February 12, 2024

Guangzhou Red Pine Medical Instrument Co.,Ltd.
Xiangfei Li
Regulatory Affairs Manager
12 F, No.87 Luoxuan Avenue,
Guangzhou International Bioisland, Huangpu District
Guangzhou, Guangdong 510200
China

Re: K232003
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: January 9, 2024
Received: January 9, 2024

Dear Xiangfei Li:

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,

Jason Roberts -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K232003

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

Indications for Use *(Describe)*
The 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 devices 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.

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510(k) SUMMARY

510(k) Number: K232004

I. SUBMITTER

Name: Guangzhou Red Pine Medical Instrument Co., Ltd.

Address: 12 F, No.87 Luoxuan Avenue, Guangzhou International Bioisland, Huangpu District, 510000 Guangzhou City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

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Date prepared: February 5, 2024

II. Proposed Device

Submission Number: K232003

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

Regulation Number: 21 CFR 884.1690

Regulation Name: Hysteroscope and accessories

Regulation class: II

Review Panel: Obstetrics/Gynecology

Product code: HIH

III. Predicate Device

510(k) Number: K202445

Device name: Hystero-V Hysteroscope

Applicant: Hysterovue, Inc.

Regulation number:21 CFR 884.1690

Regulation Name: Hysteroscope and accessories

Regulation class: II

Review Panel: Obstetrics/Gynecology

Product code: HIH

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

IV. Reference Device

510(k) Number: K210270

Device name: Medical Endoscope Image Processing System

Applicant: Jiangsu Jiyuan Medical Technology Co., Ltd

Regulation number:21 CFR 884.1690

Regulation Name: Hysteroscope and accessories

Regulation class: II

Review Panel: Obstetrics/Gynecology

Product code: HIH

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

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.

Although the subject device lacks integrated biopsy functionality compared to the predicate device, the intended use of both is the same. In addition, the indications for use is the same for the subject and reference device.

VI. Description of the Device

The Single-Use Video Hysteroscope is intended to be used for viewing of the adult cervical canal and uterine cavity and it is provided sterile (sterilized by EO) and intended for single use only.

The Single-Use Video Hysteroscope is composed of a handle part, including the video cable interface, working channel port and instrument channel port, and an insertion portion, of which a camera module and LED light source are integrated inside the distal tip.
There are two models of The Single-Use Video Hysteroscope, RP-G-C24 and RP-G-C0101. The model RP-G-C24 is identical to RP-G-C0101 except for the direction of view, width size of insertion port and width size of instrument channel, as shown in the table below:

Model / Spec.	RP-G-C24	RP-G-C0101
Direction of View	22°	30°
Maximum width of insertion portion	5.5mm(16.7Fr)	4.8mm(14.4Fr)
Minimum width of instrument channel	2.3mm(6.9Fr)	2.0mm(6.0Fr)

The principle of optical imaging: the light source illuminates the inspected site of the patient, which is imaged by the photosensitive surface of CMOS camera module. The optical signal received by the CMOS sensor is converted into electrical signal after processing. The electrical signal is then transmitted by the cable to the signal processing chip embedded on the Endoscopic Video Image Processor where it is restored after processing and finally displayed on the screen of Endoscopic Video Image Processor.
The materials used in construction of the insertion portion of Hysteroscope are low-density polyethylene (LDPE), Polyether-polyamide block copolymers (PEBAX), and polycarbonate (PC). The insertion portion is considered to contact a breached or compromised surface for a duration of less than 24 hours. The biocompatibility evaluation was conducted in accordance with 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,” as recognized by FDA.
The handle does not contact the patient.

The Single-Use Video Hysteroscope shall be used in conjunction with REDPINE Endoscopic Video Image Processor, which has been cleared under another 510(k) (K221158) to process the images collected by the video endoscope and send it to the display screen, as well as to provide power to the hysteroscope.

VII. Comparison with the Predicate Devices

- **Comparison of Indications with the Predicate Devices**

Regarding the indications for use, although the subject device lacks integrated biopsy functionality compared to the predicate device, the intended use of both of them are the same.

- **Comparison of Technological Characteristics with the Predicate Devices**

Subjective device and the predicate device have the same intended use. The subject and predicate device have similar technological characteristics as evidenced by the table below. All differences have been discussed in detail and concluded that these differences in technological characteristics do not raise new questions regarding safety or effectiveness of the subject device.

a. The following basic technological elements are the same or similar for the subject and predicate devices:

Table VI Descriptive Comparison				
Item	**Subject Device** **Hysteroscope System**	**Predicate device** **Hystero-V hysteroscope**	**Reference device** **Medical Endoscope Image Processing System**	**Discussion**
510(k) number	K232003	K202445	K210270	
Classification Product Code	HIH	HIH	HIH	same

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 Hystero-V hysteroscope is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial tissue sample (biopsy) in an outpatient or office setting.	The Medical Endoscope Image Processing System is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.	Difference 1
Route of Advancement	Advanced to uterine cavity via the cervical canal	Advanced to uterine cavity via the cervical canal	Advanced to uterine cavity via the cervical canal	Same
Site of use	Hospitals and physician offices	Hospitals and physician offices	Hospitals and physician offices	Same
Device Features				
Components	The hysteroscope system is composed of Single-Use Video Hysteroscope and endoscopic video image processor.	Reusable handle with video screen Attachable cannula with a working channel along its length and an illumination source and camera at its tip	The medical endoscope system is composed of disposable electronic hysteroscope and medical endoscope image processor.	Difference 2

Cannula Outer Diameter	RP-G-C24:5.5mm RP-G-C0101:4.8mm	4.25mm	4.8mm	Difference 3
Cannula Total Length	270mm±3%	254mm	200mm±3%	Difference 4
Illumination light source	LED	LED	LED	Same
Image transmission	Transmits images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the image showing on a monitor.	Image transmitted from a video camera at the tip of the cannula to a video monitor on the handle	Transmits images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the image showing on a monitor.	Same
LCD Display Size	10.1 inches	3.5 inches (diagonal) on the handle	The image processor of reference device with no display (It is connected by an external display to display images)	Difference 5
Optical Image	CMOS	CMOS	CMOS	Same
Image Resolution	160,000 pixels	Unknown	160,000 pixels	Same as the reference device

Field of View	120°	140°	120°	Same as the reference device; similar to the predicate device
Depth of field	RP-G-C24: 3 to 50 mm RP-G-C0101: 5 to 50 mm	5 to 50 mm	3 to 50 mm	Model RP-G-C24 is the same as the reference device; RP-G-C0101 is the same as the predicate device
Direction of view from center axis	RP-G-C24:22° RP-G-C0101:30°	30°	16±3°	Difference 6
Adjust brightness of illumination	Press the Brightness +/- button in the Processor to adjust to the appropriate brightness level.	Adjust by depressing a button on the handle to change settings	The brightness of the LED can be adjusted with a button on the medical endoscope image processing system	Same
Capture still images or video images during the	Capture images or video during procedure by the image processor	Capture still images or video during procedure by depressing a camera button on the handle	Capture images or video during procedure by the image processor	Same

procedure				
Duration of use	≤ 24 hours	≤ 24 hours	≤ 24 hours	Same
Sterilization	The Endoscopic Video Image Processor is not sterile. The Single-Use Video Hysteroscopes is sterile following exposure to ethylene oxide (EO)	The handle is not provided sterile. The handle is cleaned and disinfected following company instructions. Disposable cannula is sterile following exposure to ethylene oxide (EO) and is single use; it is disposed after the procedure following the institution's procedures.	Video Processor: Non-Sterile The Disposable Electronic Hysteroscope is provided sterilized by EO. Re-sterilization is not permitted.	Same
Tissue contact materials	Compliant with IS0 10993	Compliant with ISO 10993	Compliant with ISO 10993	Same

b. Discussion on differences between the subject and the predicate device Difference 1 Indication for use

Although the subject device lacks integrated biopsy functionality compared to the predicate device, the intended use of both is the same. In addition, the indications for use is the same for the subject and reference device.

Difference 2 Components

Regarding Components, both the subject and reference device are composed of a single-use (disposable) endoscope and an image processor (for displaying imaging). The difference from the predicate device is that the image processor (video screen) and reusable handle of the predicate device are designed as one, and the handle is connected to the insertion part, while the handle and insertion part of the subject device and the reference device are integrated (which are single use), and the handle is connected to the image processor. These differences do not raise different questions of safety and effectiveness.

Difference 3 Cannula outer diameter

The diameter of the hysteroscope is usually in the range of 4-6 mm; thus there are no new risks associated with 4.8 or 5.5 mm diameter.

Difference 4 Cannula total length

Longer cannula length does not affect the safety and effectiveness of the product.

Difference 5 LCD display size

Larger screen size does not affect the safety and performance of the product.

Difference 6 Direction of view from center axis

The difference in this parameter has only a minor effect on the observed image and does not affect the effectiveness of its use.

VIII. Summary of Non-clinical Performance

All non-clinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate device and reference device. Tests setup and execution were performed in accordance with applicable standards. Results of the testing

demonstrate compliance to the standards and matching the performance of subject device to the reference device. The following performance data were provided in support of the substantial equivalence determination.

- **Biocompatibility**

The biocompatibility evaluation for the Single-Use Video Hysteroscope was conducted in accordance with 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," as recognized by FDA. The insertion portion of Single-Use Video Hysteroscope is considered to contact a breached or compromised surface for a duration of less than 24 hours; therefore, the following tests are considered and passed:

Biocompatibility testing summary	
Test	**Testing Summary**
Cytotoxicity test (ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity, Annex C)	Pass-Non-cytotoxic
Skin Sensitization test (ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization, GPMT)	Pass-Non-irritation
Intracutaneous test (ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization)	Pass-Non-sensitization
Acute Systemic Toxicity test (ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity)	Pass-Non-acutely toxic

- **Electrical Safety and Electromagnetic Compatibility**

Electrical safety and EMC testing were conducted on the Hysteroscope System and the device complies with the following standards:

• AAMI ES 60601-1:2005 + AMD1:2012 + AMD2:2021 Medical electrical

equipment - Part 1: General requirements for basic safety and essential performance.

• IEC 60601-2-18: 2009 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment.

• IEC 60601-1-2: 2014 + A1: 2020 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances -Requirements and tests.

- **Photobiological safety**

The subject device was tested according to the following FDA recognized standards:

• IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems.

- **Sterilization Validation**

The EO sterilization of the Single-Use Video Hysteroscope has been validated according to the following applicable standards:

• ISO11135:2014+A1:2018 Sterilization of medical device- validation and routine control of ethylene oxide sterilization

• ISO 11737-2:2019 Sterilization of Medical Device-Microbiological methods part 2: Tests of sterility performed in the validation of a sterilization process

• ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

• USP <85> Bacterial endotoxins test

- **Shelf Life and Sterile Barrier System (Packaging)**

Shelf Life and Sterile Barrier System of the Single-Use Video Hysteroscope has been validated according to the following applicable standards:

• ASTM F1980-16 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 1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

• ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials

- **Performance Data – Bench**

The following performance data were provided in support of the substantial equivalence, as shown in the table below.

The optical performance testing was conducted in accordance with applicable parts of ISO 8600-1:2015, ISO 8600-3:2019, ISO 12233-2017, ISO15739-2017 and ISO/CIE 11664-4 standards, and the mechanical performance testing was conducted in accordance with applicable parts of ISO 8600-1:2015, ISO 8600-4:2014, YY/T 1028-2023 standards. The field of view was measured according to the test method in the article: Wang et al., "Endoscope field of view measurement." Biomedical Optics Express 8, no. 3 (2017): 1441-1454, and geometric distortion was measured according to section 3 of the article: Wang, et al., "Development of the local magnification method for quantitative evaluation of endoscope geometric distortion." Journal of Biomedical Optics 21, no. 5 (2016): 056003. The tensile strength of each joint in the insertion portion should be greater than 15 N and be free of any breakage, splitting, or deformation.

Test category	Test item
Optical performance	Direction of view
	Resolution
	Depth of Field
	Field of view
	Geometric Distortion

	Signal-To-Noise Ratio
	Dynamic Range
	Image Intensity Uniformity (IIU)
	Color Performance
Mechanical performance	Surface Safety (Surface and Edges)
	Basic Size
	Water Supply System
	Sealing Performance
	Tensile strength

- **Performance Data – Animal**

N/A, no animal studies are available for the subject device.

IX. Clinical Evidence

N/A.

X. Conclusion

In conclusion, the technological characteristics, features, specifications, and intended use of the subject device are substantially equivalent to the predicate device quoted above. The differences between the subjective device and the predicate device do not raise new questions of safety and effectiveness. Performance testing demonstrated that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.