

K962271

[REDACTED]

SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Electrosurgical Electrodes

Proprietary Name: Vapor-Tech Roller Ball, Vapor-Tech Roller Barrel,
Vapor-Tech Cross Grooved, Vapor-Tech Grooved Roller
Vapor-Tech Ball, Vapor-Tech Sled™, Cutting Loop, and
Knife Electrosurgical Electrodes

AUG - 8 1997

Classification: CLASS II

Materials:

All materials used to manufacture the Northgate Technologies Inc. Electrodes are non-toxic and have been previously used to manufacture other medical devices.

Description:

Northgate's Cutting Loops and Knife Electrosurgical Electrodes are designed to be used with most major brands of Resectoscopes. The electrodes are used to cut and coagulate soft tissue during electrosurgical procedures.

The Vapor-Tech Series Electrodes are designed with several tip configurations: roller ball, roller barrel, cross grooved, grooved roller, ball, and Sled™.

Substantial Equivalence:

Northgate's Electrosurgical Electrodes are substantially equivalent in design, materials, and intended use to numerous currently marketed devices. Other manufacturers of similar devices are Circon/ACMI, Olympus, Storz Products, Inc., and Richard Wolf.

Intended Use:

1. Directed Biopsy
2. Removal of submucous fibroids and large polyps
3. Submucous myomectomy
4. Transection of intrauterine adhesions
5. Transection of intrauterine septa
6. Endometrial ablation



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 1997

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

Re: K962271
Vapor-Tech™ Hysteroscopic Electrosurgical Electrodes
(Roller Ball, Roller Barrel, Cross Grooved, Grooved
Roller, Ball, Sled™, Cutting Loop and Knife)
Dated: May 13, 1997
Received: May 14, 1997
Regulatory Class: II
21 CFR §884.1690/Product Code: 85 HIH
21 CFR §884.4120/Product Code: 85 HGI

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 requirement, 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/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): K962271

Device Name: Vapor-Tech™ Hysteroscopic Electrosurgical Electrodes
(Roller Ball, Roller Barrel, Cross Grooved, Grooved Roller, Ball,
Sleeve™, Cutting Loop and Knife)

Indications For Use:

1. Directed Biopsy
2. Removal of submucous fibroids and large polyps
3. Submucous myomectomy
4. Transection of intrauterine adhesions
5. Transection of intrauterine septa
6. Endometrial ablation

Cosy Kurk 8.8.97
C. Kurk, Regulatory Manager

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin Ballard
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K962271

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)