DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 26, 2016

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

Re: K161838
Trade/Device Name: Xenocor Xenoscope Laparoscopic System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, HET
Dated: August 23, 2016
Received: August 29, 2016

Dear Mr. 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. 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 Part 803); good manufacturing practice requirements as set forth

in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Indications for Use

510(k) Number (if known): K161838

Device Name: Xenocor® Xenoscope™ Laparoscopic System

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.

Prescription Use __x__ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office Of Device Evaluation (ODE)

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: June 30, 2016

Trade Name: Xenocor® Xenoscope™ Laparoscopic System

Classification Name: Endoscope and Accessories
21 CFR §876.1500, Product Code GCJ, Class II

Gynecologic Laparoscope and Accessories
21 CFR §884.1720, Product Code HET, Class II

Predicate Device(s):

- K935279 - Karl Storz, Hopkins Rigid Autoclavable Telescope;
- K993045 - Stryker, Bariatric Laparoscope;
- K150633 – Olympus Winter & Ibe GmbH, ULTRA Telescope;

Device Description:

The Xenoscope™ System contains two separate functioning components. First, the Xenoscope™ Laparoscope Device is a 0°, 30 Fr (10mm), 10 - 36 cm long, single-use, 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. Second, the Xenoscope™ Dongle, which converts the camera image onto the video display screen for the surgeon to use, is provided with the Xenoscope™. Together, the Xenoscope™ and the Xenoscope™ Dongle comprise the Xenoscope™ Laparoscopic System and work synergistically together.

- **Xenoscope™ Laparoscope**

  The Xenoscope™ Device is used like other laparoscopes, and has the following features:
  - Camera Housing: 0°lens, sensor and a single LED light,
  - Rigid Shaft: 30 Fr (10mm) in diameter, and approximately 10 - 36 cm long
  - Ergonomic handle

- Video cable attached to scope to connect to the Dongle (Micro-HDMI D).
- Inserted through a trocar/port
- Packaged sterile and designed for single-use only
- High-definition video image

- **Xenoscope™ Dongle**
  The Xenoscope™ Dongle is a multi-use device and is provided with the Xenoscope™ and has multiple connections. The Dongle converts the digital information into a video image displayed on an HDMI monitor that the surgeon uses. The Xenoscope™ connects to the Dongle via a cable with a micro-HDMI connector. The Dongle connects to the viewing screen via an HDMI cord. The Dongle portion of the Xenoscope™ consists of the following parts:
  - Protective case
  - Internal PCB board
  - Cable connections
    - Power (5V, 1A),
    - Micro-HDMI D (connect to scope),
    - HDMI v1.3 (connect to display monitor),
    - USB 3.0 service port (Manufacturing)

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.

Comparative Analysis:
It has been demonstrated that the Xenoscope™ Laparoscopic System is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The Xenoscope™ Laparoscopic System has been fully assessed within the Xenocor® Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria.

Functional/Safety Testing:

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

- **Biocompatibility** – Per ISO 10993-1 for External communicating device, direct tissue contact, duration ≤ 24 hours.

- **Electrical Safety and Essential Performance Requirements** – The Xenoscope™ Laparoscope and the Xenoscope™ Dongle were tested to verify safety and essential performance requirements to the following standards:
    - IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012
    - EN 60601-1:2006 / A1:2013 / A11:2011 / A12:2014; CAN/CSA-C22.2 No. 60601-1:14;
    - AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; IEC 60601-1-6:2010 + A1:2013; IEC 60601-2-18:2009;
    - IEC 62366:2007 + A1:2014; IEC 62304:2006 + A1:2015

- **Electromagnetic Compatibility (EMC)** – The (EMC) series of test demonstrates the EMC characteristics of the Xenoscope™. The Xenoscope™ Laparoscope was tested to the requirements of the following standards:
    - IEC 60601-1-2 Medical Device (2007)
    - IEC 61000-4-2 (2008)
    - IEC 61000-4-3 (2006), A1(2007), A2(2010)
    - IEC 61000-4-4 (2012) IEC 61000-4-5 (2005)
    - IEC 61000-4-6 (2008) IEC 61000-4-8 (2009)
    - IEC 61000-4-11 (2004)
    - CISPR 11 Emissions Class A (2009), A1(2010)
    - Radiated Emissions Conducted Emissions
    - IEC 61000-3-2 AC Current Harmonic Emissions (2006), A1(2009), A2(2009)
    - IEC 61000-3-3 Voltage Fluctuations Emissions (2008)

- **Software Testing** – The only software in the Xenoscope™ system is in the form of firmware on a processor in the dongle that converts the digital video signal into an HDMI signal that displays the video image on commonly used HD monitors. The Xenoscope™ Laparoscope software level of concern has been determined to be moderate, and is deemed to not result in harm to the patient or misdiagnosis of the patient condition when the device is used by a trained surgeon.
- **Design Validation** – Design was validated through an evaluation of the Xenoscope™ System by three (3) trained surgeons (intended users) using a simulated use model in an environment that simulated the intended clinical settings.

Conclusion:

The Xenoscope™ Laparoscopic System is substantially equivalent to the cited predicate device. Additionally, the Xenoscope™ Laparoscopic System met all acceptance criteria.