December 12, 2022

Precision Robotics (Hong Kong) Limited
% Sharon Hsu
Consultant
Vee Care (Asia) Limited
17th Chung Pont Commercial Building, 300 Hennessy Road
Hong Kong, Hong Kong 0000
China

Re: K221642
Trade/Device Name: SIRIUS Endoscope System
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope And Accessories
Regulatory Class: Class II
Product Code: HET, GCJ, FGB
Dated: November 9, 2022
Received: November 9, 2022

Dear Sharon Hsu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jessica Carr -S

for Long Chen, PhD
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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.

510(k) Number *(if known)*

K221642

Device Name
Sirius Endoscope System

Indications for Use *(Describe)*

It is intended for use for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs. Not suitable for use for observation and treatment of the heart and must not contact the heart or its vicinity.

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

1. SUBMITTER

Name :	Precision Robotics (Hong Kong) Limited
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Date Prepared:	2022-12-03

2. DEVICE

Device Name/ Trade Name:	SIRIUS Endoscope System
Common Name	Endoscope system
Classification Name:	876.1500 Endoscope and Accessories 884.1720 Laparoscope, Gynecologic (And Accessories)
Classification Panel:	General & Plastic Surgery Obstetrics/Gynecology
Product Code:	HET, GCJ, FGB
Device Class:	II

3. PREDICATE DEVICE

K123365: Olympus LTF-190-10-3D, Endoeye Flex 3D Deflectable Videoscope, MAJ-Y1054 3D Processor, Olympus CV-190 EVIS Extra III Video system center

4. DEVICE DESCRIPTION

The SIRIUS Endoscope System as a robotic endoscope consists of Video Processor, Laparoscope Handle, Laparoscope Head and Joystick. The SIRIUS Endoscope System is developed for minimal invasive surgery application.

The SIRIUS Endoscope System is a fully integrated compact 3D laparoscopic camera system with a flexible tip that can change its viewing direction. The Laparoscope Head is made of biocompatible materials. The articulated tip has three degrees of freedom enabling C and S shaped bending. The insertion section is 10 mm diameter and 340 mm working length. Stereo camera with 1080 high-definition resolution. It has 120 degrees field of view, 10-100mm depth of view and bright light with 300 lumen.

The SIRIUS Endoscope System is to be used only under the supervision of a trained surgeons and professional clinical staff with trained use of the device.

The device is intended for use in Hospital operating theatres only.

5. INDICATION FOR USE

It is intended for use for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs. Not suitable for use for observation and treatment of the heart and must not contact the heart or its vicinity.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SIRIUS Endoscope System is substantially equivalent to the predicate device in terms of intended use and technological characteristics. The differences between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device.

The following are comparisons between subject device and the predicate device.

	Subject Device (K221642)	Predicate Device (K123365)	Comments
Trade Name	SIRIUS Endoscope System	Olympus LTF-190-10-3D, Endoeye Flex 3D Deflectable Videoscope MAJ-Y1054 3D Processor Olympus CV-190 EVIS Extra III Video system center	--
Manufacturer	Precision Robotics (Hong Kong) Limited	Olympus Medical System Corp.	--
Device Class	Class II	Class II	Same
Product Code	HET, GCJ, FGB	HET, GCJ, NWB, FGB	Similar
Regulation number	876.1500 884.1720	876.1500 884.1720	Same
Regulation Name	Endoscope and Accessories	Endoscope and Accessories	Same
Intended Use/ Indications for Use	It is intended for use for endoscopy and endoscopic surgery within the thoracic and abdominal cavities	This instrument is indicated for use within the thoracic and abdominal cavities	Same

	including female reproductive organs. Not suitable for use for observation and treatment of the heart and must not contact the heart or its vicinity.	including female reproductive organs. This instrument must not be used for observation or treatment of the heart and must not contact the heart or any area near the heart. In addition, this instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.	
Operating Principles	Tendon driven articulating 3D video endoscope driven electromechanically using motors in the handle.	Cable steered articulating 3D video endoscope driven manually using mechanical levers in the scope handle.	Different The laparoscope head movement of subject device is controlled electromechanically. It shas validated and compliance to IEC60601-1, IEC 62304 and ISO8600.
Anatomical Access	Thoracic and abdominal cavities including female reproductive organs.	Thoracic and abdominal cavities including female reproductive organs.	Same
Direction of View	0° camera angle	0° camera angle	Same
Shaft diameter (OD)	10 mm	10 mm	Same
Tip Articulation	± 90° for each up-down joint allowing retroflexion ± 45° for left-right joint	± 100°	Similar Angle of deflection meet the requirement of ISO 8600-1:2015.
Working Length	340 mm	370 mm	Different Physical difference.
Shaft material	TPU, Stainless steel, FLUORZ-UPF75-2	Carbon Fiber, covered with heat shrink sheathing	Different Differences are addressed through biocompatibility testing per ISO10993.
Optics Type	Color	Color	Same
Resolution	1920 x 1080	1080 x 601	Subject has higher resolution
Single Use	Yes	No	Different The sterilization validation has been performed by ISO 11135:2014.

Sterilization	EO sterilization	Product is provided non-sterile	Different The sterilization validation has been performed by ISO 11135:2014.
Biocompatibility	Patient contacting components meet ISO10993 standard	Patient contacting components meet ISO10993 standard	Same
Electrical Safety and EMC	complies with IEC 60601-1, IEC60601-2-18 standards for safety and IEC 60601-1-2 standard for EMC	complies with IEC 60601-1, IEC60601-2-18 standards for safety and IEC 60601-1-2 standard for EMC	Same

Discussion:

The tip articulation of subject device is within the range of predicate device. The specification of tip articulation of subject device fulfils the requirement of ISO 8600-1:2015. The difference does not affect the effectiveness and safety of the device.

The subject device has shorter working length than predicate device, this physical different does not impact the effectiveness and safety of the device.

The shaft material of subject device and predicate device are made of different materials, but both are biocompatible materials. The biocompatibility tests conducted demonstrated the safety of subject device.

The subject device is singe use device with EO sterilization validated by ISO 11135:2014. This difference does not impact the effectiveness and safety of the device.

Therefore, the differences between the subject device and its predicate do not affect substantially equivalent on safety and effectiveness.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Laparoscope Head was conducted in accordance with International Standard ISO 10993-1:2005, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-11:2017 as recognized by FDA. The evaluation included the following tests:

- Cytotoxicity
- Sensitization

- Irritation
- Acute systemic toxicity
- Pyrogen

Sterility

The sterilization of the product is achieved using ethylene oxide sterilization. Sterilization condition is validated per ISO 11135: 2014 overkill half-cycle approach. The sterility assurance level (SAL) is 10-6. The amount of ethylene oxide and chlorohydrin residual levels are within the limit and in compliance with ISO 10993-7: 2008 requirement.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on SIRIUS endoscope system. The device complies with IEC 60601-1, IEC60601-2-18 standards for safety and the IEC 60601-1-2 standard for EMC.

Light source safety

Light source safety was conducted on SIRIUS endoscope system. The lamp is certified as Risk group 2 and complies with IEC 62471: 2006.

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 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

Usability Evaluation

The Usability evaluation for SIRIUS endoscope system is conducted in accordance with ANSI AAMI IEC 62366-1:2015+AMD1:2020, and, therefore, by extension IEC 60601-1-6 Edition 3.2. The usability verification and validation are well defined with criteria specified in the Usability Engineering Report. Usability testing results and improvement action demonstrated that residual risk regarding usability is minimized and acceptable. It is concluded that the usability evaluation is well performed and acceptable.

Performance testing

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- ISO 8600-1:2015, Endoscopes - Medical endoscopes and endotherapy devices -- Part 1: General requirements
- ISO 8600-3:2019, Endoscopes - Medical endoscopes and endotherapy devices Part 3:

Determination of field of view and direction of view of endoscopes with optics.

- ISO 8600-4:2014, Endoscopes - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion
- ISO 8600-7:2012, Endoscopes — Medical endoscopes and endotherapy devices — Part 7: Basic requirements for medical endoscopes of water-resistant type

8. CONCLUSIONS

The SIRIUS Endoscope System is substantially equivalent to the predicate device and present no new questions of safety or effectiveness.