U.S. FOOD & DRUG ADMINISTRATION

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January 27, 2020

Xenocor, Inc
% Spencer Walker
Director of Regulatory Affairs
630 Komas Dr., Suite 200
Salt Lake City, Utah 84108

Re: K193315
Trade/Device Name: Xenocor Articulating Xenoscope Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, HET, GCQ
Dated: November 26, 2019
Received: November 29, 2019

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193315

Device Name
Xenocor Articulating Xenoscope Laparoscope

Indications for Use *(Describe)*
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.

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

Submitter: Xenocor®, Inc

Contact Person: Spencer Walker, MSC - Director Regulatory Affairs
630 Komas Dr. Suite 200
Salt Lake City, UT 84108
(801) 581-5080

Date Prepared: Jan. 4, 2020

Trade Name: Xenocor® Articulating Xenoscope™ 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(s):

- K161838 – Xenocor®, Xenoscope™ Laparoscopic System

Device Description:

The Articulating Xenoscope™ System contains two separate functioning components. First is the single-use, sterile Articulating Xenoscope™ Laparoscope Device, which includes a 0° camera on 5 mm rigid shaft with a ± 30° articulating tip, 10 cm or 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. Together, the Xenoscope™ and the Xenobox™ comprise the Xenoscope™ Laparoscopic System and work synergistically together.

Indications for Use:

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

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.

Technological Characteristics and Substantial Equivalence Comparative Analysis:
Modifications in design and materials of the previously 510(k) cleared Xenoscope Laparoscope device (K161838) resulted in two (2) additional models (XSA-0-0510, XSA-0-0536) which include a smaller 5mm diameter rigid carbon fiber shaft with articulating tip and handle features. The camera is the same as the predicate, and the combined 6 smaller LED's of the subject device equal the 1 larger LED of the predicate in energy and light output.
It has been demonstrated that the modified Xenoscope™ Laparoscopic device is comparable to the predicate and reference device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations and is substantially equivalent as summarized in **Table 1**. The Articulating Xenoscope™ 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 and reference devices.

Table 1: Xenoscope System Table of Substantial Equivalence

Product Attribute	Predicate Device: Xenoscope Laparoscope (K161838)	Reference Device: Xenoscope Laparoscope (K171344)	Subject Device: Articulating Xenoscope Laparoscope (K193315)
Indications for Use	The 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.	Same	Same
Classification Info.	Gastroenterology-Urology Devices - Endoscope and Accessories (21 CFR §876.1500), Product code: GCJ Obstetrical and Gynecological Diagnostic Devices - Gynecologic Laparoscope and Accessories (21 CFR §884.1720), Product code: HET Class II	Same	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
Single Use	Yes	Same	Same
Sterile	Provided Sterile (EO gas)	Same	Same

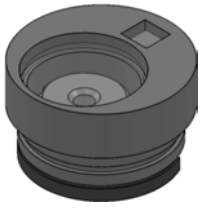
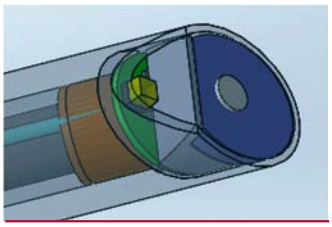
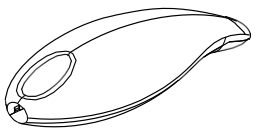
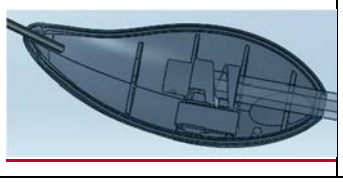
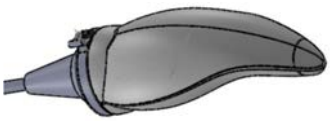
Table 1: Xenoscope System Table of Substantial Equivalence			
Product Attribute	**Predicate Device: Xenoscope Laparoscope (K161838)**	**Reference Device: Xenoscope Laparoscope (K171344)**	**Subject Device: Articulating Xenoscope Laparoscope (K193315)**
Prescription	Yes	Same	Same
Anatomical Access	Thoracic and abdominal body cavities, hollow organs, and canals, including female reproductive organs.	Same	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	Same
Part No.	XS-0-1010, XS-0-1036, XD-A1	XS-30-1010, XS-30-1036	XSA-0-0510, XSA-0-0536,
Design	0° camera angle, 10 mm rigid shaft	30° camera angle, 10 mm rigid shaft	0° camera angle, 5 mm rigid shaft with articulating tip
Shaft Diameter (OD)	10 mm	10 mm	5 mm
Shaft Tip	Rigid (0º)	Rigid (30º)	Articulating Tip (≥ 30º)
Shaft Lengths	10 cm, 36 cm	Same	Same
Shaft Material	Gray Polycarbonate Lexan shaft	Gray Fiber reinforced polymer Polygon PG-F-5400 shaft	Carbon Fiber, covered with heat shrink sheathing
Camera Angle	0º camera angle 	30º camera angle with 30º view when rotated 	0º camera angle with ≥ 30º view when articulated 
Light Source	1 LED	1 LED	6 LEDs (ring)
Handle	Basic Ergonomic Handle 	Handle with rotation mechanism 	Handle with articulation mechanism 

Table 1: Xenoscope System Table of Substantial Equivalence			
Product Attribute	**Predicate Device: Xenoscope Laparoscope (K161838)**	**Reference Device: Xenoscope Laparoscope (K171344)**	**Subject Device: Articulating Xenoscope Laparoscope (K193315)**
Packaging	Double Pouched Tyvek/ Mylar Pouch, and backer card	Same	Same
Sterilization	EO Sterile (SAL 10^{-6})	Same	Same
Shelf Life	1 years	Same	Same
Biocompati-bility	Patient contacting components meet ISO 10993 standard	Same	Same
Applied Part Class (per IEC 60601-2-18; (2009))	Type CF	Same	Same

Verification and Functional/Safety Testing:

The following functional tests were performed. All data met pre-determined acceptance criteria.

- **Biocompatibility** – Biocompatibility testing was done due to the new shaft materials. All tests were done per the same protocol and acceptance criteria as the predicate device, and per ISO 10993-1 and in accordance with the 2016 FDA guidance document "Use of International Standard ISO 10993-1 for External communicating device, direct tissue contact, duration ≤ 24 hours, the following tests were performed and passed:
  - *Cytotoxicity*
  - *Sensitization*
  - *Irritation/ Intracutaneous Toxicity*
  - *Systemic Injection*
  - *Material Mediated Pyrogenicity*

- **Shaft Bend Strength Testing** – Due to the smaller 5 mm shaft diameter and shaft material change to carbon fiber with addition of the heat shrink sheath, per internal requirements, and based on the risk evaluation for this change, the inspection of the laparoscope shaft to confirm functionality after bending the shaft was done. The protocol and acceptance criteria were the same as the predicate device. All devices tested passed.

- **Accelerated Aging -** Per internal requirements and based on the risk evaluation for this device, all devices were mechanically functional after 1-year shelf life testing. The protocol and acceptance criteria were the same as the predicate

device with the added visual examination of the heat shrink materials and the ≥ 30º articulation in both the X and Y axis.

- **Software Validation –** The software for the Xenobox and the subject device has not changed. The subject and predicate devices use the same software.

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

- **Design Validation –** The modified design was validated by intended users (trained surgeons) through an evaluation of the Articulating Xenoscope™. The study protocol & acceptance criteria were the same as the predicate, with the only deviation being the predicate was evaluated by 3 physicians, and the subject device was evaluated by 10 physicians).

Conclusion:

The modifications to the Xenoscope™ were made per Xenocor's quality procedures and design control systems. The Articulating Xenoscope™ Laparoscopic System is substantially equivalent to the cited predicate device. Additionally, the Articulating Xenoscope™ Laparoscopic System met all acceptance criteria to confirm safety and effectiveness.