[redacted]

SEP 2 8 2004

K041560

SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: System, Irrigation, Urological

Proprietary Name: Flo-Assistant™

Classification: Unclassified

Materials:

The main unit of the Flo-Assistant™ is fabricated from aluminum and stainless steel within a plastic housing. Enclosed in the main unit is the squeezing mechanism, which is simply a brake caliper manufactured from aluminum. The caliper is activated by a cable assembly that runs down to the pedal mechanism, which is also manufactured from aluminum and stainless steel.

Description:

The Flo-Assistant™ is designed to be used with the Nortech® 7-510-33 Flo-Assistant™ tubing set for increased fluid capacity. The device is comprised of a main unit, cable and foot pedal assembly.

Substantial Equivalence:

Northgate's Flo-Assistant™ is a mechanical device that is substantially equivalent in design materials and intended use to numerous currently marketed devices. Other manufacturers of similar devises are Microvasive and B. Braun.

Intended Use:

The Nortech® Flo-Assistant™ product is indicated to provide a squeezing mechanism to a tubing set, increasing capacity fluid and irrigation for arthroscopic procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2004

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

Re: K041560
Trade/Device Name: Flo-Assistant™
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: September 1, 2004
Received: September 3, 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 (301) 594-4659. 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 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,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041560

Device Name: Flo-Assistant™

Indications For Use:

The Nortech Flo-Assistant™ Product is indicated to provide a squeezing mechanism to a tubing set, providing increased capacity fluid irrigation for arthroscopic procedures.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041560