K973447

SEP 30 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Laparoscopic Insufflator

Proprietary Name: Omniflator® 6630

Classification: CLASS II

Materials:

All materials used to manufacture the Northgate Technologies Inc. Omniflator® Model 6630 and tubing sets are non-toxic and have been previously used to manufacture other medical devices.

Description:

The Omniflator® Model 6630 CO_2 Gas Insufflator incorporates front panel controls similar to our current Omniflator® Model #6600. The 6630 has an adjustable gas flow rate from 0-30 LPM. The unit shall have direct patient pressure monitoring which can be used by attaching the direct patient monitoring tubing set to the Omniflator's® patient monitoring connector and subsequently into a cannula or trocar after initial insufflation has been achieved. The user has an option to utilize CO_2 from a central supply or E-Cylinder tank.

Substantial Equivalence:

Northgate's 6630 Insufflator/tubing sets are substantially equivalent in design, materials, and intended use to other currently marketed devices. Other manufacturers of similar devices are Snowden - Pencer.

Intended Use:

The Nortech® 6630 Insufflator shall be used for gas 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 30 1998

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

Re: K973447
Nortech Omniflator® 6630
Dated: July 14, 1998
Received: July 16, 1998
Regulatory Class: II
21 CFR 884.1730/Procode: 85 HIF

Dear Mr. Kurek:

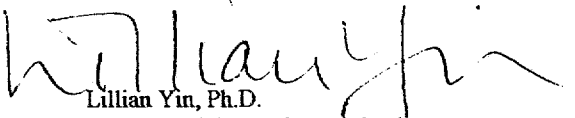
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973447

CONFIDENTIAL

Device Name: OMNIFLATOR® 6630

Indications For Use:

THE NORTECH OMNIFLATOR® 6630 SHALL BE USED FOR GAS DISTENTION OF THE ABDOMEN FOR DIAGNOSTIC AND / OR OPERATIVE LAPAROSCOPY.

Casey Kurek 9.8.97
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, ENT, and Radiological Devices
510(k) Number K973447

(Optional Format 1-2-96)

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