April 11, 2025

SmartSurgN Inc
Jocelyn Long
Chief Compliance Officer
1038 Leigh Ave Ste 101B
San Jose, California 95126

Re: K242772
Trade/Device Name: AirSurgN Insufflator (10030/AirSurgN)
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: July 25, 2024
Received: March 14, 2025

Dear Jocelyn Long:

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242772

Device Name

AirSurgN Insufflator (10030/AirSurgN)

Indications for Use *(Describe)*

The AirSurgN Insufflator is intended for use during diagnostic and/or therapeutic laparoscopic procedures to distend the abdominal cavity and maintain pneumoperitoneum by filling it with carbon dioxide (CO2) gas. The AirSurgN Insufflator provides user-selectable variable CO2 gas flow and pressure rates.

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.

SmartSurgN™

This summary statement is submitted in accordance with the requirements of CFR § 807.92

510 (k) Sponsor:		SmartSurgN Incorporated
Address		1038 Leigh Ave, Suite 101B San Jose, CA 95126 USA

Correspondence Person:	Jocelyn Long
Contact Information:	jocelyn.long@smartsurgn.com 408-802-8586

Date of Preparation:		April 10, 2025
Device Identification: Common Name: Classification Name: Regulation Number: Product Code: Regulatory Class		Trade Name: AirSurgN Insufflator (10039/AirSurgN) Insufflator, Laparoscopic Endoscope and Accessories 21 CFR 884.1730 HIF II

Device Description		The AirSurgN Insufflator is intended for use during diagnostic and/or therapeutic laparoscopic procedures to distend the peritoneal cavity and maintain pneumoperitoneum by filling the cavity with carbon dioxide (CO_2) gas and to evacuate surgical smoke. The device helps establish and maintain a path of entry for laparoscopic instruments. The AirSurgN Insufflator is intended to be used in a hospital setting on the adult population of 22 years and older. The AirSurgN Insufflator is a microprocessor-based CO_2 insufflator, controlling pneumatic valves, vacuum pump, and pressure sensors. User input to an LCD touchscreen graphical user interface (GUI) initiates the selected pressure, flow rate, and displays the output. Feedback control loop manages pneumoperitoneum. If smoke evacuation is desired, the user can activate this vacuum function for a fixed time period before shutting off automatically. The device is reusable. It is not intended to be used in the sterile field and cannot be sterilized.
Predicate Device:		PNEUMOCLEAR (K170784) The predicate device has not been subject to a design-related recall.

Comparison of Technological Characteristics with the Predicate Device

Item/Feature	Proposed Device AirSurgN Insufflator	Predicate Device PNEUMOCLEAR (K170784)	Comparison
System Components	AirSurgN Insufflator Power Cord	PNEUMOCLEAR Insufflator Power Cord	Same
Distension Medium	CO_2	CO_2	Same
Indications for Use	The AirSurgN Insufflator is intended for use during diagnostic and/or therapeutic laparoscopic procedures to distend the abdominal cavity and maintain pneumoperitoneum by filling it with carbon dioxide (CO_2) gas. The AirSurgN Insufflator provides user-selectable variable CO_2 gas flow and pressure rates.	The device PNEUMOCLEAR™ 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, High Flow/Bariatric, Pediatric and Advanced Flow operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The Pediatric operating mode is indicated for pediatric laparoscopic procedures. The Vessel Harvest operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery. The TAMIS operating mode is indicated to fill and distend the rectum and colon using CO_2 gas during trans anal minimally invasive surgery.	Similar; subject device is indicated for use in the abdominal cavity only
User Interface	Touch panel (LCD touchscreen)	Touch panel (LCD touchscreen)	Similar
Flow Rate	1-50 L/min	▪ Standard (1-40 L/min) ▪ Pediatric (0.1-20 L/min) ▪ High Flow/Bariatric (1-45 L/min) ▪ Advanced Flow (1-50 L/min) ▪ Vessel Harvest (1-10 L/min) ▪ TAMIS (0.5-40 L/min)	Similar
Pressure Range	1-30 mmHg	▪ Standard (1-30 mmHg) ▪ Pediatric (1-20 mmHg) ▪ High Flow/Bariatric (1-30 mmHg)	Similar

Item/Feature	Proposed Device AirSurgN Insufflator	Predicate Device PNEUMOCLEAR (K170784)	Comparison
		▪ Advanced Flow (1-30 mmHg) ▪ Vessel Harvest (1-20 mmHg) ▪ TAMIS (1-20 mmHg)	
Automatic Pressure Relief	Yes	Yes	Same
Vacuum Setting / Smoke Evacuation	Manual On/Off	On	Similar
Tubing Included?	No, compatible tubing sold separately	Yes	Different
Packaging: Physical Dimensions (W x D x H)	30 cm x 30 cm x 11 cm	31 cm x 43 cm x 15 cm	Similar
Packaging: Weight	6.8 kg	10 kg	Similar
Electrical Standard Compliance	100-240 VAC (0.8A) @50/60 Hz	100-240 VAC (0.8A) @50/60 Hz	Same
Safety Class	Type BF, Class I	Type CF, Class I	Similar
Electrical Safety Standard	IEC 60601-1: 2005/AI: 2012, ANSI/AAMI ES60601-1: 2005(R) 2012	IEC 60601-1: 2005/AI: 2012, ANSI/AAMI ES60601-1: 2005(R) 2012	Same
EMC Standard	IEC 60601-1-2 Edition 4.1 En: 2020-09	IEC 60601-1-2 Edition 4.0 2014-02 ANSI/AAMI,60601-1-2:2014 Class A	Similar

Discussion of Differences:

Both the subject and the predicate device are indicated to insufflate the abdominal cavity with gas and provide suction and evacuation functionality to facilitate laparoscopic surgery. The predicate device is additionally indicated to insufflate the saphenous vein and colon area, whereas the subject device does not include indications for the additional cavities nor Pediatric use. In this way, the proposed device differs from the predicate device in its reduced functionality. This does not result in a new intended use and the differences in pre-select modes, tubing, and device size do not raise different questions of safety and effectiveness.

Performance Testing

Safety and performance of the AirSurgN Insufflator has been evaluated and verified in accordance with design specifications and applicable performance standards through electrical safety and EMC testing, software validation, and non-clinical/bench testing. The following performance testing are conducted and summarized in this submission:

- Electrical Safety and electromagnetic compatibility testing was performed in accordance with *IEC 60601-1:2005- Medical electrical equipment- Part 1: General requirements for basic safety and essential performance* and *IEC 60601-1-2 Edition 4.1 En: 2020-09 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic disturbances – Requirement and tests*, respectively. Testing indicates that the proposed device conforms to the aforementioned voluntary standards.

- The software validation activities were performed in accordance with *IEC 62304:2006/A1:2016 - Medical device software – Software life cycle processes,* in addition to the 2023 FDA Guidance document, *"Content of Premarket Submissions for Device Software Functions"* for an "Enhanced" documentation level.

Non-Clinical/Bench Testing:

The following non-clinical testing was performed to support the determination of safety and substantial equivalence. The results met the predetermined acceptance criteria, thereby demonstrating substantial equivalence.

- Pressure Accuracy and Comparison to Predicate
- Flow Delivery Accuracy and Comparison to Predicate
- Volume Accuracy and Comparison to Predicate
- Transient Leaks and Comparison to Predicate
- Alarm Prioritization
- Accessory Compatibility
- System Durability and Reliability Testing
- Overpressure Response and Comparison to Predicate

Note: No clinical investigations were required for a determination of substantial equivalence.

Conclusion

Based on the indications for use, technological characteristics, and performance testing, AirSurgN Insufflator raises no different questions of safety or effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy and performance.