August 29, 2025

Precision Robotics (Hong Kong) Limited
℅ Kacia Mak
Regulatory Affairs Manager
Vee Care Asia Limited
8/F-1, No. 80, Zhouzi Street, Neihu District
Tai Pei City, 114
Taiwan

Re: K250939
Trade/Device Name: SIRIUS Endoscope System (PR-SI-1230)
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope And Accessories
Regulatory Class: Class II
Product Code: HET, GCJ, GCQ
Dated: July 31, 2025
Received: July 31, 2025

Dear Kacia Mak:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.08.29 10:17:48 -04'00'

Colin Kejing Chen
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
SIRIUS Endoscope System (PR-SI-1230)

Device Name
K250939

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. SUBMITTER

Name :	Precision Robotics (Hong Kong) Limited
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Contact Name:	Alan Kwok
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Email Address:	a.kwok@prhk.ltd
Date Prepared:	2024-12-05

2. DEVICE

Device Name/ Trade Name:	SIRIUS Endoscope System
Model Number:	PR-SI-1230
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

K221642: SIRIUS Endoscope System

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 342 mm working length. Stereo camera with 1080 high-definition resolution. It has 90 degrees field of view, 10-100 mm depth of view.

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

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

5. INDICATIONS 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	Predicate Device (K221642)	Comments
Trade Name	SIRIUS Endoscope System	SIRIUS Endoscope System	--
Model No.	PR-SI-1230	N/A	
Manufacturer	Precision Robotics (Hong Kong) Limited	Precision Robotics (Hong Kong) Limited	Same
Device Class	Class II	Class II	Same
Product Code	HET, GCJ, FGB	HET, GCJ, FGB	Same
Regulation number	884.1720 876.1500	884.1720 876.1500	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 including female reproductive organs. Not suitable for use for observation and treatment of the heart and must not contact the heart or its vicinity.	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.	Same
Operating Principles	Tendon driven articulating 3D video endoscope driven electromechanically using motors in the handle.	Tendon driven articulating 3D video endoscope driven electromechanically using motors in the handle.	Same
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	± 90° for each up-down joint allowing retroflexion ± 45° for left-right joint	Same
Working Length	342 mm	340 mm	Different Physical difference; no difference in performance
Shaft material	TPU, Stainless steel, UPF75-2	TPU, Stainless steel, UPF75-2	Same
Optics Type	Color	Color	Same
Resolution	1920 x 1080	1920 x 1080	Same
Single Use	Yes	Yes	Same
Sterilization	EO sterilization	EO sterilization	Same
Biocompatibility	Patient contacting components meet ISO10993 standard	Patient contacting components meet ISO10993 standard	Same
Electrical Safety	Comply with EMC standards for medical electrical equipment in IEC 60601-1-2	Comply with EMC standards for medical electrical equipment in IEC 60601-1-2	Same
Joystick Design	Customized joystick	Off-the-shelf joystick	Different Performance verified to be equivalent
Locking Mechanism	Locking mechanism was added for the laparoscope handle	No locking mechanism for the laparoscope handle	Different Performance verified to be equivalent

Discussion:

The subject device has the same intended use and technological characteristics as the predicate device. Operating principles, anatomical access, shaft material and other technical specifications are the same for both devices. Mechanical and electronic feature differences between the subject device and its predicate were verified by electrical safety and electromagnetic compatibility tests and usability tests. These differences have no impact on the effectiveness and safety of the device, so it does not affect substantial equivalence 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 documentation level applied for this device was considered as Basic Documentation.

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

Usability Engineering Testing

Usability engineering tests were conducted on SIRIUS endoscope system according to ANSI AAMI IEC 62366-1:2015+AMD1:2020. Formative and summative evaluations were conducted. Results and improvement action demonstrated that residual risk regarding usability is minimized and acceptable. The benefits of the evaluated medical device SIRIUS Endoscope System significantly exceed its possible risks of use-error concerns.

8. CONCLUSIONS

Based on the information provided within the 510(k) submission, proposed SIRIUS Endoscope System substantially equivalent to the predicate device and is as safe, as effective and perform as well as the legally marketed predicate device.