September 20, 2023

Guangdong OptoMedic Technologies, Inc.
Weijuan Guo
Regulatory Affairs Engineer
Suite 503, Building A, Golden Valley Intellicreation
Community, No. 2 Yonganbei Street, Daxu, Guicheng, Nanhai,
Foshan, 528200
China

Re: K231342
Trade/Device Name: Insufflator (OPTO-IFL1000)
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: August 28, 2023
Received: August 28, 2023

Dear Weijuan Guo:

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)*
K231342

Device Name
Insufflator (OPTO-IFL1000)

Indications for Use *(Describe)*
The Insufflator (OPTO-IFL1000) is intended to generate and maintain pneumoperitoneum by filling the abdominal cavity with gas to distend it during diagnostic or therapeutic 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.

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

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510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Date Prepared: September 14, 2023

I. General Information

510(k) Submitter/Owner:	Guangdong OptoMedic Technologies, Inc. Suite 503, Building A, Golden Valley Intellicreation Community, No. 2 Yonganbei Street, Daxu, Guicheng, Nanhai, Foshan, Guangdong, 528200, P.R. China Establishment Registration Number: Not yet registered
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II. Device Identification

Device Trade Name:	Insufflator (OPTO-IFL1000)
Common or Usual Name:	Insufflator
Model:	OPTO-IFL1000
Regulation Name:	Laparoscopic Insufflator
Regulation Number:	21 CFR 884.1730
Regulatory Class:	Class II
Product Code:	HIF

III. Predicate Device

510(k) Number:	K030837
Product Name:	40 L High Flow Insufflator F108

IV. Device Description

Insufflator (OPTO-IFL1000) is a CO2 insufflation device for creating and maintaining a pneumoperitoneum during laparoscopic examinations and operations. It is capable of establishing the surgical field of view and operating space. CO2 gas can be injected into abdominal cavity by the device, and the gas separates the abdominal wall from the internal organs of the abdominal cavity, forming a space for the operation and visual field. The device is to be used with the following insufflation tubes:

1. OPTO-T1000H (with heating function)
2. OPTO-T1000 (without heating function)

V. Indications for Use

The Insufflator (OPTO-IFL1000) is intended to generate and maintain pneumoperitoneum by filling the abdominal cavity with gas to distend it during diagnostic or therapeutic laparoscopic procedures.

VI. Comparison of Technological Characteristics with The Predicate Device

Table 1 General Comparison

Description	**Subject Device**	**Predicate Device (K030837)**
Regulation Number	21 C.F.R. § 884.1730	21 C.F.R. § 884.1730
Product Code	HIF	HIF
Device class	Class II	Class II
Indication for use	The Insufflator (OPTO-IFL1000) is intended to generate and maintain pneumoperitoneum by filling the abdominal cavity with gas to distend it during diagnostic or therapeutic laparoscopic procedures.	The 40 L High Flow Insufflator F108 is a device intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.
Prescription/ Over-the-counter use	Prescription	Prescription
Distension Medium	CO2	CO2
Pressure range:	5-25 mmHg	1-30 mmHg
Overpressure alarm	When the nominal pressure is exceeded by more than 4 mmHg, visual and audible	When the nominal pressure is exceeded by more than 4 mmHg and with a pressure >29 mmHg, visual and audible

	alarms will be issued.	alarms will be issued.
Overheating alarm	At >41ºC, visual and acoustic alarm	At >42ºC, a warning signal is audible
Reprocessing Method	Steam sterilization	Steam sterilization
Dimensions (W*H*D)	370mm*410mm *166.5mm	267 x 138 x 410 (mm)
Weight	11Kg (N.W.)	approx. 7 kg
Power supply	110-240 V~	100-240 V~

The differences technological characteristics do not raise different questions of safety and effectiveness.

VII. Performance data

Non-clinical tests were conducted to verify that the proposed device met all design specifications as is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI/AAMI ES 60601-1: 2005+A2 (R2012) +A1 Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Edition 4.1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
- IEC 60601-1-8 Edition 2.2 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- AAMI TIR 30:2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- AAMI TIR 12:2020 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

The software verification and validation testing were conducted and the test results demonstrated the software function met the requirements. The software for this device was considered a "Major" level of concern.

Performance testing were also conducted and demonstrate that the proposed system performs according to specifications and functions as intended. And the test result shows that the preset acceptance criteria are met.

1. Gas Supply Indication
2. Accuracy of the Pressure

3. Accuracy of the Pressure-Under Leak Condition (Continuous leakage compensation testing)
4. Overpressure Alarm
5. Overpressure Reduction
6. Under-pressure Replenishment (Transient leakage compensation testing)
7. Accuracy of the Flow
8. Heating Function
9. Overheating Alarm
10. Accuracy of Gas Consumption Display

VIII. Conclusions

The performance testing demonstrate that the subject device is as safe and as effective as the legally marketed predicate device to support a substantial equivalence determination.