August 2, 2024

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: K241987
Trade/Device Name: Single-Use Video Hysteroscope (RP-G-C24, RP-G-C0101)
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: July 8, 2024
Received: July 8, 2024

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.

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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
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.

510(k) Number *(if known)*
K241987

Device Name
Single-Use Video Hysteroscope (RP-G-C24, RP-G-C0101)

Indications for Use *(Describe)*
Single-Use Video Hysteroscope is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

The device is suitable for professional healthcare facility environments such as hospitals and clinics.

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: K241987

I. Contact Details

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Correspondent Contact: Mrs. Ping Yang

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Date prepared: August 2, 2024

II. Subject Device

Device Trade Name: Single-Use Video Hysteroscope (RP-G-C24, RP-G-C0101)

Common Name: Hysteroscope and accessories

Classification Number: 21 CFR 884.1690

Classification Name: Hysteroscope and accessories

Product Code: HIH

III. Legally Marketed Predicate Device

Predicate 510(k) Number: K232003

Device name: Single-Use Video Hysteroscope: RP-G-C24, RP-G-C0101

Product Code: HIH

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

IV. Device Description Summary

The subject device, Single-Use Video Hysteroscope is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

The device is suitable for professional healthcare facility environments such as hospitals and clinics.

The subject device consists of an endoscope (a hysteroscope) which includes an insertion portion and handle, and the following accessories: 2 pieces of two-way valves and 1 piece of silicone cap.

The subject Single-Use Video Hysteroscope is the same as the predicate Single-Use Video Hysteroscope (cleared under K232003) with respect to its indications for use, design, operating principle, and fundamental technology.

The subject device differs from the predicate device showed as below,

1. All features of the new device (subject device) are identical to the predicate, with 2 accessories added to its primary package, consisting of 2 pieces of two-way valves and a silicone cap;

2. The depth of field (DOF) of RP-G-C0101 is changed from 5 mm~50 mm to 3 mm~50 mm.

V. Indications for use

Single-Use Video Hysteroscope is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

The device is suitable for professional healthcare facility environments such as hospitals and clinics.

VI. Indications for Use Comparison

The subject device, Single-Use Video Hysteroscope, has the same indications for use in comparison to the predicate device, Single-Use Video Hysteroscope.

VII. Technological Comparison

The subject Single-Use Video Hysteroscope is the same as the predicate Single-Use Video Hysteroscope (cleared under K232003) with respect to its indications for use, design, operating principle, and fundamental technology.

The subject device differs from the predicate device showed as below,

1. All features of the new device (subject device) are identical to the predicate, with 2 accessories added to its primary package, consisting of 2pcs of two-way valves and a silicone cap;

2. The depth of field (DOF) of RP-G-C0101 is changed from 5 mm~50 mm into 3 mm~50 mm.

These differences between the subject and predicate device do not raise different questions of safety or effectiveness. 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 subject device passed all testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject 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 previously submitted methods and acceptance criteria cleared under K232003, additional biocompatibility testing per ISO 10993 standards, shelf life testing, and simulated transportation testing were conducted to evaluate the modifications. The subject device passed all the testing in accordance with internal requirements and applicable standards.

- **Biocompatibility Summary**

The biocompatibility evaluation for the patient contacting components was conducted in accordance with the 2023 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," as recognized by FDA. The following testing was conducted based on contact category of "Surface – Breached or Compromised Surface" with a contact duration of "Limited (< 24 hours)":

- Cytotoxicity test per ISO 10993-5:2009
- Sensitization test per ISO 10993-10:2011
- Intracutaneous Reactivity test per ISO 10993-23:2021
- Acute Systemic Toxicity test per ISO 10993-11:2017
- Material-Mediated Pyrogenicity test per USP <151>

- **Sterilization Validation**

The subject device is sterilized via ethylene oxide (EO). The sterilization method has been validated to ISO 11135:2014 half-cycle method, which has thereby determined the routine control and monitoring parameters.

EO/ethylene chlorohydrin (ECH) residual testing was performed according to ISO 10993-7:2008 and was below the stated residual limits.

- **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
- ISO 11607-1:2019 Packaging for terminally sterilized Medical Device Part 1: Requirement for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 Packaging for terminally sterilized Medical Device Part 2: Validation Requirement for forming, sealing and assembly process
- ASTM F 1929-15 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**

The following performance testing was conducted using previously submitted methods and acceptance criteria cleared under K232003 in support of the substantial equivalence, as shown in the table below.

Test category	Test Item
Mechanical performance	Surface and Edges Visual Assessment
	Water Delivery System (Flow Rate and Leakage Testing)
	Basic Size (Dimensional Analysis and Compatibility Testing of the Two-way Valve)
	Comprehensive Performance of Luer Taper per ISO 80369-7:2021 and ISO 80369-20:2015
	Pullout Force of Silicone Cap
	Compatibility with Accessories When Installing Silicone Cap
	Sealing Test after Installing the Two-way Valve (Leakage Testing under Pressure)
Optical performance	Depth of field

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.