March 25, 2021

Northgate Technologies Inc.
Todd Gatto
Director of Quality Assurance and Regulatory Affairs
1591 Scottsdale Court
Elgin, Illinois 60123

Re: K202944
Trade/Device Name: NEBULAE SRS Laparoscopic Surgical Smoke Removal System
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-Handling Apparatus For A Surgical Operating Room
Regulatory Class: Class II
Product Code: FYD
Dated: February 25, 2021
Received: February 26, 2021

Dear Todd Gatto:

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,

Clarence W. Murray, III, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202944

Device Name
NEBULAE® SRS Laparoscopic Surgical Smoke Removal System

Indications for Use *(Describe)*
To remove airborne particles generated by tissue combustion during laparoscopic surgery, via filtration of gaseous media contained within the distended pneumoperitoneum in order to improve visualization. NEBULAE® SRS may be used in any laparoscopic surgery, as appropriate.

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.

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510(k) Summary – K202944

Submitter: Northgate Technologies Inc.
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Contact Person: Todd Gatto
Director of Quality Assurance and Regulatory Affairs
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Email: TGatto@NTISurgical.com

Preparation Date: Tuesday, March 23, 2021

Registration #: 1450997

Trade Name: NEBULAE® SRS Laparoscopic Surgical Smoke Removal System / 7-700-00

Common Name: Laparoscopic Smoke Removal System

Classification Name: Apparatus, Exhaust, Surgical 21 C.F.R. 878.5070

Regulatory Class: II

Product Code(s): FYD

Predicate Devices: MEDTEK DEVICES, INC. LAPEVAC, Filtration device for the Peritoneum (K052797)

MEDTEK DEVICES

Device Description: This 510(k) submission for the NEBULAE® SRS Laparoscopic Surgical Smoke Removal System (henceforth referred to as NEBULAE® SRS) covers the following product codes:

- NEBULAE® SRS Pump (7-700-00)
- NEBULAE® SRS CO_2 Gas Filtration Tubing Sets (7-510-57)

The NEBULAE® SRS is intended to recirculate CO_2 gas in the pneumoperitoneum whilst removing surgical smoke during laparoscopic procedures. The system consists of two parts: a Pump and dedicated single-use, sterile Tubing Sets.

The NEBULAE® SRS Pump is a microprocessor driven, mains-powered device containing a DC motor. The single-use, disposable Tubing Set consists of an integrated cartridge, containing a diaphragm pump, an in-line ultra-low particulate air (ULPA) with activated carbon filter, fluid trap(s), 10 feet of DEHP-free PVC tubing and two connectors for connecting the tubing to the trocars. The NEBULAE® SRS Pump's DC motor drives the pump head in the Tubing Set's cartridge to create the flow of CO_2 gas from the patient's pneumoperitoneum, through the fluid trap(s) and filter before re-entering the patient.

The NEBULAE® SRS Pump can be positioned on a level surface (e.g. a surgical trolley in the operating room) or fixed to a vertical IV pole using a dedicated bracket, which is available as an accessory (See VOLUME 011 for further information).
The re-circulating CO2 gas can also be warmed by the addition of an in-line gas warmer, also available as an optional accessory.

Indications for Use:

To remove airborne particles generated by tissue combustion during laparoscopic surgery, via filtration of gaseous media contained within the distended pneumoperitoneum in order to improve visualization. NEBULAE® SRS may be used in any laparoscopic surgery, as appropriate.

Northgate Technologies, Inc.

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Technological Characteristic Comparison Table:

In the table below is a technological comparison between the subject device and the predicate device.

Manufacturer	Northgate Technologies, Inc.	MEDTECH DEVICES	Comparison
Catalog Number	7-700-00	LAPEVAC	different
FDA Clearance 510(k)	K202944	K052797	different
Photo	**NEBULAE® SRS** 	**LapEvac™** 	different

Manufacturer	Northgate Technologies, Inc.	MEDTECH DEVICES	Comparison
Catalog Number	7-700-00	LAPEVAC	different
FDA Clearance 510(k)	K202944	K052797	different
Functionality	Recirculates CO_2 gas within the peritoneal cavity	Recirculates CO_2 gas within the peritoneal cavity	Same

Manufacturer	Northgate Technologies, Inc.	MEDTECH DEVICES	Comparison
Catalog Number	7-700-00	LAPEVAC	different
FDA Clearance 510(k)	K202944	K052797	different
Indications for Use	To remove airborne particles generated by tissue combustion during laparoscopic surgery via filtration of gaseous media contained within the distended pneumoperitoneum in order to improve visualization. NEBULAE® SRS may be used in any laparoscopic surgery, as appropriate.	To remove airborne particles generated by tissue combustion during laparoscopic surgery via filtration of gaseous media contained within the distended pneumoperitoneum in order to significantly improve visualization. LapEvac may be used in any laparoscopic surgery, as appropriate.	Same
Weight	Device: 8.6 lbs. (3.9 kg) Disposable: 0.9 lbs (0.4 kg)	0.84 lbs. (0.38 kg)	The disposable weight is similar.

Manufacturer	Northgate Technologies, Inc.	MEDTECH DEVICES	Comparison
Catalog Number	7-700-00	LAPEVAC	different
FDA Clearance 510(k)	K202944	K052797	different
Controls and Interface	Full Color, Touch Screen Technology	Toggle Power Switch	
Configuration	Reusable Device + Disposable Tubing	Self-contained disposable (Device + Tubing)	Different
Flow Range	Min. 10 L/min*	4 L/min	Different
Flow Characteristics	Continuous Flow	Continuous Flow	Same
Gas Filtration	0.1 µ ULPA activated carbon filter 99.999% efficacy	0.1 µ ULPA activated carbon filter 99.999% efficacy	Same
Tubing Connectivity	Attaches to standard luer lock fittings	Attaches to standard luer lock fittings	Same
Tubing Length	120” of conjoined tubing	24” of tubing on each end	Different
Power Source/Input Voltage	Auto Voltage Adjustment for use in all countries (100/240 V)	4 AA Batteries	Different
Sterilization Method	Device is Reusable Disposable is sterilized by Gamma Irradiation	Method not precisely known	Not Clear
Heat Capable	In-line Gas Warmer as an optional accessory	No	Different
Condensation Control	One or two in-line fluid traps within the Tubing Set	No	Different
Operating Noise Level	≤ 55 dB	≤ 47 dB	Similar
Operational Life	Device: 6 years (7020 hours) Disposable: ≥ 2 hours of uninterrupted usage	3.5 – 4 hours	Different
Procedure Usage	All laparoscopic procedures that utilize CO2 gas for insufflation	All laparoscopic procedures that utilize CO2 gas for insufflation	Same

Manufacturer	Northgate Technologies, Inc.	MEDTECH DEVICES	Comparison
Catalog Number	7-700-00	LAPEVAC	different
FDA Clearance 510(k)	K202944	K052797	different
Flow Occlusion Detection	Automatic detection of occlusions caused by gas blocking moisture accumulations within the tubing line, obstruction of the trocar sleeve, a kink in the tubing line, or a disconnected tubing line.	None	The NEBULAE® SRS utilizes a reusable device to effect air flow in the disposable. This device also verifies function, and includes logic for proper, and safe operation. The LAPEVAC does not offer such functionality.

Summary of Non-clinical Testing:

Shown below is the non-clinical testing with the subject device to demonstrate that the subject device's performance testing met the acceptance criteria of the standard described below.

Test Methodology	Purpose	Acceptance Criteria	Results
Run the NEBULAE® SRS device for two hours, with the two tubing lines connected to flow meters, connected to two standard laparoscopic trocars, inserted into a laparoscopy simulation pressure chamber, insufflated with CO_2 gas. Log the flow rate through each side of the Tubing Set.	Design Verification, Software Validation— Functionality; Flow Rate	Verify that the device maintains a minimum flow rate of 10L/min, on each side of the disposable Tubing Set, throughout the two hours.	Pass.
Connect the two NEBULAE® SRS tubing lines connected to two standard laparoscopic trocars, and introduce various sources of occlusion to the flow. Test	Design Verification, Software Validation— Functionality; Occlusion Detection	Verify that the device detects each of the following sources of occlusion, stops flow, and produces an audiovisual alert: gas blocking moisture	Pass.

Test Methodology	Purpose	Acceptance Criteria	Results
introducing the occlusion before and after starting the flow.		accumulations within the tubing line, closure of the trocar valve, obstruction of the trocar cannula, a kink in the tubing line, or a disconnected tubing line.	
Connect the in-line gas warmer to the device, and use a thermal camera to measure the temperature of the in-line gas warmer. Introduce each of the various fault conditions to the warmer.	Design Verification, Software Validation— Functionality, Essential Performance; In-Line Warmer	Verify that the in-line warmer reaches and maintains the set temperature. Verify that the user interface generates the designed audiovisual alert for each warmer fault condition.	Pass.
IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)	Electrical Safety	Test procedure: Informative. Standard test methods.	Pass.
IEC 60601-1-2:2014	Electrical Safety – Electromagnetic Compatibility; Emissions: General, Harmonic, Flicker	Class A/ Group 1, IEC 61000-3-2:2014, IEC 61000-3-3:2013	Pass.
	Electrical Safety – Electromagnetic Compatibility; Immunity: Electrostatic Discharge, Radiated Electromagnetic, Fast Transient, Surge, Conducted, Magnetic Field, Voltage Dips/ Interruptions/ Variations/fluctuations	IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8, IEC 61000-4-11	Pass.
ISO 10993-1:2018	Biocompatibility	ISO 10993-5:2009 /(R) 2014: Fluid Extract / L929 Mouse Fibroblast (Preliminary Assessment) and Fluid Extract / L929 Mouse Fibroblast	Pass.
		ISO 10993-10:2010 /(R)2014: Dermal Sensitization Guinea Pig Maximization (Cottonseed Oil and 0.9% NaCl) and Intracutaneous Test	Pass.
		ISO 10993-11:2017: Rabbit Pyrogen Test and Acute Systemic Toxicity Test	Pass.
ISO 11137-1:2006 ISO 11137-2:2006	Sterilization Validation	Microbiological Validation of 25kGy Radiation Sterilization by	Pass.

Test Methodology	Purpose	Acceptance Criteria	Results
		ANSI/AAMI/ISO 11137-2 Method VD_{max}^{25}	
ISO 11607-1: 2006 ISO 11607-2: 2006 ISTA 3A:2018 Dye Penetration Test Seal Strength Test Pull strength Test	Packaging Integrity	Test outer packaging cases per ISTA 3A:2018, and verify that there are no significant visual signs of degradation. Perform dye penetration tests using sterile-packaged units and verify visually that no dye is present in the package. Verify that the sterile package seal maintains a strength of minimum 1 lb. Verify that the Tubing Set maintains a pull strength greater than 8 lbs.	Pass.
Condition the NEBULAE® SRS device per ISTA 3A:2018 and subsequently, per the shipping and storage environmental conditions of IEC 60601-1-11: 2015.	Shipping and Storage	Verify that the device still meets all the functional requirements that were previously verified in manufacturing (FQC).	Pass.
Qualitative assessment of users' ability to perform operational tasks and troubleshoot clinical use scenarios in a simulated environment.	Validation— Usability	Greater than 80% successful usability by subjects (clinicians)	Pass.
Qualitative evaluation of surgical environment visual clarity while running the NEBULAE® SRS, during monopolar and bipolar electrocautery and ultrasonic coagulation, in a simulated environment.	Validation— Device Performance	≤ 20% of subjects (surgeons) disagree that the NEBULAE® SRS helped maintain visual clarity by removing smoke and particulates from the field of vision.	Pass.

Conclusion: The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.