April 16, 2026

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, Guangdong 528200
CHINA

Re: K252318
Trade/Device Name: Insufflator (OPTO-IFL1000)
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: July 23, 2025
Received: July 25, 2025

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 (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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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

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.	K252318

Please provide the device trade name(s).

Insufflator (OPTO-IFL1000)

Please provide your Indications for Use below.

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.

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) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Date Prepared: April 15, 2026,

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
Primary Contact Person:	Weijuan Guo Regulatory Affairs Engineer Tel: +86 (757) 8670 2920 Email: guoweijuan@optomedic.com
Alternative Contact Person:	Minghua Wu Regulatory Affairs Engineer Tel: +86 (757) 8670 2920 Email: Minghua Wu @optomedic.com

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:	K222812
Product Name:	Insufflator (SL102)

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

IV. Reference Device

510(k) Number: K231342
Product Name: OPTO-IFL-1000
Sponsor: Guangdong OptoMedic Technologies, Inc.

V. Device Description

Insufflator (OPTO-IFL1000) is a CO_2 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. CO_2 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)

VI. 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.

VII. Comparison of Technological Characteristics with the Predicate Device

Table 1 Technological Characteristics Comparison

Description	**Subject Device (K252318)**	**Predicate Device (K222812)**
Product	Insufflator (OPTO-IFL1000)	Insufflator (SL102)
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 Insufflator 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	CO_2	CO_2
Configuration	Insufflator, heatable insufflation tube set insufflation tube, central intake pipe (optional), gas filter, power supply cord, fuse (F3.15AH250V), cart	Insufflator (housing, power supply, pressure reducers, venting system, fluid sensor, gas heater, various setting keys and display elements), high pressure tube and pneumoperitoneum tube
Insufflation Mode Selection	Pediatric Mode: 1-15 mmHg, 0.1-15 L/min Adult Mode: 1-20 mmHg， 1-50 L/min Obese Mode: 1-30 mmHg， 1-50 L/min Veress Mode: 1-15 mmHg， 1-5 L/min	Pediatric mode:1-10mmHg, 1-20 L/min Adult mode: 1-30mmHg, 1-50 L/min Bariatric mode: 1-30mmHg, 1-50 L/min
Pressure range	1-30 mmHg	1-30 mmHg
Accuracy of the measured pressure	±2mmHg	±2mmHg
Flow Rate Range	0.1~50L/min	1-50L/min
Accuracy of the measured flow	the measured flow＜2L/min: ±0.5L/min; 2L/min≤the measured flow≤10L/min: ±2L/min; the measured flow>10L/min: ±20%	the measured flow≤10L/min:±2L/min； the measured flow＞10L/min: ±20%
Overpressure alarm	When the nominal pressure is exceeded by more than 4 mmHg, visual and audible alarms will be issued. When the measured pressure exceeds 30 mmHg for 0.5 seconds, a medium priority overpressure alarm will be triggered	When the actual pressure is > 3 mmHg above the nominal pressure, the overpressure warning is initiated.
Gas supply warning function	When gas cylinder pressure falls below 15 bar or central gas supply pressure falls below 3 bar, injection will be interrupted, device warning initiated.	When gas cylinder pressure falls below 15 bar or central gas supply pressure falls below 2 bar, injection will be interrupted, device warning initiated.
Gas Overheating alarm	At >41ºC, visual and acoustic alarm; gas injection interrupted	At>41ºC, visual and acoustic alarm; gas injection interrupted
Heating Function	Support heating function (with OPTO-T1000H tubing)	Does not support heating function (SL102)
Contamination warning	If liquid enters the device through the insufflation connection port, the device warning will be initiated and device will be allowed to complete the current operation. Insufflation cannot be restarted after device is	When the fluid penetrates into the device through the pneumoperitoneum tube joint, the gas injection will be interrupted, device warning initiated.

	turned off.	
Reprocessing for insufflation tube	Yes, Steam sterilization	Yes, Steam sterilization
Dimensions (W*H*D)	370mm* 410mm *166.5mm	267mm x 395mm x134mm
Weight	11Kg (N.W.)	About 8.2kg
Power supply	110-240 V~	110-240 V~

The differences between the subject and predicate device include the mode, flow rate and pressure accuracy, overpressure alarm indications and actions, gas supply warning indication, heating functions, and dimensions/weight. The different technological characteristics do not raise different questions of safety and effectiveness.

VIII. Performance data

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

- IEC 60601-1-2:2020 Edition 4.1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances

The reference device is the previous version of the subject device, without modes. The operation of the subject hardware is unchanged from the reference device. Therefore, electrical safety information from the reference device is leveraged to support the electrical safety of the subject device.

Per the FDA guidance document *Content of Premarket Submissions for Device Software Functions*, issued June 2024, 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 “Enhanced” software documentation level.

Performance testing was also conducted and demonstrated that the proposed system performs according to specifications and functions as intended and substantially equivalent to the predicate device. And the test result shows that the preset acceptance criteria are met and are substantially equivalent to the predicate device performance:

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

IX. 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.