August 15, 2012

510(k) Summary

AUG 17 2012

High Flow Insufflation Unit
Nebulae™ I

1. General Information

Applicant Name:	Northgate Technologies Inc. 1591 Scottsdale Court Elgin, IL 60123 Telephone: 224-856-2222 Fax: 847-608-9405
Contact Person:	Casey Kurek Regulatory Manager Telephone: 224-856-2222 Fax: 847-608-9405 E-Mail: ckurek@northgate-tech.com
Manufacturer:	Northgate Technologies Inc. 1591 Scottsdale Court Elgin, IL 60123 Telephone: 224-856-2222 Fax: 847-608-9405
Registration #:	1450997

2. Device Identification

Device Trade Name:	Nebulae™ I 50 LPM Insufflator / REF# 7-650-00
Common Name:	Carbon Dioxide Insufflator for Laparoscopy and Endoscopic Vessel Harvesting
Classification Name:	Insufflator, Laparoscopic 21 CFR 884.1730, Insufflator, Carbon Dioxide for Endoscope 21 CFR 876.1500
Regulatory Class:	II
Product Code:	HIF, FCX, OSV

3. Predicate Device Information

1.	Device Name:	45L CORE Insufflator F114
	Common Name:	Carbon Dioxide Insufflator for Laparoscopy and Endoscopic Vessel Harvesting
	Manufacturer:	W.O.M. World of Medicine
	510(k) No.	K063367
2.	Device Name:	40LPM ABDOMINAL
	INSUFFLATOR, CATALOG #	72-00203-0
	Common Name:	Insufflator
	Manufacturer:	Northgate Technologies Inc.
	510(k) No.	K022052

4. Device Description

The Nebulae™ I 50 LPM Insufflator is microprocessor controlled. This CO_2 (Carbon Dioxide) High Flow Insufflator has touch screen control and multiple operating modes. The System can be used for General Laparoscopic, Pediatric Laparoscopic, Bariatric Laparoscopic, and Minimally Invasive Vessel Harvesting procedures.

The system includes the following major components:

- Selectable Power Supply, 100, 115 or 230 VAC ± 10%, 47-63 Hz
- True Abdominal Pressure Sensing (TAP™) feature
- Variable Volume Alarm
- Recognizes Wall or Bottle CO2 Gas Source
- Touch Screen Buttons work in timed, auto increment / decrement manner
- Interfaces to control or work with data collection systems, such as a RS232
- Display indicates "Restriction"
- Supports a minimum of one (1) gas warmer
- Fifty (50) LPM at output port of the Insufflator when utilizing a standard Northgate style (#7-510-28) Tubing Set. Approximately 9 LPM at the Veress Needle, 22 LPM at most Trocars.

- Relieves over pressure conditions of 5mmHg above the preset and returns to the preset in three (3) seconds or less.

The following are cleared medical devices that may be used with this device: tubing Sets, 7-510-28 (General Use) and 7-510-31 (TAP™ set that provides continuous pressure information when connected to the insufflator) cleared under K983326 on February 5, 1999; and the 6-820-00 (In-Line Warmer) cleared under K022052 on January 24, 2003.

5. Indications for Use

The Nebulae™ I 50 LPM Insufflator provides CO_2 gas distention of surgical cavities for diagnostic and/or operative endoscopy. The insufflator has multiple operating modes which can be used for the following procedures:

General Laparoscopic
Pediatric Laparoscopic
Bariatric Laparoscopic
Minimally Invasive Vessel Harvesting

Typical Endoscopic Surgical Procedures requiring the need for CO2 Insufflation:

Categories

General Laparoscopy
Cholecystectomy
Hernia Repair
Appendectomy
Hysterectomy
Bowel Resection

Pediatric Laparoscopy
Cholecystectomy
Appendectomy
Gastric Surgery
Bowel Resection
Splenectomy

Bariatric Laparoscopy
Gastric Banding
Gastric Bypass

Endoscopic Vessel Harvesting
Saphenous Vein Harvesting for arterial bypass procedures

6. Technological Differences

The Nebulae™ I device is like the 40L Abdominal Insufflator (K022052) except it flows 50LPM out of a single output port, has a touchscreen, and has one warmer port.

The Nebulae™ I device is like the 45L CORE Insufflator F114 (K063367) except it flows 5LPM more, has Custom Mode, and does not contain a proprietary connection for a tubing set.

7. Performance Data

Both Design Verification and Design Validation have been completed.

Performance testing was completed to demonstrate that the Nebulae™ I functions as intended and performs as intended for safety purposes.

Device Flow Rates– Bench testing was done in a simulated use environment for all operating modes and the device performed within the specified flow rates.

Fill Time – Bench testing was done in a simulated use environment and proved that the Nebulae I could fill an abdomen simulator within the specified time period.

Flow Accuracy – Bench testing was done to prove that the Nebulae™ I could maintain specified flow accuracy for the flow rates in all modes and the device performed within the specified flow accuracy range.

Overpressure Relief - Bench testing was done to prove that the Nebulae™ I would relieve over pressure conditions of 5mmHg above the preset and return to the preset within the specified time range. The device was tested with different size abdominal simulators (to address all modes and sizes of pediatric patients) and at all flow rates specified, the device relieved pressure within the specified time range.

Comparative Flow Rate Testing – The predicate devices were tested along with the Nebulae™ I to compare the flow rates of the devices using an 11mm trocar with a 10mm laparoscope. The highest flow rates measured were 32 LPM.

Pediatric Mode Comparative Testing – The Nebulae™ I was tested along with the predicate device in pediatric mode, in each of the weight modes, with a veress needle and also with a trocar. A simulated abdomen of an appropriate size for each weight mode was used. During testing in each of the weight modes, a leak was introduced and removed, and then overpressure and under pressure conditions were created. The response times were measured and compared with the predicate device and the Nebulae™ I was found to perform as well as, or better, than the predicate device.

Tissue Desiccation Effect Testing – The Nebulae™ I and the 40L Abdominal Insufflators were used in a cross comparison test to demonstrate the tissue desiccation or drying effect at their maximum flow rates while connected to a standard 5mm trocar. A typical 5mm laparoscopic instrument was inserted into the trocar sleeve to simulate an actual usage scenario. Moist bovine liver was used to show the drying effect.
Both Insufflators were set to allow their maximum achievable flow rates of CO_2 to come in contact with the moist liver tissue samples. The gas flow was to remain on for 30 seconds and 60 seconds. The 5mm trocar sleeve distal opening was set in close proximity to the surface of the tissue sample. Results in both cases showed a negligible change to the tissue surface with no perceivable depth of desiccation. This was clearly evident in the cross-sectional tissue samples. It was concluded that the 50LPM and the 40LPM insufflators described above were identical relative to tissue desiccation and drying.

The Nebulae™ I was tested and shown to conform to the following standards:
Electrical Safety – IEC 60601-1:2005
EMC – EN 60601-1-2:2007

8. Conclusion

The different technological characteristics and information submitted to the FDA do not raise new questions of safety and efficacy. Testing has shown that the device is at least as safe and effective as the legally marked predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2012

Ms. Casey Kurek
Regulatory Manager
Northgate Technologies Inc.
1591 Scottsdale Court
ELGIN IL 60123

Re: K120151
Trade Name: Nebulae™ I 50 LPM Insufflator
Regulation Number: 21 CFR § 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF, OSX, FCX
Dated: August 2, 2012
Received: August 3, 2012

Dear Ms. Kurek:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120151

Device Name: Nebulae™ I 50 LPM Insufflator/ REF #7-650-00

Indications For Use:

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Pediatric Laparoscopic
Bariatric Laparoscopic
Minimally Invasive Vessel Harvesting

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120151