



December 16, 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: K251951

Trade/Device Name: Single-Use Video Flexible Ureterorenoscope (RP-U-C03R9, RP-U-C03R3, RP-U-C03S9, RP-U-C03S3); Endoscopic Video Image Processor (RP-IPD-V2000EF); Endoscopic Video Image Processor (RP-IPD-V1000F)

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and Accessories

Regulatory Class: II

Product Code: FGB

Dated: November 19, 2025

Received: November 19, 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 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

Indications for Use

510(k) Number (if known)

K251951

Device Name

Single-Use Video Flexible Ureterorenoscope (RP-U-C03R9, RP-U-C03R3, RP-U-C03S9, RP-U-C03S3); Endoscopic Video Image Processor (RP-IPD-V2000EF); Endoscopic Video Image Processor (RP-IPD-V1000F)

Indications for Use (Describe)

The device has been developed to be used with endoscopic accessories 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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510(k) Summary

I. Contact Details

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Correspondent Contact: Ms. Ping Yang

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Date prepared: December 4, 2025

II. Subject Device

Device Trade Name:

Single-Use Video Flexible Ureterorenoscopy (RP-U-C03R9, RP-U-C03R3, RP-U-C03S9, RP-U-C03S3); Endoscopic Video Image Processor (RP-IPD-V2000EF); Endoscopic Video Image Processor (RP-IPD-V1000F)

Common Name: Endoscope and accessories

Classification Number: 21 CFR 876.1500

Regulatory Class: II

Classification Name: Ureteroscope and accessories, flexible/rigid

Product Code: FGB

III. Legally Marketed Predicate Device

Predicate 510(k) Number: K221158

Device name: Single-Use Video Flexible Ureterorenoscopy System

Product Code: FGB

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

IV. Device Description Summary

The proposed device, Ureterorenoscope System, which includes a Single-Use Video Flexible Ureterorenoscope, an Endoscopic Video Image Processor (model: RP-IPD-V2000EF) which has been cleared under K241500 and an Endoscopic Video Image Processor (model: RP-IPD-V1000F) which has been cleared under K243321 is intended for endoscopy and endoscopic surgery within urinary tract and interior of the ureter and kidney.

V. Indications for use

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

VI. Indications for Use Comparison

The indication for use (IFU) of the proposed device and the predicate device are similar. They have the same principle of operation, and target location. Therefore, the difference in description does not affect the safety and effectiveness of the proposed device.

VII. Technological Comparison

The proposed device contains an identical principle of operation, single use/reusability, white balance, brightness adjustment, working length, field of view, and direction of view to the predicate device. The minimum instrument channel width of the proposed device is also extremely close to the predicate device.

The main configuration, dimension and weight, video signal output, zoom, OD of flexible insertion portion, maximum insertion portion width, bending angle and depth of field of the proposed device are different to the predicate device. These differences do 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. See the following table 1 and table 2 for the detailed comparison information.

Table 1: Specifications Comparison of Endoscopic Image Processor

Item	Proposed device (Image Processor RP-IPD-V2000EF)	Proposed device (Image Processor RP-IPD-V1000F)	Predicate device (Image Processor RP-IPD-V800)	Remark
Model	RP-IPD-V2000EF	RP-IPD-V1000F	RP-IPD-V800	/
Dimension	352mm (W)×333mm (D) ×144.5mm (H)	327mm (W)× 214mm (D)×54mm (H)	211mm (W)×264mm (D) ×41.5mm (H)	Similar Analysis 1
Weight	10.5Kg	2.44 Kg	1.7KG	Similar Analysis 1
Video signal output	HDMI DVI SDI CVBS	HDMI SDI CVBS	HDMI CVBS	Similar Analysis 2
White balance	Manual	Manual	Manual	Same

Brightness adjustment	Yes	Yes	Yes	Same
ZOOM	1.0X → 1.4X → 1.6X	1.0X → 1.4X → 1.6X	0.5X → 1.0X → 2.0X → 3.0X	Similar Analysis 3
Type of protection against electric shock	Class I device	Class I device	Class II device	Similar Analysis 4
Degree of protection against electric shock	type BF applied part	type BF applied part	type BF applied part	Same

Similar Analysis 1-Dimension and Weight

The dimension and weight for the proposed image processors are different from the predicate device. The dimension and weight in physical specification differences do not raise any issues in safety and effectiveness of the proposed device.

Similar Analysis 2- Video signal output

The proposed device has two additional video signal outputs compared to the predicate device. Specifically, a DVI interface and an SDI interface; the difference on video signal output does not affect the safety and effectiveness of the proposed device based on the following reasons:

- Both the proposed system and predicate system are the high-definition endoscope system; they all have the standard -definition interface and high-definition interface. The proposed system has an extra direct output interface than the predicate system to improve the system's versatility.
- SDI interface is similar as HDMI interface. The display of the monitor can be switched to SDI signal output in case of the HDMI interface doesn't work or suddenly crashes.

Similar Analysis 3-ZOOM

The ZOOM function of the proposed image processor is different from predicate image processor. The ZOOM function is used to adjust the image size without changing the image content; this difference does not raise any issues in safety and effectiveness.

Similar Analysis 4-Type of protection against electric shock

The type of protection against electric shock is different from the predicate device. But based on the test results of *Electrical Safety Test Report of Ureterorenoscope System*, the design on both the proposed device and the predicate device, comply with IEC 60601-1 and ANSI/AAMI ES 60601-1, Class I grounding provides comparable risk reduction to Class II double insulation. The proposed device is substantially equivalent to the predicate in safety and effectiveness, as the electrical protection method difference.

Table 2: Specifications Comparison of Single-Use Video Flexible Ureterorenoscope

Item	Proposed Device (Single-Use Video Flexible Ureterorenoscope)	Predicate Device (Single-Use Video Flexible Ureterorenoscope) K221158	Remark
Model	RP-U-C03R9, RP-U-C03R3, RP-U-C03S9, RP-U-C03S3	RP-U-C12 RP-U-C0304 RP-U-C0305	/

OD of flexible insertion portion	Φ2.50 mm (7.5 Fr)	Φ2.9mm(8.7Fr) for RP-U-C12 Φ2.85mm(8.6Fr) for RP-U-C0304/ RP-U-C0305	Similar Analysis 5
Maximum Insertion Portion Width	2.75 mm (8.25 Fr)	3.2mm (9.6Fr) for RP-U-C12 3.15mm (9.5Fr) for RP-U-C0304 3.18mm (9.5Fr) for RP-U-C0305	Similar Analysis 6
Minimum Instrument Channel Width	1.10 mm (3.3 Fr)	1.2mm (3.6Fr)	Similar Analysis 7
Working Length	670 mm, tolerance: ±3%	670 mm, tolerance: ±3%	Same
Bending Angle	Up 285°, Down 285° tolerance ±15°	Up 275°, Down 275° tolerance ±15°	Similar Analysis 8
Field of View	120°, tolerance: ±15%	120°, tolerance: ±15%	Same
Depth of Field	3~50mm, tolerance ± 10°	5~50mm, tolerance ± 10°	Similar Analysis 9
Direction of View	0°, tolerance:± 10°	0°, tolerance:± 10°	Same

Similar Analysis 5- Outer Diameter (OD) of flexible insertion portion

The OD of the flexible insertion portion is similar to the predicate device. The diameter meets the industrial standard.

In addition, the nominal value of the proposed device is less than that of the predicate device. The smaller OD of flexible insertion portion, the better the cross ability. Therefore, the difference do not affect the safety and effectiveness of the proposed device.

Similar Analysis 6- Maximum Insertion Portion Width

The Maximum Insertion Portion Width of the proposed device is similar to the predicate device. The diameter meets the industrial standard.

In addition, the nominal value of the proposed device is less than that of the predicate device. The smaller maximum insertion portion width, the better the cross ability. Therefore, the difference do not affect the safety and effectiveness of the proposed device.

Similar Analysis 7- Minimum Instrument Channel Width

The Minimum Instrument Channel Width of proposed device is similar as the predicate device. The diameter meets the industrial standard.

Based on the test result of **Performance Comparison Test Report**, the water delivery system test values of the proposed device demonstrate equivalent performance compared to the predicate device, and the size of the endoscopic accessories used in conjunction with the proposed device and the predicate device are the same, it can be considered that the minimum width of instrument channel of the proposed device is equivalent to that of the predicate device.

Similar Analysis 8- Bending Angle

The Bending Angle of the proposed device is similar to the predicate device.

Although the measured value and nominal value of the proposed device is slightly higher than that of the predicate device, the proposed endoscope meets the angle requirement during endoscopic observation and diagnosis. Therefore, the slight difference on bending angle between the proposed device and predicate device does not affect the safety and effectiveness of the proposed device.

Similar Analysis 9- Depth of Field

The Depth of Field of proposed device is similar as the predicate device.

Based on the test result of **Performance Comparison Test Report**, the resolution test value of the

proposed device at 3mm is similar to that of the predicate device, and the resolution test value of the proposed device at 50mm is higher than that of the predicate device. The proposed device allows doctors to observe clear images over a larger area, it can be considered that the proposed device is slightly better than the predicate device in this performance. Therefore, the difference does not affect the safety and effectiveness of the proposed device.

VIII. Non-Clinical Tests Summary

1. Performance testing:

The performance testing was conducted on the proposed Ureterorenoscope System including a Single-Use Video Flexible Ureterorenoscope, an Endoscopic Video Image Processor (model: RP-IPD-V2000EF) and an Endoscopic Video Image Processor (model: RP-IPD-V1000F).

The performance testing includes optical performance and mechanical performance. The performance testing includes ISO 8600 testing that 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 Ureterorenoscope system and the 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.

The Performance Comparative Testing and Performance Testing were completed and the results proved that the proposed device and the predicate device have same or similar design features and performance specifications.

3. Biocompatibility testing:

Biocompatibility of the Single-Use Video Flexible Ureterorenoscope was evaluated per ISO 10993-1.

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,” was used.

4. Sterilization and Shelf life testing:

The Single-Use Video Flexible Ureterorenoscope contains a shelf life of 3 years. Sterilization was validated in accordance with ISO 11135:2014. Shelf life testing was conducted in accordance with ASTM F1980-21. Package validation was conducted according to ASTM F1886/F1886M-16, ASTM D4169-23, ASTM F1929-23, and ASTM F88/F88-23.

5. Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing was conducted on the Single-Use Video Flexible Ureterorenoscope and Endoscopic Video Image Processors (RP-IPD-V2000EF and RP-IPD-V1000F) in accordance with IEC 60601-1:2005/AMD1:2012/AMD2:2020, IEC 60601-2-18:2009, and IEC 60601-1-2:2014+A1:2020, EN 60601-1-2:2015+A1:2021

6. 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”.

Therefore, the tests demonstrate that the proposed device is as safe, as effective, and performs as well 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.