Freyja Healthcare, LLC
% Christine Brauer
Regulatory Affairs Consultant
Brauer Device Consultants, LLC
7 Trail House Court
Rockville, Maryland 20850

October 20, 2025

Re: K252640
Trade/Device Name: VereSee Optical Veres Needle and Endoscopic Camera
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, HIF
Dated: August 20, 2025
Received: August 21, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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: 2025.10.20 15:08:37 -04'00'

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.	K252640

Please provide the device trade name(s).

VereSee Optical Veres Needle and Endoscopic Camera

Please provide your Indications for Use below.

The VereSee Optical Veres Needle and Endoscopic Camera 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).

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

510(k) #: K252640

510(k) Summary

Prepared on: 2025-08-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Freyja Healthcare, LLC
Applicant Address	38 Wareham Street Boston MA 02118 United States
Applicant Contact Telephone	563-650-3259
Applicant Contact	Dr. Ryan Goff
Applicant Contact Email	ryan@freyjahealthcare.com
Correspondent Name	Brauer Device Consultants, LLC
Correspondent Address	7 Trail House Court Rockville MD 20850 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 Optical Veres Needle and Endoscopic Camera (VER-120-202 VER-100-203)
Common Name	Endoscopic Camera and Veress Needle
Classification Name	Endoscope and Accessories, and Laparoscopic Insufflator
Regulation Number	21 CFR 876.1500, and 21 CFR 884.1730
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
K243008	Arthrex NanoScope System	GCJ
K232464	VereSee Optical Veres Needle System	HIF

Device Description Summary

21 CFR 807.92(a)(4)

The VereSee Optical Veres Needle and Endoscopic Camera System consists of two components: 1) VereSee Optical Veres Needle and Endoscopic Camera, and 2) VereSee Camera Control Unit.

The VereSee Optical Veres Needle and Endoscopic Camera consists of a series of three concentric stainless steel cannulas with a handle and an umbilical cable to connect it to the VereSee Camera Control Unit. It is provided sterile, for single patient use. The three concentric stainless steel cannulas include: 1) an Outer Cannula (or Insufflation Cannula), 2) a Central Cannula (or Access Cannula) with a clear, pointed tip for penetration and visualization during body cavity entry, and 3) Inner Cannula (or Camera Cannula) with a CMOS camera

surrounded by light fibers at its tip.

The VereSee Camera Control Unit connects the CMOS camera in the VereSee Optical Veres Needle and Endoscopic Camera to HDMI compatible monitors to provide an image for endoscopic procedures. The VereSee Camera Control Unit (CCU) includes an LED driver to power the LED. The CCU connects to the Optical Veres Needle and Endoscopic Camera via an umbilical cable. The CCU converts signals from the CMOS camera in the VereSee Optical Veres Needle and Endoscopic Camera to a format compatible with HDMI display input requirements.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The VereSee Optical Veres Needle and Endoscopic Camera 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)

The VereSee Optical Veres Needle and Endoscopic Camera has the same intended use as each predicate device.

Both the VereSee Optical Veres Needle and Endoscopic Camera and the Arthrex Nanoscope System share the same intended use – each device provides illumination and visualization of body cavities, tissues and organs during diagnostic and surgical endoscopic and laparoscopic procedures. Each device shares the same purpose of providing users visualization during minimally invasive endoscopic or laparoscopic procedures. Each shares the same key functions of illuminating a body cavity or surgical site, collecting images using a camera and displaying the collected images to the user on a monitor. Each device is a prescription device, used by surgeons in hospitals, surgical centers, or operating rooms. Each device shares the same target patient population – that is, patients requiring an endoscopic or laparoscopic procedures. Each device also has the same patient body contact.

There are slight differences in the indication for use statements. The differences include that the predicate device identifies specific endoscopic and laparoscopic diagnostic and surgical procedures and identifies pediatric patients as part of the target population. These slight differences do not constitute a new intended use for the reasons previously described.

Both the VereSee Optical Veres Needle and Endoscopic Camera and the VereSee Optical Veres Needle System share the same intended use as a veress needle. Each device is used to enable closed abdominal entry techniques 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. The devices share the same indication for use statement for the function of the veress needle, except for a slight modification to the tradename.

Technological Comparison

21 CFR 807.92(a)(6)

Although there are many similarities in technological characteristics between the VereSee Optical Veres Needle and Endoscopic Camera System and the Arthrex Nanoscope System, there are some light differences.

With respect to similarities, both the VereSee Laparoscopic Camera System and the Arthrex Nanoscope System consist of the same two system components: 1) a sterile handpiece that provides for distal LED illumination and a CMOS camera and 2) a camera control unit. Both are rigid endoscopes. Both use a CMOS camera chip for visualization, providing imaging to the user. Both use a monitor to display the images during use. Both are similar in dimensions (length and outer diameter), but the predicate device is available in additional lengths. Both devices have a similar field of view and direction of view, but the predicate device also incorporates a wide view. Lastly, the predicate device provides a means to save and store the images, but the VereSee Optical Veres Needle and Endoscopic Camera does not.

The VereSee Optical Veres Needle and Endoscopic Camera shares the same technological characteristics as the VereSee Optical Veres Needle System as there have been no design changes associated with the change in the indication.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The VereSee Optical Veres Needle and Endoscopic Camera shares the same design as the Veres Optical Veres Needle System, cleared via 510(k) notification K232464. The same performance testing provided in the prior 510(k) notification K232464 remains applicable to the new device and is incorporated in this 510(k) notification by cross-reference. Prior performance testing included:

1) Optical performance, including ISO 8600-3 through ISO 8600-5
2) Physical characteristics (such as weight and maximum handle temperature)
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 and to evaluate spring obturator testing and needle penetration tip force

Not Applicable

All verification activities were successfully completed to confirm the subject device meets product requirements and design specifications established for the device.

The VereSee Optical Veres Needle and Endoscopic Camera did not require animal testing or clinical studies to support the determination of substantial equivalence.
Based on the same intended use and the same or similar indications for use and technological characteristics, and successful completion of bench testing, the VereSee Optical VereSee Needle and Endoscopic Camera is as safe and as effective as the legally marketed predicate devices. Any differences between the subject device and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.

The data provided in this 510(k) notification demonstrate that the VereSee Optical Veres Needle and Endoscopic Camera 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.