February 16, 2024

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

Re: K232043
Trade/Device Name: Endoscopic Video Image Processor (RP-IPD-V2000A, RP-IPD-V2000B, RP-IPD-V2000C, RP-IPD-V2000D), Single-Use Video Gastroscope (RP-GI-G02A, RP-GI-G02B), Single-Use Video Colonoscope (RP-GI-C02A, RP-GI-C02B)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF, FDS, FET
Dated: January 17, 2024
Received: January 17, 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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232043

Device Name

Endoscopic Video Image Processor (RP-IPD-V2000A, RP-IPD-V2000B, RP-IPD-V2000C, RP-IPD-V2000D);
Single-Use Video Gastroscope (RP-GI-G02A, RP-GI-G02B);
Single-Use Video Colonoscope (RP-GI-C02A, RP-GI-C02B)

Indications for Use *(Describe)*

Endoscopic Video Image Processor
This device is used in conjunction with the video endoscopes produced by our company to process the images collected by the video endoscopes and send them to the display, and provide power for the endoscope.

Single-Use Video Gastroscope
This product is used in conjunction with Endoscopic Video Image Processor and other peripheral equipment for the observation, diagnosis, photography and treatment of upper digestive tract.
The device is suitable for professional healthcare facility environments such as hospitals and clinics.
This product is designed for use in adults.

Single-Use Video Colonoscope
This product is used in conjunction with Endoscopic Video Image Processor and other peripheral equipment for the observation, diagnosis, photography and treatment of lower digestive tract.
The device is suitable for professional healthcare facility environments such as hospitals and clinics.
This product is designed for use in adults.

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.

510(k) #: K232043

510(k) Summary

Prepared on: 2024-02-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Guangzhou Red Pine Medical Instrument Co., Ltd.
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Correspondent Contact	Ms. Ping Yang
Correspondent Contact Email	regulation@gzredpine.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Endoscopic Video Image Processor (RP-IPD-V2000A, RP-IPD-V2000B, RP-IPD-V2000C, RP-IPD-V2000D); Single-Use Video Gastroscope (RP-GI-G02A, RP-GI-G02B); Single-Use Video Colonoscope (RP-GI-C02A, RP-GI-C02B)
Common Name	Endoscope and accessories
Classification Name	Colonoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code	FDF, FDS, FET

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K100584	EVIS EXERA II 180 System	NWB, FDF, FE

Device Description Summary

21 CFR 807.92(a)(4)

The proposed device, Digestive Endoscopy System, which includes a Single-Use Video Gastroscope and Single-Use Video Colonoscope, and Endoscopic Video Image Processor is intended for observation, diagnosis, photography and treatment of the disease of the upper and lower gastrointestinal tract.

The Single-Use Video Gastroscope is available in two models with different length of image processor connection section, RP-GI-G02A, RP-GI-G02B. The Single-Use Video Colonoscope is available in two models with different length of image processor connection section

and different diameters, RP-GI-C02A, RP-GI-C02B. The Endoscopic Video Image Processor is available in four models with different hard disk space, RP-IPD-V2000A, RP-IPD-V2000B, RP-IPD-V2000C, RP-IPD-V2000D.

The Single-Use Video Gastroscope and Single-Use Video Colonoscope are sterile and single-patient-use device. The Endoscopic Video Image Processor is non-sterile and multi-patient-use device, and it will be cleaned and disinfected before first use and after each use.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Endoscopic Video Image Processor
This device is used in conjunction with the video endoscopes produced by our company to process the images collected by the video endoscopes and send them to the display, and provide power for the endoscope.

Single-Use Video Gastroscope
This product is used in conjunction with Endoscopic Video Image Processor and other peripheral equipment for the observation, diagnosis, photography and treatment of upper digestive tract.
The device is suitable for professional healthcare facility environments such as hospitals and clinics.
This product is designed for use in adults.

Single-Use Video Colonoscope
This product is used in conjunction with Endoscopic Video Image Processor and other peripheral equipment for the observation, diagnosis, photography and treatment of lower digestive tract.
The device is suitable for professional healthcare facility environments such as hospitals and clinics.
This product is designed for use in adults.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indication for use of the proposed device and the predicate device is similar. They have the same principle of operation, target population and target location. The indication for use of the proposed device and the predicate device is only different in expression. The difference will not affect the safety and effectiveness of the proposed device.

Technological Comparison 21 CFR 807.92(a)(6)

The principles of operation, color tone adjustment, image enhancement, Minimum instrument channel width, working length of colonoscope, bending angle, field of view of gastroscope, direction of view and depth of field of the proposed device are same as the predicate device.

The main configuration, single use or reuse, sterile, dimension and weight, video signal output, white balance, zoom, outer diameter of insertion tube, working length of gastroscope and field of view of colonoscope of the proposed device are different from or similar as the predicate device. These differences will not raise new question on safety and effectiveness of the proposed device based on the comparison test report of the proposed device and predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing
The performance testing was conducted on the proposed Digestive Endoscopy System.
The performance testing includes optical performance, mechanical performance, interoperability with accessories and image quality simulation test.
The optical performance testing includes ISO 8600 test, intensity uniformity, depth of field, signal-to-noise ratio, color reducibility, geometric distortion and dynamic range test.
The mechanical performance testing includes Surface and Edge, General Size, Water Supply/Air Supply System, Suction/Instrument Channel System, Bending Section Control System, Fatigue Test of Bending Section and Bending Knob, Vertical Pressure Test of Bending Section, Tensile Strength of Insertion Portion, Tensile Resistance Strength Between Image Processor Connection Section and Endoscopic Video Image Processor and Connecting Fore Test of Suction Connector, Auxiliary Water Supply Outlet, Air Supply Connector, Water Supply Connector, and Accessories.

Performance Testing-Image Frame Frequency and System Delay
The Image Frame Frequency and System Delay testing was conducted on the proposed Digestive Endoscopy System.

Performance Comparison Testing

The comparison testing includes optical performance, mechanical performance, interoperability with accessories and image quality simulation test.
The optical performance testing includes ISO 8600 test, intensity uniformity, depth of field, signal-to-noise ratio, color reducibility, geometric distortion and dynamic range test.
The mechanical performance testing includes Surface and Edge, General Size, Water Supply/Air Supply System, Suction/Instrument Channel System, Bending Section Control System, Fatigue Test of Bending Section and Bending Knob, Vertical Pressure Test of Bending Section, Tensile Strength of Insertion Portion, Tensile Resistance Strength Between Image Processor Connection Section and Endoscopic Video Image Processor and Connecting Fore Test of Suction Connector, Auxiliary Water Supply Outlet, Air Supply Connector, Water Supply Connector, and Accessories.

Performance-Backflow Prevention
The Backflow Prevention Testing was conducted on the proposed Digestive Endoscopy System.

Not Applicable

Comparison testing of the proposed device manufactured by Guangzhou Red Pine Co., Ltd. and the predicated device manufactured by OLYMPUS MEDICALSYSTEMS CORP was completed, the Single-Use Video Gastroscope has the same intended use as the EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE marketed by Olympus, and the Single-Use Video Colonoscope has the same intended use as the EXERA II COLONOVIDEOSCOPE marketed by Olympus. In terms of optical properties, mechanical properties and interoperability with diagnostic accessories, the proposed device has proved to be basically equivalent to the predicate device. Meanwhile, in the image quality evaluation (simulation test), the image quality of the proposed device was similar to that of the predicate device.