May 2, 2024

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

Re: K232464
Trade/Device Name: VereSee Optical Veres Needle System
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: April 2, 2024
Received: April 3, 2024

Dear Christine Brauer, PhD:

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.

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,

Jason Roberts -S

Jason R. Roberts, PhD
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232464

Device Name
VereSee Optical Veres Needle System

Indications for Use *(Describe)*
The VereSee Optical Veres Needle System 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.

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.

510(k) SUMMARY
VereSee Optical Veres Needle
K232464

Applicant Information

Applicant and 510(k) Owner: Freyja Healthcare, LLC
488 Pleasant Street
North Andover, Massachusetts 01845 USA

Contact: Ronald Adams
Chief Technology Officer
Freyja Healthcare, LLC
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Date of Preparation: 30 April 2024

510(k) Number: K232464

Device and Classification Information

Trade Name:	VereSee Optical Veres Needle
Common Name:	Veres Needle
Regulation Name:	Laparoscopic Insufflator
Regulation Number:	21 CFR 884.1730
Product Code:	HIF (Insufflator, Laparoscopic)
Class:	II

Device Description

VereSee Optical Veres Needle System is comprised two components:

1) Optical Veres Needle, and
2) Camera Control Unit.

Optical Veres Needle

The Optical Veres Needle 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. The device is provided sterile for single-patient use. Each of the three concentric, stainless steel cannulas is described below:

1. **Outer Cannula** (or Insufflation Cannula) provides a luer fitting for connection of insufflation tubing with an integral flow control stopcock and a set of seals to prevent leakage of insufflation gas.
2. **Central Cannula** (or Access Cannula) consists of a stainless steel hypo tube with a clear, point tip for penetration and visualization during abdomen penetration.
3. **Inner Cannula** (or Camera Cannula) is composed of a stainless steel hypo tube with a CMOS camera surrounded by light fibers at its tip. The light fibers carry the light from an integral LED which is mounted to a heat sink to distribute heat from the LED.

VereSee Camera Control Unit

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

Indication for Use

The indication for use for the VereSee Optical Veres Needle System is shown below.

The VereSee Optical Veres Needle System 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.

Predicate Device Identification

For purposes of demonstrating substantial equivalence, the following predicate device was selected:

- LaproLight Veress Needle (by Buffalo Filter, LLC) cleared via K171139 on May 18, 2017.

Comparison of the Indication for Use and Intended Use

The LaproLight Veress Needle ("LaproLight") and VereSee Optical Veres Needle System share the same intended use – each device is used to enable closed abdominal entry techniques for laparoscopy. Specifically, each device has a spring-loaded tip that is inserted into the patient's peritoneal cavity to allow for insufflation with carbon dioxide gas, creating a pneumoperitoneum for laparoscopic surgery (see **Table 1**). Each device has the same indication for use statement except for the tradename, demonstrating the devices have the same intended use.

Table 1. Summary Comparison of the Intended Use and Indication for Use for the Subject Device and Predicate Device

Characteristic	VereSee Optical Veres Needle System (K232464)	LaproLight Veress Needle (K171139)
Regulation Number	21 CFR 884.1730	21 CFR 884.1730
Product Code	HIF Laparoscopic Insufflator	HIF Laparoscopic Insufflator
Class	II	II
Indication for Use	The VereSee Optical Veres Needle System 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.	The LaproLight 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.
Intended Use	Facilitate entry of laparoscope using a closed (veres needle) technique	Facilitate entry of laparoscope using a closed (veres needle) technique
Conditions of Use	Rx Only; Single Use Only	Rx Only; Single Use Only
Purpose	To establish pneumoperitoneum prior to placement of trocars during a laparoscopic procedure	To establish pneumoperitoneum prior to placement of trocars during a laparoscopic procedure
Functions	To puncture peritoneum wall To allow for the flow of liquid or gas through the needle To insufflate the peritoneal cavity with carbon dioxide To provide visualization during veres needle entry	To puncture peritoneum wall To allow for the flow of liquid or gas through the needle To insufflate the peritoneal cavity with carbon dioxide

As shown in the table above, the subject device includes the function of visualization using a camera during veres needle entry. This difference does not raise different questions of safety and effectiveness.

Comparison of the Technological Characteristics

The VereSee Optical Veres Needle System and the LaproLight share many similar technological characteristics. Both devices utilize a spring loaded obturator mechanism to provide the user with haptic feedback when entering the body. Both include a luer fitting connection for either a syringe to perform a saline flow test and/or insufflation tubing for gas delivery. For both devices, the stop cock is downstream of luer connection to control the flow of liquid or gas through the cannula with variable positions between ON and OFF. Both veres needles include a visualization element although for different purposes (see Table 2). The VereSee Optical Veres Needle System includes an optical obturator tip designed to enable visualization during body cavity entry whereas the LaproLight includes an LED, which turns on when the healthcare provider has punctured into the peritoneal cavity.

Table 2. Comparison of the Technological Similarities and Differences Between the Subject Device and the Predicate Device

Technological Characteristic	VereSee Optical Veres Needle System	LaproLight Veress Needle (K171139)
Needle Design	Spring loaded stylet mechanism which provides haptic feedback.	Spring loaded stylet mechanism which provides haptic feedback.

Technological Characteristic	VereSee Optical Veres Needle System	LaproLight Veress Needle (K171139)
Outer Cannula	Beveled needle point for cutting through abdominal wall tissue	Beveled needle point for cutting through abdominal wall tissue
Inner Cannula	Spring loaded inner stylet	Spring loaded inner stylet
Needle Length	127 mm	120 mm 150 mm
Outer Diameter (tip)	2.4 mm	2 mm
Material	Stainless steel	Stainless steel
Sterility	Single use sterile	Single use sterile
Seal System	Integrated two component seal system to maintain pneumoperitoneum. A dome seal to seal when camera or visualization camera are not in use and a self-adjusting back-up seal when they are in use.	Standard veres needle seal system
Stopcocks	An integral stopcock assembly with a standard luer lock fitting which provides for attachment of insufflation tubing or syringe for saline flow test.	An integral stopcock assembly with a standard luer lock fitting which provides for attachment of insufflation tubing or syringe for saline flow test.
Visualization	CMOS camera chip to provide visualization during entry	LED to indicate peritoneal cavity entry

As shown in the table above, there are differences between the subject and predicate devices. The subject device is available in one needle length rather than two for the predicate device. The outer diameter (tip) of the subject device is different (larger) than the predicate device. The subject device has a different seal system than the predicate device. The subject device has a different mode of visualization than the predicate device. None of these technological differences raise different questions of safety and effectiveness.

Performance Data

The following is a summary of the performance data to establish the substantial equivalence of the VereSee Optical Veres Needle System to the predicate device.

Sterilization:

The VereSee Optical Veres Needle is sterilized by ethylene oxide (EO). Sterilization was performed as described in ISO 11135:2014, Sterilization of healthcare products - Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices. The sterilization assurance level (SAL) is 10^{-6}.

Testing of EO residuals was conducted per ISO 10993-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals. VereSee Optical Needle devices met the requirements of the standard.

Transit Simulation and Shelf-Life:

Transit simulation and shelf-life testing was conducted for the VereSee Optical Needle to establish the suitability of the packaging to protect the device during simulated transportation, product shelf-life and ability of the packaging to maintain a sterile barrier.

Transit simulation testing was conducted per ASTM D4169-22. The final packaging was tested following simulated transportation, including the following: Seal Strength Test (ASTM F88), Visual Inspection (ASTM F1886), and Bubble Leak testing (ASTM F2096).

Accelerated aging was conducted per ASTM F1980-21 followed by performance testing and package integrity testing. A shelf-life of 6 months was established based upon accelerated aging testing.

Biocompatibility:

The VereSee Optical Veres Needle has been tested according to ISO 10993-1 recommendations for externally communicating devices with bone/tissue/dentin contact of limited contact duration (≤ 24 hours). Biocompatibility studies were performed to show the device materials are safe, biocompatible, and suitable for their intended use. Both ISO 10993 and FDA Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" were utilized to guide the biocompatibility testing. The following biocompatibility studies were successfully completed.

Table 3. Summary of the Biocompatibility Tests and Results

Test Performed	Test Method	Test Results
Cytotoxicity	ISO 10993-5:2009	Pass
Intracutaneous Reactivity	ISO 10993-23:2021	Pass
Guinea Pig Maximization Sensitization	ISO 10993-10:2021	Pass
Pyrogenicity	ISO 10993-11:2017	Pass
Systemic Toxicity	ISO 10993-11:2017	Pass

Electrical Safety and EMC Testing:

The VereSee Optical Veres Needle System has undergone testing to demonstrate that the device meets the requirements for medical device safety, including electrical safety, according to the following international standards: IEC 60601-1, 3rd Edition, Medical electrical equipment – General requirements for basic safety and essential performance.

The VereSee Optical Veres Needle System Camera Control Unit has undergone testing to demonstrate the device meets the following international standard: IEC 60601-1-2, 4.1 Edition, Medical electrical equipment – Part 1-2, General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

Bench and Functional Performance Testing:

Bench testing was performed to demonstrate that the VereSee Optical Veres Needle System functions as intended, including the following:

- Optical performance, including ISO 8600-3 through ISO 8600-5
- Physical characteristics (such as weight and maximum handle temperature)
- Mechanical testing (flow and leakage testing, spring obturator testing and needle penetration tip force testing) to evaluate key performance requirements
- Mechanical testing (destructive) to evaluate the physical strength of the bonds between components

The mechanical testing included comparative testing to legally marketed veres needles for flow and leakage testing, needle spring obturator testing and needle penetration tip force testing. The Veres Optical Veres Needle System had comparable performance to the legally marketed veres needles.

Conclusion

The VereSee Optical Veres Needle Optical System is substantially equivalent to the predicate device.