August 13, 2026

Freyja Healthcare, LLC
% Christine Brauer
Regulatory Affairs Consultant
Brauer Device Consultants, LLC
22004 Summerwalk
Bethany Beach, Delaware 19930

Re: K261139
Trade/Device Name: VereSee (VER150, VER200, VER151, VER201, VER200C, and VER-100-103)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, HIF
Dated: April 7, 2026
Received: April 7, 2026

Dear Christine Brauer:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.08.13 22:08:57 -04'00'

Colin K. 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

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.	K261139

Please provide the device trade name(s).

VereSee (VER150, VER200, VER151, VER201, VER200C, and VER-100-103)

Please provide your Indications for Use below.

VereSee is intended for:

• Percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic surgery

• Use as an endoscopic video camera to provide visible light imaging in a variety of endoscopic and laparoscopic diagnostic and surgical procedures

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K261139

510(k) Summary

Prepared on: 2026-04-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Freyja Healthcare, LLC
Applicant Address	1253 Worcester Road Suite 101 Framingham MA 01701 United States
Applicant Contact Telephone	978-766-8680
Applicant Contact	Mr. Eric Frattura
Applicant Contact Email	eric@freyjahealthcare.com
Correspondent Name	Brauer Device Consultants,LLC
Correspondent Address	22004 Summerwalk Bethany Beach DE 19930 United States
Correspondent Contact Telephone	301-545-1990
Correspondent Contact	Dr. Christine Brauer
Correspondent Contact Email	chris.brauer@comcast.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VereSee (VER150, VER200, VER151, VER201, VER200C, and VER-100-103)
Common Name	Endoscope and accessories
Classification Name	Laparoscope, general & plastic surgery
Regulation Number	876.1500
Product Code(s)	GCJ, HIF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K252640	VereSee Optical Veres Needle and Endoscopic Camera	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

VereSee consists of the following components: 1) the Endoscopic Camera (or "Camera") and its protective cover; 2) the Access-Insufflation Cannula Set; and 3) the Camera Control Unit (CCU). The VereSee Camera and Access-Insufflation Cannula Sets are provided in two nominal lengths: 150mm and 200mm.

The VereSee Camera and Access/Insufflation Cannula Set consist of three concentric stainless-steel hypotubes with a handle and an umbilical cable for connection to the CCU. The three cannulas include: 1) Access Cannula with a clear, pointed tip for penetration and visualization during abdomen entry, 2) Insufflation Cannula, which connects to insufflation tubing and seals to prevent leakage of insufflation gas; and 3) Camera, a stainless-steel hypo tube with a CMOS camera surrounded by light fibers at its tip.

The Access/Insufflation Cannula Set is provided sterile for single-patient use, whereas the Camera is provided non-sterile and for reuse.

The VereSee Camera Control Unit (CCU) connects the CMOS camera to HDMI compatible monitors to provide an image during use. The CCU converts signals from the VereSee CMOS Camera to a format compatible with HDMI display input requirements

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

VereSee is intended for:

• Percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic surgery

• Use as an endoscopic video camera to provide visible light imaging in a variety of endoscopic and laparoscopic diagnostic and surgical procedures

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

VereSee shares the same intended use as the predicate device, the VereSee Optical Veres Needle and Endoscopic Camera. Both devices have the same intended use and function as a Veress needle to enable a closed abdominal entry technique for laparoscopy. Each device is inserted into the patient's peritoneal cavity to allow for insufflation with carbon dioxide gas, creating a pneumoperitoneum for laparoscopic surgery. Both devices provide visualization during needle insertion.

Both devices share the same intended use as an endoscopic camera, providing illumination and visualization of body cavities, tissues and organs during diagnostic and surgical endoscopic and laparoscopic procedures. Both devices share the same purpose –to provide users visualization during minimally invasive endoscopic or laparoscopic procedures. Both devices share the same key functions – namely, illuminating a body cavity or surgical site, collecting images using a camera and displaying the images to the user on a monitor.

Both devices are prescription devices, used by surgeons in hospitals, surgical centers, or operating rooms. Both devices share the same target patient population – that is, patients requiring an endoscopic or laparoscopic procedure. Both devices have the same patient body contact.

There are two differences between the devices: 1) the trade name and 2) one component of VereSee – the Camera – is reusable whereas this component is a sterile, single-use, disposable component in the predicate device. This characteristic is not new for laparoscopic and endoscopic devices – many laparoscopic and endoscopic devices undergo reprocessing and sterilization between patient uses to provide a cost-effective option for healthcare facilities.

Technological Comparison 21 CFR 807.92(a)(6)

Although there are some differences in technological characteristics, VereSee and the predicate VereSee Optical Veres Needle and Endoscopic Camera share many of the same technological characteristics.

Both consist of the same two components: 1) a handpiece that provides for distal LED illumination and a CMOS camera and 2) a camera control unit. Both are rigid endoscopes. Both handpieces share the same design, consisting of three cannulas: 1) Access Cannula, 2) Insufflation Cannula and 3) Camera Cannula (Camera). Both use a CMOS camera chip for visualization, providing video imaging to the user. Both use a monitor to display the images during use. Both have the same field of view and direction of view.
One key difference is that the VereSee Camera is reusable whereas the VereSee Camera in the predicate device was intended for single-patient use. The main differences in technological characteristics stem from design changes associated with the Camera to improve reprocessing and sterilization. VereSee is also offered in a new longer length for user preference. The spring from the Camera was removed as the spring created small areas which could potentially be difficult to clean. In the predicate device, the spring feature was intended to provide a form of tactile feedback similar to a standard Veress needle. Tactile feedback is still provided when the Access Cannula tip penetrates the peritoneum.

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

Performance testing included:
1) Optical performance (ISO 8600-3 through ISO 8600-5)
2) Physical characteristics
3) Mechanical testing (flow and leakage testing) to evaluate key performance requirements
4) Mechanical testing (destructive) to evaluate the physical strength of the bonds between components

Not Applicable

Verification and validation activities were successfully completed to confirm the subject device meets product requirements and design

specifications. VereSee did not require animal testing or clinical studies to support the determination of substantial equivalence.

Based on the same intended use, similar technological characteristics, and successful completion of bench testing, VereSee is as safe and as effective as the legally marketed predicate device. Any differences between the subject device and predicate device are considered minor and do not raise different questions concerning safety and effectiveness.

The data provided in this 510(k) notification demonstrate that VereSee is as safe and effective for its intended use as the predicate device and does not raise any new safety or effectiveness questions compared to the predicate devices.