May 16, 2023

Scivita Medical Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K222812
Trade/Device Name: Insufflator
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: April 14, 2023
Received: April 14, 2023

Dear Diana Hong:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
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)*
K222812

Device Name
Insufflator

Indications for Use *(Describe)*
The Insufflator is a device intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: __K222812____

1. Date of Preparation: 05/12/2023

2. Sponsor Identification

**Scivita Medical Technology Co., Ltd.**
No. 8, Zhong Tian Xiang, Suzhou Industrial Park, 215000 Suzhou, Jiangsu Prov., P.R. CHINA.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd.**
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Email: info@mid-link.net

4. Identification of Subject Device

Trade Name: Insufflator
Common Name: Laparoscopic Insufflator

Classification Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF (Insufflator, Laparoscopic)
Regulation Number: 21 CFR 884.1730
Review Panel: Obstetrics/Gynecology

Indications for Use:
The Insufflator is a device intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

Device Description:
The subject device consists of an insufflator, a high pressure tube and a pneumoperitoneum tube. The insufflator is a microprocessor-controlled $CO_2$ insufflator that consists of the following major components and features: housing, power supply, pressure reducers, venting system, fluid sensor, gas heater, various setting keys and display elements. The insufflator is not intended to enter the sterile field and cannot be sterilized. The pneumoperitoneum tube shall be cleaned, disinfected, and sterilized prior to subsequent use.

Table 1. System Configuration

| System name | Component name | Model |
|---|---|---|
| Insufflator | Insufflator | SL101, SL102 |
| | Pneumoperitoneum tube | IL-QFH02, IL-QF02 |
| | High pressure tube | High pressure Tube for Central Gas supply:<br>IL-GY(G)02, IL-GY(E)02, IL-GY(A)02<br>High pressure Tube for Gas Cylinder:<br>IL-GY02 |

The SL101 insufflator has the gas heating function, while the SL102 insufflator does not have the gas heating function. And the IL-QFH02 pneumoperitoneum tube has the gas heating function, while the IL-QF02 pneumoperitoneum tube does not have the gas heating function. The high pressure tube is provided in two types, connected to Central Gas supply and to Gas Cylinder. The high pressure tube for Central Gas supply can be available in 3 models, IL-GY(G)02, IL-GY(E)02, IL-GY(A)02; while the high pressure tube for Gas Cylinder can only be available in IL-GY02 model.

5. Identification of Predicate Devices

Predicate Device
510(k) Number: K030837
Trade/Device Name: 40 L HIGH FLOW INSUFFLATOR F108

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

Reference Device
510(k) Number: K153513
Trade/Device Name: Insufflator 50L FM134

6. Summary of Technological characteristics

Table 2. General Comparison

| ITEM | Subject Device | Predicate Device K030837 | Reference Device K153513 | Remark |
|---|---|---|---|---|
| Product | Insufflator | 40 L HIGH FLOW INSUFFLATOR F108 | Insufflator 50L FM134 | / |
| Product Code | HIF | HIF | HIF, OSV | Same |
| Regulation No. | 21 CFR 884.1730 | 21 CFR 884.1730 | 21 CFR 884.1730 | Same |
| Class | II | II | II | Same |
| Indications for Use | The Insufflator is a device intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it. | The 40L High Flow Insufflator F108 with low flow mode is a device intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it. | The device Insufflator 50L FM134 is a $CO_2$ insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The Standard, Pediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic | Same |

| | | | | |
|---|---|---|---|---|
| | | | procedure. The Pediatric operating mode is specifically indicated for pediatric laparoscopic procedures. The Vessel Harvesting operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery. | |
| Configuration | Insufflator (housing, power supply, pressure reducers, venting system, fluid sensor, gas heater, various setting keys and display elements), high pressure tube and pneumoperitoneum tube | Housing, power supply, pressure reducers, a venting system, a fluid sensor, a gas heater, various setting keys and display elements | Casing, world power supply, pressure reducers, venting system, redundant pressure measurement, fluid sensor, gas heater, software controlled graphical user interface (GUI) touch screen and various setting keys and display elements | Different |
| Mechanism of Action | Microprocessor controlled $CO_2$ insufflator | Microprocessor controlled $CO_2$ insufflator | Microprocessor controlled $CO_2$ insufflator | Same |

Table 3. Performance and Safety Comparison

| ITEM | Subject Device | Predicate Device K030837 | Reference Device K153513 | Remark |
|---|---|---|---|---|
| Product | Insufflator | 40 L HIGH FLOW INSUFFLATOR F108 | Insufflator 50L FM134 | / |
| Operating Modes | Pediatric mode, adult mode and bariatric mode | Veress operating mode, High Flow operating mode | Standard, Pediatric and Bariatric operating mode | Different |
| Set Pressure Range | Pediatric mode: 1-10mmHg<br>Adult mode and bariatric mode: 1-30mmHg | 1-30mmHg | / | Different |
| Accuracy of Pressure | ±2mmHg | ±1mmHg | / | Different |
| Set Gas Flow Range | 1-50L/min | 1-40L/min | 1-50L/min | Different |
| Power Supply | 100-240V, 50/60Hz | 100-240V, 50/60Hz | / | Same |
| Weight | About 8.2kg | About 7kg | / | Different |
| Dimension (W x H x D) | 267mm x 395mm x 134mm | 267mm x 138mm x 410mm | / | Different |
| Overpressure warning function | Has the overpressure warning function;<br>When the actual pressure is > 3 mmHg above the nominal pressure, the overpressure warning is initiated. | Has the overpressure warning function;<br>When the actual pressure is > 4 mmHg above the nominal pressure, the overpressure warning is initiated. | / | Different |
| Gas supply warning function | When gas cylinder pressure falls below 15 bar or central gas supply pressure falls below 2 bar, injection will be interrupted, device warning initiated. | When gas cylinder pressure falls below 15 bar or central gas supply pressure is too low, injection will be interrupted, device warning initiated. | / | Different |
| Contamination warning function | When the fluid penetrates into the device through the pneumoperitoneum tube joint, the gas injection will | When the fluid penetrates into the device through the pneumoperitoneum | / | Same |

| | | | | |
|---|---|---|---|---|
| | be interrupted, device warning initiated. | tube joint, the gas injection will be interrupted, device warning initiated. | | |
| Venting defect warning function | When the device vents defect, the gas injection will be interrupted, device warning initiated. | / | / | Different |
| Heater defect warning function | When the gas temperature is greater than 41℃, the gas injection will be interrupted, device warning initiated. | When the gas temperature is greater than 42℃, the gas injection will be interrupted, device warning initiated. | / | Different |
| Material | Insufflator: The shell material is steel plate, and the front panel is resin composite material.<br>High Pressure Tube: Synthetic rubber, double braided steel wire<br>Pneumoperitoneum Tube: Silicone, SUS304, PSU | Host: The outer surface is steel plate and resin.<br>Tube: Silicone, PSU, Special steel | / | Different |
| Electrical Safety | Comply with IEC 60601-1 | Comply with IEC 60601-1 | Comply with IEC 60601-1 | Same |
| EMC | Comply with IEC 60601-1-2 | Comply with IEC 60601-1-2 | Comply with IEC 60601-1-2 | Same |

The differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

7. Summary of Non-Clinical Performance Testing

Non clinical tests were conducted to verify that the subject device met all design specifications as was same/similar to the predicate device and reference device. The test results demonstrated that the subject device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance, including the US National Differences

- IEC 60601-1-2:2014 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- AAMI TIR 30: 2011/ (R) 2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
- AAMI TIR 12:2020 Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers.
- ISO 15883-2:2006 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
- ISO 17665-1: 2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 14971: 2019 Medical devices - Application of risk management to medical devices
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

The software verification and validation for software with a Major Level of Concern were conducted in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. The test results demonstrated the software function met the requirements.

The following comparative performance testing was also conducted on the subject and predicate devices:

- Compensation of leakages
- Flow rate
- Gas temperature
- Overpressure release time
- Overpressure alarm test
- Set pressure output

8. Summary of Clinical Testing

No clinical study is included in this submission.

9. Conclusion

The results of nonclinical testing demonstrate that the subject devices are as safe and effective as the predicate device to support a substantial equivalence determination.