February 12, 2026

Xenocor, Inc.
Brandon Kessler
Quality and Regulatory Manager
615 Arapeen Dr.
Suite #205
Salt Lake City, Utah 84108

Re: K260177
Trade/Device Name: Saberscope™ Laparoscope (SAS-A-536L); Xenocor® Video Processing Unit (VPUX-1)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, GCQ, HET
Dated: January 20, 2026
Received: January 21, 2026

Dear Brandon Kessler:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2026.02.12 10:54:13 -05'00'

For
Colin Kejing Chen, Ph.D.
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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K260177 |

Please provide the device trade name(s).

Saberscope™ Laparoscope (SAS-A-536L);
Xenocor® Video Processing Unit (VPUX-1)

Please provide your Indications for Use below.

The Saberscope™ 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K260177

# 510(k) Summary

Prepared on: 2026-02-10

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Xenocor, Inc |
| Applicant Address | 615 Arapeen Drive Suite # 205 Salt Lake City UT 84108 United States |
| Applicant Contact Telephone | 801-318-9744 |
| Applicant Contact | Mr. Brandon Kessler |
| Applicant Contact Email | brandon@xenocor.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Saberscope Laparoscope (SAS-A-536L);<br>Xenocor Video Processing Unit (VPUX-1) |
| Common Name | Endoscope and accessories |
| Classification Name | Laparoscope, General & Plastic Surgery |
| Regulation Number | 876.1500 |
| Product Code(s) | GCJ, GCQ, HET |

## 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 |

## Device Description Summary

21 CFR 807.92(a)(4)

The Saberscope™ Laparoscope device contains two separate functioning components. First is the single-use, sterile Saberscope™ Laparoscope Device, which includes a 0° camera on a 5 mm rigid shaft with a ± 90° articulating tip, 36 cm long shaft, and high-definition video image. The second is the Xenocor® VPU which converts the digital signal from the camera to HDMI signal for display onto the HD video screen for the surgeon to view.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Saberscope™ 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.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

There is no change to the Indications for Use from the predicate device.

## Technological Comparison

21 CFR 807.92(a)(6)

It has been demonstrated that the modified Saberscope™ Laparoscopic System is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations and is substantial equivalent. The Saberscope™ 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 those already identified for the predicate device. Some risks have been reduced, and this has been captured by risk management.

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

Design validation and verification activities were performed on the Saberscope system to show substantial equivalence to the predicate device.
Xenocor tested device for the following: ISO 10993 biocompatability of the modified device; Imatest image quality testing for the new camera and imaging chain; performance & durability of the new laser-cut hypotube bending section; electrical, thermal, mechanical, and electromagnetic compatibility & safety testing per IEC 60601-1, 60601-1-2, & 60601-2-18; user studies to test the user experience with the modified design; Video Processing Unit validation to confirm function and proper electrical and safety performance, per IEC 60601 standards; packaging & sterilization validation and verification for the new device packaging; and a shelf life study, including AA & RTA conditioning.
The device met all acceptance criteria, and has been found to be safe, effective, and substantially equivalent to the predicate.