NORTECH

K992381

SEP 17 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Insufflator, Laparoscopic Accessory

Proprietary Name: CO_2 Gas Warmer II

Classification: Class II

Materials:

All materials used to manufacture the Northgate Technologies Inc. CO_2 Gas Warmer II Unit are non-toxic and have been previously used to manufacture other medical devices.

Description:

The CO_2 Gas Warmer II Unit is designed to be used in conjunction with an insufflator to provide continuous non-adjustable heating of gas to a laparoscopic instrument. The CO_2 Gas Warmer II Unit is comprised of a control unit and re-usable heat exchanger and power cords.

Substantial Equivalence:

Northgate's CO_2 Gas Warmer II Unit which is comprised of a control unit/heat exchanger and power cords are substantially equivalent in design, materials, and intended use to numerous currently marketed devices. Other manufacturers of similar devices are Snoden Pencer and Wisap.

Intended Use:

The Nortech CO2 Gas Warmer II Unit shall be used as a means of supplying warm gas for the distention of the abdomen for diagnostic and/or operative laparoscopy.

Northgate Technologies Incorporated 600 Church Road, Elgin, IL 60123 1-800-348-0424 IL: 847-608-8900 FAX: 847-608-9405

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 1999

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

Re: K992381
CO_2 Gas Warmer II
Dated: August 16, 1999
Received: August 19, 1999
Regulatory Class: II
21 CFR §884.1730/Procode: 85 HIF

Dear Mr. Kurek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

510(k) Number (if known K992381

Device Name: CO_2 Gas Warmer II

Indications For Use:

THE NORTECH GAS WARMER II IS INDICATED FOR WARMING GAS (95-105°F/35-40.5°C) USED FOR THE DISTENTION OF THE ABDOMEN FOR DIAGNOSTIC AND/OR OPERATIVE LAPAROSCOPY.

Casey Kurek
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 X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992381

(Optional Format 1-2-96)