June 25, 2026

Weyo Surgical Technology Ltd.
% Jack Fang
R&D Director
APlus Healthcare Technology (Shanghai) Co., Ltd.
1201 Floor, Zhongzhi Building, #9299 Humin Road, Xuhui Dis
Shanghai, 200030
CHINA

Re: K252584
Trade/Device Name: Insufflator (wAlcor C50A, wAlcor C50B, wAlcor C50C, wAlcor C35A, wAlcor C35B, wAlcor C35C)
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: May 21, 2026
Received: May 22, 2026

Dear Jack Fang:

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.	K252584

Please provide the device trade name(s).

Insufflator (wAlcor C50A, wAlcor C50B, wAlcor C50C, wAlcor C35A, wAlcor C35B, wAlcor C35C)

Please provide your Indications for Use below.

The Insufflator is intended for use during diagnostic and/or therapeutic laparoscopic procedures to establish and maintain pneumoperitoneum by filling the abdominal cavity with carbon dioxide (CO_2) gas and distending the cavity.

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

I Submitter

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Preparation date: June 24, 2026

II Proposed Device

Trade Name of Device: Insufflator

Models: wAlcor C50A, wAlcor C50B, wAlcor C50C, wAlcor C35A, wAlcor C35B, wAlcor C35C

Regulation Description: Laparoscopic insufflator

Regulation Number: 21 CFR 884.1730

Regulatory Class: Class II

Product codes: HIF

III Predicate/Reference Device

Predicate 510(k) Number: K222812

Trade Name: Insufflator

Regulation Number: 21 CFR 884.1730

Regulatory Class: Class II

Product codes: HIF (Laparoscopic Insufflator)

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

Reference 510(k): K161554

Trade Name: ENDOFLATOR 40 & 50

IV Device description

The Insufflator is a microprocessor controlled CO_2 Insufflator used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

The Insufflator consists of a control circuit, power supply section, gas pipeline and accessories (Pressure Regulator, Hose). The control circuit obtains external gas through the connected gas supply pipeline. After pressure and flow adjustment by the internal gas regulation system, the gas is delivered from the gas outlet connected to the insufflation tube to the patient's abdominal cavity. At the same time, the gas pressure is monitored to ensure the safety of the surgery.

The Insufflator has the heating function when used with heatable insufflation tube. Based on the size of the intra-abdominal cavity, the system presets three abdominal modes, each with preset values for pressure, flow rate, and over-pressure time.

Principles of Operation

The Insufflator is a device used for establishing and maintaining pneumoperitoneum during abdominal endoscopic surgery. The Insufflator can be used to inject medical CO_2 into the abdominal cavity. The gas separates the abdominal wall from the abdominal organs, creating a surgical operation and visual field space. When the preset pressure is reached, the Insufflator can automatically stop the air intake and maintain a certain amount of gas to keep the abdominal cavity in a predetermined pressure inflation state all the time. Whenever the intra-abdominal pressure decreases during the surgical operation, the Insufflator can automatically inflate to maintain the necessary operation and observation space required for the surgical operation.

V Indications for use

The Insufflator is intended for use during diagnostic and/or therapeutic laparoscopic procedures to establish and maintain pneumoperitoneum by filling the abdominal cavity with carbon dioxide (CO_2) gas and distending the cavity.

VI Comparison of technological characteristics with the predicate device

The comparison between the overall specifications of the predicate device and the proposed device is shown in Table 1. Comparison between the Insufflator and the predicate device was conducted with respect to intended use, technological characteristics and principles of operations, providing more detailed information regarding the bases for the determination of substantial equivalence. The differences in technological characteristics do not raise any different questions of safety or effectiveness.

Table 1 Comparison of technological characteristics with the predicate device

Item	Proposed Device **Insufflator**	Predicate Device **Insufflator** (K222812)
Product Code	HIF	HIF
Regulation No.	21 CFR 884.1730	21 CFR 884.1730
Class	II	II
Indications for Use	The Insufflator is intended for use during diagnostic and/or therapeutic laparoscopic procedures to establish and maintain pneumoperitoneum by filling the abdominal cavity with carbon dioxide (CO_2) gas and distending the cavity.	The Insufflator is a device intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.
Configuration	Insufflator (control circuit, power supply section), gas pipeline and accessories (Pressure Regulator, Hose)	Insufflator (housing, power supply, pressure reducers, venting system, fluid sensor, gas heater, various setting keys and display elements), high pressure tube and pneumoperitoneum tube
Mechanism of Action	Microprocessor controlled CO_2 insufflator	Microprocessor controlled CO_2 insufflator
Operating Modes	Pediatric mode, adult mode and bariatric mode	Pediatric mode, adult mode and bariatric mode
Set Pressure Range	Pediatric mode: 0-15mmHg Adult mode/Bariatric mode: 0-30mmHg	Pediatric mode: 1-10mmHg Adult mode and bariatric mode: 1-30mmHg
Accuracy of Pressure	±2mmHg (266.6Pa)	±2mmHg
Set Gas Flow Range	0-50 L/min	1-50L/min
Power Supply	100-240V, 50/60Hz	100-240V, 50/60Hz
Weight	About 8.5kg	About 8.2kg
Dimension (W x H x D)	350mm x 390mm x 145mm	267mm x 395mm x 134mm
Overpressure warning	Has the overpressure warning function; Detected	Has the overpressure warning function;

Item	Proposed Device **Insufflator**	Predicate Device **Insufflator** (K222812)
function	pressure exceeds the set value by more than 4mmHg for 1 second, or the detected pressure exceeds the set value by more than 2mmHg and exceeds the over-pressure time setting, the overpressure warning is initiated.	When the actual pressure is > 3 mmHg above the nominal pressure, the overpressure warning is initiated.
Gas supply warning function	Yes	Yes
Contamination warning function	Yes, liquid detected in insufflator tubing via a sensor	Yes, via fluid backflow sensor
Heater defect warning function	When Heating temperature exceeds 41℃, the gas injection will stop, device warning initiated.	When the gas temperature is greater than 41℃, the gas injection will be interrupted, device warning initiated.

VII Performance Data

The following performance data were provided in support of the substantial equivalence determination.

- Electrical safety test was conducted per IEC 60601-1:2005+AMD1:2012+AMD2:2020.
- Electrical safety and electromagnetic compatibility (EMC) testing were conducted per IEC 60601-1-2: 2014+AMD1:2020.
- Alarm system was tested per IEC 60601-1-8:2006+AMD1:2012+AMD2:2020.
- Particular requirements for the basic safety and essential performance of endoscopic equipment per IEC 60601-2-18:2009.

Non-Clinical Testing

The following comparative non-clinical testing was performed on the subject device and predicate or reference device to demonstrate substantial equivalence:

- Adjustable Range of Set Pressure
- Accuracy of Pressure Preset and Display
- Overpressure Alarm Threshold
- Overpressure Release Time

- Underpressure Compensation Time
- Compensation of Leakages (Transient)
- Compensation of Leakages (Continuous)
- Adjustable Range of Set Flow Rate
- Accuracy of Flow Set and Flow Display
- Accuracy of Displayed Gas Consumption
- Heating (Gas Temperature)
- Manual Smoke Evacuation
- Liquid Contamination

Software

- Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The software for this device required enhanced documentation.

- Cybersecurity

The cybersecurity documentation was provided according to FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

The subject device has the same indications for use and has similar design features and technological characteristic as the predicate device. The differences between the predicate device and the subject device do not raise different questions of safety or effectiveness. Performance testing data demonstrates that the proposed device is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.