K971986 p 1 of 2

EXHIBIT XI.

510(k) Number K971986

Device Name: Bipolar Loop Electrode

AUG 26 1997

SUMMARY OF SAFETY AND EFFECTIVE INFORMATION

Valley Forge Scientific Corp, the manufacturer of several Malis bipolar coagulation/cutting systems, now plans to introduce Bipolar Loop Electrodes for gynecological procedures. As the world's foremost authority on bipolar electrosurgery Dr. Leonard I. Malis has used bipolar loops to core all types of brain and spinal cord neoplasms such as meningiomas, neuromas, and gliomas bloodlessly, while the contiguous tissues remain functioning normally, and the removed specimens show no damage whatsoever. Dr. Malis further states that "Bipolar cutting loops restrict cutting current to the very small space between the paired loops. There is no current flow outside of the loops to any other tissues and no current to any ground. Accordingly, there is no heat spread."

Bipolar electrosurgery has been used successfully to cut tissue or coagulate blood vessels for over 30 years. Dr. Malis says that "Bipolar cutting loops have been used in neurosurgery since 1981, and have made possible the safe and complete removal of tumors previously considered unresectable....The use of these bipolar loops has produced excellent pathology specimens in a wide variety of benign and malignant tumor types, without the confusing thermal damage produced by monopolar loops."

In his Thomas Jefferson University Hospital Study, Dr. Martin Weisberg concludes that "Bipolar loop excision allows for adequate specimens to be obtained with minimal blood loss and short operating time. Because of the characteristics of bipolar energy, bipolar loop excision may represent a safer treatment for CIN because no grounding pad or insulated speculum is required for bipolar procedures." In a recent Philadelphia Business Journal (August 8-14, 1997) article, Dr. Weisberg said "The main thing about bipolar technology is the safety issue...the bipolar technology is much safer."

Some of the effective safety features of Bipolar Electrosurgery are:

* Bipolar Technology eliminates the need for grounding pads and the possibility of patient burns.

* Bipolar Coagulation minimizes damage to adjacent tissue since the patient is no longer the return path for the electrical current.

* Bipolar Technology works at voltages approximately ¼th the voltage required for monopolar technique.

* Localized Bipolar Coagulation gives the surgeon precise control of the electric current at the tissue site.

* The system's patented waveform and exceedingly low output impedance provide superior coagulation and the absence of charring and sticking even in a dry field.

* Because of the high output impedance of monopolar and other bipolar systems, instruments short-out in an irrigated or bloody field.

* Unlike monopolar systems, bipolar electrosurgery provides smooth, progressive coagulation with the option of precise, flow-controlled irrigation.

* Bipolar technology permits the physician to coagulate in an irrigated field thereby minimizing heat build-up or thermal damage to adjacent tissues.

* The waveform parameters of the Valley Forge Bipolar Electrosurgery Systems are programmed for the smoothest, most gentle, precise and efficient cutting and coagulation of tissue during any surgical procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 1997

Mr. Thomas J. Gilloway
Executive Vice President
Valley Forge Scientific Corporation
136 Green Tree Road
Oaks, Pennsylvania 19456

Re: K971986
Valley Forge Bipolar Loop for Gynecological Indications
Dated: May 27, 1997
Received: May 29, 1997
Regulatory class: II
21 CFR §884.4120/Product code: 85 HGI

Dear Mr. Gilloway:

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

EXHIBIT XII.

510(k) Number (if known): K971986

Device Name: Bipolar Loop Electrodes

Indications for Use: (revised)

Valley Forge bipolar loop electrodes are designed for electrosurgical excisions in a dry, infiltrated or wet field. Gynecological indications are as follows:

* loop excisions of the cervix
* cervical conizations
* external anogenital lesions
* large vaginal intraepithelial neoplastic lesions

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Gatling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971986

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)