JUL 2 9 2004

K033614

Summary of Safety and Effectiveness

Common / Usual Name: Laparoscopic Insufflator

Proprietary Name: Nortech *IntraMyst* Humidification System

Classification: Class II

Materials: Materials used to manufacture Nortech's *IntraMyst* Humidification System Tubing Sets are non-toxic and have been previously utilized to manufacture other devices.

Description: Nortech's *IntraMyst* Humidification System incorporates front panel controls that are similar to Northgate's current Insufflators. The system is designed to provide continuous or on demand humidification to the laparoscopic environment. This may reduce the incidence of postoperative pain, diminish the likelihood of adhesion formation and reduce laparoscope lens fogging.

The controller will contain the appropriate pneumatics for supplying and controlling the gas to the catheter at 100 PSI and 5 LPM. In addition, the controller will have displays for indicating abdominal pressure, overpressure, gas supply low, mist active, active pressure sense and amount of fluid dispensed.

Northgate Technologies Inc. shall contract the appropriate testing of the system to meet standards such as UL-2601-1, CAN/CSA-C22.2 No. 601.1, EN 60601-1 and EN 60601-1-2. Also, any microbiological testing to meet ISO 10993-X shall be performed.

Substantial Equivalence: Northgate's *IntraMyst* Humidification System and Accessories is substantially equivalent in materials, and intended use to numerous currently marketed devices. Predicate devices are indicated in Exhibit # 5.

Intended Use: The Nortech *IntraMyst* Humidification System is indicated for use as a means of supplying humidity within the intra-abdominal cavity during diagnostic and / or operative laparoscopic procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2004

Mr. Casey Kurek
Regulatory Manager
Northgate Technologies, Inc.
600 Church Road
ELGIN IL 60123

Re: K033614
Trade/Device Name: IntraMyst Humidification System
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: 85 HIF
Dated: June 1, 2004
Received: June 4, 2004

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

CONFIDENTIAL

510(k) Number (if known): K033614

Device Name: IntraMyst Humidification System

Indications For Use:

The NORTECH IntraMyst Humidification System is indicated for use as a means of supplying humidity within the intra-abdominal cavity during diagnostic and/or operative laparoscopic procedures.

Casey Kurek

Casey Kurek, Regulatory Manager, Northgate Technologies, Inc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033614