July 24, 2024

OUI Medical Inc.
Pavan Kumar Palamkota
Regulatory Consultant
3000 Pegasus Park Dr. Suite 1330
Dallas, Texas 75247

Re: K241502
Trade/Device Name: P-scope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, GCQ
Dated: May 28, 2024
Received: May 28, 2024

Dear Pavan Kumar Palamkota:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.07.24 15:43:48 -04'00'

Long Chen, Ph.D.
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.

Submission Number *(if known)*

K241502

Device Name

P-SCOPE

Indications for Use *(Describe)*

P-Scope is intended to be used in diagnostic and therapeutic procedures for endoscopy within the peritoneal cavities including the female reproductive organs.

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

Prepared on: 2024-07-24

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Mr. Pavan Kumar Palamkota
Correspondent Contact Email	pavan@oui-medical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	P-Scope
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Number	876.1500
Product Code(s)	GCJ, GCQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220872	Saberscope5 Laparoscope	GCJ
K211250	VisionPort System	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

The device contains two separate functioning components. First is the single-use, sterile P-scope laparoscope device, which includes a 0° camera mounted on a 3 or 5 mm rigid shaft and reusable high-definition video display. The video display includes ports such as USB and HDMI, which allow for connections to external high-definition video screens. This feature enables the surgeon to have a larger and more detailed view of the surgical field during the procedure.
In summary, the P-scope combines the single-use laparoscope device with a high-definition video camera for imaging, and a reusable video display with an image processor for displaying the video feed, along with connectivity options to external video screens.

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

P-Scope is intended to be used in diagnostic and therapeutic procedures for endoscopy within the peritoneal cavities including the female reproductive organs.

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

The Indications for Use is the same as the predicate device

Technological Comparison 21 CFR 807.92(a)(6)

The P-scope, alongside its predicate devices Saberscope and VisionPort System, shares significant technological similarities that establish a foundation for their use in diagnostic and therapeutic procedures within peritoneal cavities. All three devices are classified under Class II with regulation number 21 CFR 876.1500 and carry the product code GCJ, underscoring their designation as endoscopes and accessories. Their design incorporates a high-definition video imaging system within a laparoscope structure designed for single use, leveraging LED lighting for illumination to ensure clear visibility of the surgical field. The devices are provided sterile, typically via EO gas, with materials that are biocompatible as per ISO 10993 standards, supporting their safe intraoperative use..

However, the P-scope and Saberscope diverge significantly in their technological characteristics, notably in terms of articulation capabilities, visualization, and display resolution. The P-scope, with its rigid shaft design, focuses on stability and simplicity, contrasting with the Saberscope's ±90° articulating tip that offers enhanced maneuverability. Additionally, the P-scope differentiates itself by offering a 120° field of view, providing broader visibility than typical endoscopes. This feature, combined with a resolution of 160K pixels (400x400), distinguishes the P-scope from the Saberscope, which boasts a higher resolution of 1080p. Despite the lower resolution, the P-scope's wider field of view aims to improve procedural efficiency by reducing the need for scope repositioning and enhancing the surgeon's ability to navigate and identify anatomical structures. Together, these features position the P-scope as an evolution in endoscopic device design, prioritizing expansive visualization and streamlined operation while maintaining the critical safety and effectiveness standards established by its predicate devices.

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

Non-clincal testing was designed and developed in accordance with applicable requirements and standards to establish performance and safety of the subject device P-SCOPE. These include performance bench testing
ISO 8600-1 "Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements", as well as EMC and Electrical safety in accordance with 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 (FDA-recognized voluntary consensus standard: 19-36) and IEC/TR 60601-4-2 Edition 1.0 2016-05, Medical Electrical Equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems (FDA-recognized voluntary consensus standard: 19-19), ANSI AAMI ES 60601-1:2005 + A1:2012 , Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (FDA-recognized voluntary consensus standard: 19-4),and IEC 60601-2-18:2009, Medical electrical equipment – Part 2-18: Particular requirements for the safety of endoscopic equipment (FDA-recognized voluntary consensus standard: 9-114). Verification and validation testing successfully completed demonstrated that the device conform with recognized safety standards, design input specifications, user needs and intended uses.

The subject devices do not require clinical studies to support the determination of substantial equivalence.

The P-SCOPE has the same intended use and indications for use, and fundamental technology as the predicate device. In summary, P-SCOPE is the same or similar with respect to safety and effectiveness to the legally marketed predicate device.