March 28, 2023

Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Guofang Ma
QA&RA Director
No.1 Xinxing Yilu Road, Emerging Industrial Cluster Area
Zonghan Subdistrict
Cixi, Zhejiang 315300
CHINA

Re: K221995
Trade/Device Name: Gas Insufflator
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: February 18, 2023
Received: February 23, 2023

Dear Guofang Ma:

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 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)*
K221995

Device Name
Gas Insufflator

Indications for Use *(Describe)*
The Gas Insufflator is designed to use carbon dioxide gas to insufflate the abdominal cavity, so as to generate and maintain pneumoperitoneum, expand the surgical field and keep sufficient space during diagnostic and 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

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

1. Submitter Information

- **510(k) Submitter:**
  Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
  No.1 Xinxing Yilu Road, Emerging Industrial Cluster Area, Zonghan Subdistrict, Cixi City, Zhejiang, 315300, China
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  Email: QARA@surgnova.com
- **Date Prepared: Mar 28, 2023**

2. Device Information

Trade/Proprietary Name: Gas Insufflator
Common Name: Gas Insufflator
Classification Name: Laparoscopic Insufflator
Classification Number: 21 CFR 884.1730
Product Code: HIF (Insufflator, Laparoscopic)
Regulatory Class: Class II

3. Predicate Device

510(k) Number: K161554
Trade/Device Name: ENDOFLATOR 40, Model UI4000
Classification Name: Laparoscopic Insufflator
Classification Number: 21 CFR 884.1730
Product Code: HIF, OSV, FCX
Regulatory Class: Class II

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

4. Device Description

The subject device is composed of Gas Insufflator Unit (Model GVS100) and accessories High-pressure Gas Pipe, Insufflation Tubing Set (Model GI-S001), and power adapter). The Insufflation Tubing Set is provided sterile and disposable. The Gas Insufflator Unit is nonsterile, reusable, and AC-powered (100 – 240 VAC, 50/60 Hz, 200 W).

The Gas Insufflator is designed to use carbon dioxide gas to insufflate the abdominal cavity to generate and maintain pneumoperitoneum during laparoscopic diagnosis and/or surgical treatment. The Gas Insufflator controls gas pressure and flow rate by the solenoid valve. The touchscreen displays the gas pressure and flow output. The Gas Insufflator is intended to insufflate CO_2 to a body cavity up to 30 mmHg/40 LPM for Adult mode and 15 mmHg/15 LPM for Child mode.

The Gas Insufflator is for professional healthcare environment use.

5. Indications for use

The Gas Insufflator is designed to use carbon dioxide gas to insufflate the abdominal cavity, so as to generate and maintain pneumoperitoneum, expand the surgical field and keep sufficient space during diagnostic and therapeutic laparoscopic procedures.

6. Comparison of the technological characteristics

Table 1 Comparison of subject and predicate device technological characteristics

Comparison Items	**Subject Device**	**Predicate Device**	**Verdict**
510(K) No.	K221995	K161554	\
Product Name	Gas Insufflator	ENDOFLATOR 40, model UI4000	\
Regulation No.	21 CFR 884.1730	21 CFR 884.1730	Same
Classification	II	II	Same
Product Code	HIF	HIF, OSV, FCX	Same
Intended use	The Gas Insufflator is designed to use carbon dioxide gas to insufflate the abdominal cavity, so as to generate and maintain pneumoperitoneum, expand the surgical field and keep sufficient space during laparoscopic diagnosis and/or surgical treatment.	CO_2 insufflators and their accessories are used to create and/or to distend a cavity during diagnostic or therapeutic endoscopic interventions.	Same

Indications for Use	The Gas Insufflator is designed to use carbon dioxide gas to insufflate the abdominal cavity, so as to generate and maintain pneumoperitoneum, expand the surgical field and keep sufficient space during diagnostic and therapeutic laparoscopic procedures.	The ENDOFLATOR 40 are used to create and/or to distend a cavity in the following diagnostic and therapeutic interventions: • Laparoscopy • Pediatric Laparoscopy • Endoscopy of the Lower Gastrointestinal Tract: (e.g., TEO, colonoscopy) • Endoscopic Vessel Harvesting	Similar
Distension Medium	CO_2	CO_2	Same
Indicated Population	Adult and Pediatric	Adult and Pediatric	Same
Modes	Adult mode, Child mode	High Flow, Pediatrics	Same
Maximum Flow Rate	Adult: 40 L/min Pediatric: 15 LPM	High flow: 40 LPM (ENDOFLATOR 40) Pediatric: 15 LPM	Same
Maximum Pressure	Adult: 30 mmHg Pediatric: 15 mmHg	High flow: 30 mmHg Pediatric: 15 mmHg	Same
Overpressure Action	Intra-abdominal pressure exceeds the set value 5mmHg and continuously exceeds 5s: visual and audible alarm followed by pressure relief after 5 seconds	Pediatric: Intra-abdominal pressure >0.1 x set pressure + 2.5 mmHg for 3 sec (max 4 mmHg) High flow: Intra-abdominal pressure >0.05 x set pressure + 3.5 mmHg for 3 sec (max 5 mmHg) Visual and audible alarms followed by pressure relief after 5 seconds	Similar
Gas Supply Shortage Action	At < 10 bar, informational signal At < 3 bar, visual warning At <1 bar, visual and audible alarm and gas supply stopped/insufflation deactivated.	At < 10 bar, informational signal At <1 bar, visual and audible alarm and gas supply stopped/insufflation deactivated	Similar
Over Temperature Protection	None, no heating available	>41℃ Heating is turned off	Different

The Gas Insufflator has the same general intended use. According to above comparison results, difference in technological characteristics do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Performance Testing

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

The Gas Insufflator has been designed and tested as follows:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Gas Insufflator in accordance to the following standards:

- IEC 60601-1:2005 + A1:2012
- IEC 60601-1-2:2014
- IEC 60601-2-18:2009
- IEC 60601-1-8:2006 + A2:2020

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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "Major" level of concern.

Sterility and Aging Effect

Sterilization of the tubing set is via EO and was validated per ISO 11135:2014, Half cycle approach, the EO limit was validated per ISO 10993-7:2008, and the packaging integrity was validated per ASTM D4169-16. In addition, testing to ASTM F1886/F1886M-16 (visual inspection), ASTM F88/F88M-15 (seal strength), ASTM F1929-15 (dye penetration) and ASTM F-1980-16 (aging) supported a shelf-life of 2 years.

Bench Performance testing

The Gas Insufflator was tested to demonstrate the performance including safety features. Tests were conducted in both Adult and Child modes. Full ranges of pressure and flow rates were tested:

- Static condition
  - Accuracy of gas pressure in normal and insufficient air supply conditions
  - Accuracy of flow rate in normal and insufficient air supply conditions
- Dynamic condition
  - Accuracy of gas pressure with continuous leak of 1, 3, 5, 7, and 10 L/min
  - Accuracy of gas pressure with transient leak of 32 L/min
- Gas consumption display
- Safety features

- Overpressure protection
- Low/high gas supply protection

8. Conclusion

The non-clinical test results described above demonstrate that the subject device is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate.