April 20, 2022

Xenocor, Inc
% Spencer Walker
CEO/ Managing Partner
Peak Regulatory Consulting, LLC
370 S. 300 E.
Salt Lake City, Utah 84111

Re: K220872
Trade/Device Name: Saberscope5 Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, HET, GCQ
Dated: March 24, 2022
Received: March 25, 2022

Dear Spencer Walker:

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,

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

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)*
K220872

Device Name
Xenocor® SaberScope5 Laparoscope

Indications for Use *(Describe)*

The SaberScope5 Laparoscope is intended to be used in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and 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.

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510(K) SUMMARY
(21 CFR 807.92)

GENERAL INFORMATION

Submitter: Xenocor, Inc.

Contact Person: Spencer Walker, MSc –
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Date Prepared: March 24, 2022

Trade Name: Xenocor® SaberScope5 Laparoscope

Classification Name: Endoscope and Accessories

21 CFR §876.1500, Product Code(s) GCJ, GCQ,

Gynecologic Laparoscope and Accessories

21 CFR §884.1720, Product Code HET,

Device Class: Class II

Predicate Device: 510(k) No.: K193315
Model: Xenocor® Articulating Xenoscope™ Laparoscope
Manufacture: Xenocor, Inc.
Classification: GCJ, GCQ, & HET

Device Description:
The Articulating Xenoscope™ System is being renamed the SaberScope5 Laparoscope. The subject device contains two separate functioning components. First is the single-use, sterile SaberScope5 Laparoscope Device, which includes a 0° camera on 5 mm rigid shaft with a ± 90° articulating tip, 10 - 36 cm long shaft, and high-definition video image. For certain procedures the shorter 10 cm laparoscope is preferred. Likewise, for other procedures, the longer 36 cm laparoscope is preferred. Except for the length difference, the scientific principles, materials of construction and design are otherwise identical. The second is the XenoBox™, which converts the digital signal from the camera to HDMI signal for display onto the HD video screen for the surgeon to view.

Table 1: SaberScope5 Model Numbers		
Product Family	**Model No.**	**Description**
Xenoscope	XSA-0-0510	SaberScope5 Laparoscope (0°, 5mm shaft, 10cm length)
	XSA-0-0536	SaberScope5 Laparoscope (0°, 5mm shaft, 36cm length)

Indications for Use:
The Indications for Use is the same as the predicate device, which is:

The SaberScope5 Laparoscope is intended to be used in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs.

Comparative Analysis:
It has been demonstrated that the modified SaberScope5 Laparoscopic System is comparable to the predicate device in intended use, fundamental scientific technology, design, materials, principles of operation and functional performance evaluations and is substantial equivalent as summarized in **Table 2**. The SaberScope5 Laparoscopic System has been fully assessed within the Xenocor® Risk Management and Design Controls systems. The differences raise no additional or different questions of safety or effectiveness from that already identified for the predicate device.

Table 2: Table of Substantial Equivalence		
Product Attribute	**Predicate Device: Articulating Xenoscope Laparoscope (K193315)**	**Subject Device: SaberScope5 Laparoscope**
Indications for Use	The Articulating Xenoscope is intended to be used in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs.	The SaberScope5 Laparoscope is intended to be used in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs.
Classification Info.	Gastroenterology-Urology Devices - Endoscope and Accessories (21 CFR §876.1500), Product code: GCJ & GCQ Obstetrical and Gynecological Diagnostic Devices - Gynecologic Laparoscope and Accessories (21 CFR §884.1720), Product code: HET Class II	Same

Table 2: Table of Substantial Equivalence		
Product Attribute	**Predicate Device: Articulating Xenoscope Laparoscope (K193315)**	**Subject Device: SaberScope5 Laparoscope**
Single Use	Yes	Same
Sterile	Provided Sterile (EO gas)	Same
Prescription	Yes	Same
Anatomical Access	Thoracic and abdominal body cavities, hollow organs, and canals, including female reproductive organs.	Same
Fundamental Scientific Technology	The tip has an imaging sensor that sends digital video information, which the Xenobox coverts to an HDMI output for display on commonly used HD monitors.	Same as predicate with the additional manual focus capability
Part No.	XSA-0-0510, XSA-0-0536	Same
Design	0° camera angle, 5 mm rigid shaft, with articulating tip with fixed focus.	Same, but with manual focus buttons on handle
Shaft Diameter (OD)	5 mm	Same
Shaft Tip	Articulating Tip (± 90º)	Same
Shaft Lengths	10 cm, 36 cm	Same
Shaft Material	Carbon Fiber, covered with heat shrink sheathing	Same
Field of View	65º-75º (Nominal 69º)	Same
HD Resolution	1080p	Same
Camera Focus	Fixed Focus	3-10cm
Focus Control Buttons	N/A	3 buttons: - forward (manual mode) - backward (manual mode) - manual/auto toggle
Frame Rate	30 fps	Same
Exposure/Gain Control	Automatic (no user adjustments)	Same
Latency <100ms	No buffering more than 3 frames	Same

Table 2: Table of Substantial Equivalence		
Product Attribute	**Predicate Device: Articulating Xenoscope Laparoscope (K193315)**	**Subject Device: SaberScope5 Laparoscope**
Light Source	6 LED (ring)	Same
White Balance	Fixed	Same
LED Color Brightness Range	2500k to 7000k	Same
Handle	Handle with articulation mechanism	Handle with articulation mechanism and focus buttons
Packaging	Double Pouched Tyvek/ Mylar Pouch, and backer card	Same
Sterilization	EO Sterile (SAL 10^{-6})	Same
Shelf Life	1 years	Same
Biocompatibility	Patient contacting components meet ISO 10993 standard	Same
Applied Part Class (per IEC 60601-2-18; (2009))	Type CF	Same

Functional/Safety Testing:

Verification activities were performed on the subject laparoscope to demonstrate substantial equivalence to the predicate device:

- **Biocompatibility** – No new patient contacting materials were introduced therefore additional biocompatibility testing was not conducted for this modification.
- **Design Verification** – Performance bench testing was conducted to ensure that the subject device met the applicable design and performance requirements throughout its shelf life, verify conformity to applicable standards, and demonstrate substantial equivalence to the predicate system. The following performance testing was performed or fulfilled with the subject SaberScope5 Laparoscope.
    - Fixed Lens Focus Testing
    - Focus Range Testing

- **Packaging –** The proposed changes to the subject device did not affect the packaging or its configuration.

Conclusion:
The subject SaberScope5 Laparoscope is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate device. The minor differences between the subject SaberScope5 Laparoscope and the predicated device have no effect on safety or effectiveness, as established through various performance tests.

The modifications to the SaberScope5 Laparoscope were made per Xenocor's procedures and quality system. The SaberScope5 Laparoscope is substantially equivalent to the cited predicate device. Additionally, the SaberScope5 Laparoscope met all acceptance criteria to confirm safety and effectiveness.