopic Video Image Processor (RP-IPD-V1000F)

Common Name: Endoscope and accessories

Classification Number: 21 CFR 876.1500

Classification Name: Endoscopic Video Imaging System/Component, Gastroenterology-Urology

Product Code: FET

III. Legally Marketed Predicate Device

Predicate 510(k) Number: K241500

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

Product Code: FAJ

Note: This predicate device has not been subject to a design-related recall.

IV. Device Description Summary

The Endoscopic Video Image Processor is a video processing system intended for use during endoscopic procedures. It receives and processes image signals from a compatible video endoscope and produces live video images during endoscopic procedures. Apart from the image processing functions, it also provides the power supply for the endoscope.

The Endoscopic Video Image Processor is a reusable device. It does not require sterilization before use, as there is no direct/indirect patient contact. The device needs to be cleaned and disinfected before use, and the cleaning and disinfection method is outlined in the Instructions for Use.

V. Indications for use

The Endoscopic Video Image Processor is used in conjunction with the Single-Use Video Flexible Cysto-Nephroscope (Models: RP-U-C01F, RP-U-C01FS) to process the images collected by the video endoscope and send them to the display, and provide power for the endoscope.

VI. Indications for Use Comparison

The Indications for Use of the subject device is nearly identical to the Indications for Use of the predicate device. The only change is the addition of the name of the compatible endoscope to the Indications for Use of the subject device.

VII. Technological Comparison

The principles of operation, white balance, color tone adjustment, image enhancement, zoom, adjusting brightness, image freezing and compatible endoscope of the subject device are identical to the predicate device.

The product code, main configuration, dimension and weight of the subject device are different from or similar to the predicate device. The differences in product code, main configuration, video signal output, dimension and weight do not raise new question of safety and effectiveness.

VIII. Non-Clinical Tests Summary

1. Performance Testing

The Endoscopic Video Image Processor is compatible with the Single-Use Video Flexible Cysto-Nephroscope which was cleared under K241500 and is manufactured by Red Pine.

The Cysto-Nephroscope system includes the Endoscopic Video Image Processor and the Single-Use Video Flexible Cysto-Nephroscope.

The following performance testing was conducted on the Cysto-Nephroscope system:

1. Direction of view
2. Field of view
3. Depth of field
4. Resolution
5. Signal-to-noise ratio
6. Geometric distortion
7. Image intensity uniformity

8. Dynamic range
9. Color performance.

The performance testing complied with the following standards:

ISO 8600-1:2015 Endoscopes - Medical endoscopes and endotherapy devices. General requirements

ISO 8600-3:2019 Endoscopes. Medical endoscopes and endotherapy devices. Part 3: Determination of field of view and direction of view of endoscopes with optics

2. Performance Testing-Image Frame Frequency and System Delay

Image Frame Frequency and System Delay testing was also conducted on the Cysto-Nephroscope System.

The Performance Testing demonstrated that the subject device and the predicate device have similar performance, and the subject device is as safe and effective as the predicate device.

IX. Clinical Evidence

N/A.

X. Conclusion

The results of nonclinical performance testing demonstrate that the subject device is as safe and effective as the predicate device to support a substantial equivalence determination.