December 14, 2023

Hangzhou Kangji Medical Instrument Co., Ltd.
℅ Esther Zhang
Official Correspondent
Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District
Shanghai, Shanghai 201102
China

Re: K232401
Trade/Device Name: Disposable Veress Needles
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: November 13, 2023
Received: November 16, 2023

Dear Esther Zhang:

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, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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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)*
K232401

Device Name
Disposable Veress Needles

Indications for Use *(Describe)*
Disposable Veress Needles
The Disposable Veress Needles are 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 procedures.

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.

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510(k) Summary
Disposable Veress Needles
K232401

1. Submitter Information

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2. Submission Correspondent

Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District, Shanghai, P.R. China
Contact person: Esther Zhang
Email: Esther.zhang@llins-tech.com

3. Date Prepared

December 13, 2023

4. Device Identification

Trade Name of Device:	Disposable Veress Needles
Common Name:	Veress Needle
Model:	I, II
Regulation Name:	Laparoscopic Insufflator
Regulation Number:	884.1730
Product Code:	HIF (Insufflator, Laparoscopic)
Class:	Class II

5. Legally Marketed Predicate Device

Trade Name:	Unimicro Veress Needle
Common Name:	Veress Needle
Manufacturer:	Unimicro Medical Systems (ShenZhen) Co., Ltd.
Regulation Name:	Laparoscopic Insufflator;
Regulation Number:	884.1730
Product Code:	HIF, FHO

510(k) number: K150068
Class: II

The predicate device has not been subject to a design-related recall.

6. Device Description

The Disposable Veress Needles are composed of needle, inner core, handle and valve and made of medical grade stainless steel, PC, PE, ABS, and Model II has a silicone sleeve on the handle. The device is packed in Tyvek dialysis bag with 4058B Tyvek dialysis paper and ESE film. The contact duration is less than 24 hours. The device 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 procedures. The device is sterilized by EO and is intended for single-use only. The proposed device is available in a variety of needle lengths.

There are two models for Disposable Veress needles: I, II. The difference between the two models is that the model II has a blue silicone sleeve outside the handle.

7. Indication for Use

The Disposable Veress Needles are intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to placement of trocars during laparoscopic procedures.

8. **Comparison of technological characteristics with the predicate device**

Table 1. Comparison of Characteristics

	Disposable Veress Needles	**Unimicro Veress Needle K150068**	**Discussion**
Manufacturer	Hangzhou Kangji Medical Instrument Co., Ltd.	Unimicro Medical Systems (ShenZhen) Co., Ltd.	
Product Code	HIF	HIF, FHO	Same
Regulation Number	884.1730	884.1730, 876.1500	Same
Class	Class II	Class II	Same
Indications for Use	The Disposable Veress Needles are 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 procedures.	The Unimicro Veress Needle 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 trocs during laparoscopic procedures	Same
Conditions of Use	Rx Only; Single Use Only	Rx Only; Single Use Only	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Models	I, II	MDN 11200, MND 11500	**Different**: The subject device is available in different models than the predicate device

			based on length and, for Model II of the subject device, a silicone sleeve on the handle. This difference does not raise different questions of safety and effectiveness (S&E).
Lengths	110±4mm, 120±4mm, 130±4mm, 140±4mm, 150±4mm	120mm, 150mm	**Different**: The subject device is available in more lengths than the predicate. This difference does not raise different questions of S&E.
Components	Needle, Inner core, Handle, and Valve	Veress Needle, Obturator	Same
Needle Material	Stainless Steel	Stainless Steel	Same
Handle Material	PC	ABS	**Different**: The subject device handle material is different than the predicate device. This does not raise different questions of S&E.
Principles of Operation	Connect the device to the insuffators with tubing, insufflate with carbon dioxide to establish pneumoperitoneum.	Connect the device to the insuffators with tubing, insufflate with carbon dioxide to establish pneumoperitoneum.	Same

As shown in the table above, there are differences in the lengths and materials of the subject and predicate devices. However, as stated in the table, the differences in technological features do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Testing

The tests listed below have demonstrated that the subject device performs as well as the predicate device based on the acceptance criteria:

- Tip Pull Test
- Switch Operation
- Spring Obturator Operation
- Needle Puncture Force Test

Biocompatibility testing

Biocompatibility of the Disposable Veress Needles was evaluated in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process*. Testing included:

Cytotoxicity	ISO 10993-5:2009
Skin Sensitization	ISO 10993-10:2021
Intracutaneous Reactivity	ISO 10993-23:2021
Acute Systemic Toxicity	ISO 10993-11:2017
Pyrogenicity	ISO 10993-11:2017

Sterilization Validation and Shelf-life Testing

Sterilization was validated in accordance with ISO 11135:2014. Sterilant residuals were evaluated in accordance with ISO 10993-7:2019.

Combined simulated shipping distribution, stability, and packaging integrity testing was performed in accordance with the 2016 FDA guidance document, *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile: Guidance for Industry and Food and Drug Administration Staff*. Testing included:

Simulated distribution testing	ASTM D4169
Packaging integrity testing	ASTM F1886/F1886M-16
	ASTM F88/F88M-15
	ASTM F1929-15

The 3 year shelf-life of the device was determined based on stability of package integrity and performance testing after aging per ASTM F1980-21.

10. Statement of Substantial Equivalence

The Disposable Veress Needles are substantially equivalent to the predicate device (Unimicro Veress Needle). The technological differences between the predicate and subject device do not raise different questions of safety or effectiveness. The results of the performance testing described above demonstrate that the subject device is as safe and effective as the predicate device.