August 8, 2025

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

Re: K252176
Trade/Device Name: 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: July 11, 2025
Received: July 11, 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
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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.

510(k) Number *(if known)*
K252176

Device Name
Single-Use Video Flexible Cysto-Nephroscope (RP-U-C01F, RP-U-C01FS)

Indications for Use *(Describe)*
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.

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

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510(k) Summary

I. Contact Details

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Correspondent Contact: Ms. Ping Yang

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Date prepared: August 7, 2025

II. Subject Device

Device Trade Name:

Single-Use Video Flexible Cysto-Nephroscope (RP-U-C01F, RP-U-C01FS)

Common Name: Endoscope and accessories

Classification Number: 21 CFR 876.1500

Classification Name: Cystoscope and accessories, flexible/rigid

Product Code: FAJ

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

IV. Device Description Summary

The Single-Use Video Flexible Cysto-Nephroscope mainly consist of insertion portion, handle and connector section which include a detachable video cable which connect the endoscope to the Endoscopic Video Image Processor.

V. Indications for use

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.

VI. Indications for Use Comparison

The proposed device, Single-Use Video Flexible Cysto-Nephroscope, has the same indications for use in comparison to the predicate device, Single-Use Video Flexible Cysto-Nephroscope.

VII. Technological Comparison

The proposed Single-Use Video Flexible Cysto-Nephroscope is the same as the predicate Single-Use Video Flexible Cysto-Nephroscope (cleared under K241500) with respect to its indications for use, design, operating principle, and fundamental technology.

The proposed device contains the following differences to the predicate device:

1. All features of the new device (proposed device) are identical to the predicate, and only a detachable video cable is added to its immediate package.
2. The downward deflection angle for all models is changed from 135° to 225°.
3. The material of immediate packaging (Tyvek pouch) is changed from DuPont Tyvek 2FS paper to DuPont Tyvek 1073B paper. Along with this immediate packaging material change, the dimensions of the middle packaging and transportation packaging have been adjusted.

As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify the risks associated with the above changes. Verification testing was conducted to evaluate the modifications. The proposed device has met the testing acceptance criteria in accordance with internal requirements and applicable standards to support substantial equivalence of the proposed device.

VIII. Non-Clinical Tests Summary

As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify the risks associated with the design changes. Verification testing including performance testing using previous submitted method and acceptance criteria cleared under K241500, additional shelf-life testing and simulated transportation testing, performance testing including deflection system etc. were conducted to evaluate the modifications. The proposed device has met the testing acceptance criteria in accordance with internal requirements and applicable standards to support substantial equivalence of the proposed device.

- **Sterilization Validation**

The sterilization method has been validated to ISO 11135:2014 half-cycle method, which has thereby determined the routine control and monitoring parameters.

- **Shelf Life and simulated transportation distribution followed by sterile packaging integrity test.**

Shelf Life and simulated transportation distribution followed by packaging integrity testing have been validated according to the following applicable standards:

- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ISO11607-1:2019 Packaging for terminally sterilized Medical Device Part 1: Requirement for materials, sterile barrier systems and packaging systems
- ISO11607-2:2019 Packaging for terminally sterilized Medical Device Part 2: Validation Requirement for forming, sealing and assembly process.
- ASTM F 1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems

➢ **Performance Testing**

The following performance testing was conducted using previous submitted method and acceptance criteria cleared under K241500 in support of the substantial equivalence, as shown below.

- Surface and Edges
- Deflection system and Fatigue test of Fatigue test of Rocker and Bending Section

IX. Clinical Evidence

N/A.

X. Conclusion

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