OCT 2 3 2001

K010053

SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Insufflator, Laparoscopic Accessory

Proprietary Name: Humi-Flow™

Classification: Class II

Materials:

Materials used to manufacture the Northgate Technologies Inc. Humi-Flow™ Unit are non-toxic and have been previously used to manufacture other devices.

Description:

The Humi-Flow™ Unit is designed to be used in conjunction with an insufflator to provide continuous non-adjustable warming and humidification of CO_2 gas to a laparoscopic instrument. The Humi-Flow™ Unit is comprised of a control unit, a gas warmer / humidifier (sold separately in two parts), and a power cord.

Substantial Equivalence:

Northgate's Humi-Flow™ Unit is substantially equivalent in performance, materials, and intended use to currently marketed devices. Georgia Biomedical, Inc. is another manufacturer of a similar device.

Intended Use:

The Nortech® Humi-Flow™ Unit shall be used as a means of supplying warmed / humidified CO_2 gas for diagnostic and/or operative laparoscopy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2001

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

Re: K010053
Trade/Device Name: Humi-Flow™
Model 6-850-00/01/02
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: 85 HIF
Dated: August 6, 2001
Received: August 8, 2001

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 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 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 this 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" (21 CFR Part 807.97). 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): K010053

Device Name: HUMI-FLOW™

Indications For Use:

The NORTECH® HUMI-FLOW™ shall be used as a means of supplying warmed/ humidified CO_2 gas for diagnostic and/or operative laparoscopy.

C. Kurek, Regulatory Manager

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010053

(Optional Format 1-2-96)

Northgate Technologies Incorporated 600 Church Road, Elgin, IL 60123 1-800-348-0424 IL: 847-608-8600 FAX: 847-608-9405