JUL 14 1999

NORTECH

K990341

EXHIBIT #9A

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[as required by 807.92(a)]

Classification/Common/Usual Name: Lithotriptor, Electro-Hydraulic

Proprietary Name: Intracorporeal Electro-Mechanical Lithotriptor

Classification: Class III (876.4480)

Materials:
All materials used to manufacture the Northgate Technologies Inc. EML generator, probe handle, and stainless steel probes (rods) are non-toxic and have been previously used to manufacture other medical devices.

Description:

The Intracorporeal Electro-Mechanical Lithotriptor (EML) generator incorporates front panel controls that include a lighted main "Power Switch." An "Energy Switch" and "Rate Switch".

Energy Switch

This switch sets the relative energy delivered with each pulse. The selected switch setting will be illuminated.

- Low The low setting transmits approximately 40mJ of energy to the probe.
- High The High setting transmits approximately 90mJ of energy to the probe.

Rate Switch

This switch sets the rate or frequency of pulses delivered. The selected switch setting will be illuminated.

- Single The Single setting delivers one pulse per footswitch activation.
- Low The Low setting delivers fifteen consecutive pulses per footswitch activation.
- High The High setting delivers thirty consecutive pulses per footswitch activation.

Probe selection is dependent on the application and physician preference.

Fragmentation occurs after the probe tip is placed in contact with the stone and the selected pulses are discharged.

Substantial Equivalence:

Northgate's EML Generator and probes are substantially equivalent in design, materials, and intended use to other currently marketed devices such as Medispecs' Lithospec™, and the Lithoclast which is manufactured by Electro Medical Systems.

Intended Use:

The Nortech® Electro-Mechanical Lithotriptor (EML) was designed to be used with Nortechs'® Intracorporeal Electro-Mechanical Lithotriptor probes for the fragmentation of urinary calculi.

Technological Comparison, Summary

	Northgate Electro-Mechanical	EMS Swiss Lithoclast
Probe Fabrication	Stainless Steel	Stainless Steel
Energy Type	Electrical	Pneumatic
Energy Transfer	Mechanical Impact	Mechanical Impact
Theory Of Operation	A drive unit converts electrical energy into mechanical force which is applied to an impact hammer that strikes the end of the probe. The probe strikes the stone.	Compressed air generates ballistic energy to a projectile within the hand piece - The projectile hits the probe. The probe strikes the stone.

Performance Data, Summary

The Northgate EML unit and EMS Swiss Lithoclast were compared during bench testing. The two (2) systems were similar in the way the calculi was fragmented. Both units require using a ridgid or semi-ridged endoscope under direct vision for ureteral and bladder calculi.

Conclusion

Different in technology i.e., energy type and Theory of Operation, the Northgate Technologies Inc. Electro-Mechanical Lithotriptor and EMS Swiss Lithoclast have many similarities.

The performance data listed above, Comparison of Features, and detailed test data, indicate that the Northgate Technologies Inc. system is substantially equivalent to the EMS Swiss Lithoclast System.

Date of Summary- March 16, 1999
Contact- Casey Kurek, Regulatory Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

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

Re: K990341
Intracorporeal Electro-Mechanical Lithotriptor
Dated: June 8, 1999
Received: June 9, 1999
Regulatory Class: III
21 CFR §876.4480/Procode: 78 FFK

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 K990341

Device Name: ELECTRO-MECHANICAL LITHOTRIPTOR (EML)

Indications For Use:

The Nortech® Electro-Mechanical Lithotriptor (EML) was designed to be used with Nortechs'® Intracorporeal Electro-Mechanical Lithotriptor Probes for the fragmentation of urinary calculi.

Casey Kurek

C. Kurek, Regulatory Manger

(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 K990341

(Optional Format 1-2-96)