EXHIBIT V

DEC 19 1997

510(k) Number (if known): K973554

Device Name: Bipolar Ball Electrodes

SUMMARY OF SAFETY AND EFFECTIVE INFORMATION

Dr. Leonard I. Malis, the world's foremost authority on bipolar electrosurgery and co-developer of the Valley Forge Scientific Corp bipolar ball coagulating electrodes, has been using bipolar coagulation since the early 1950's. The bipolar ball electrodes are an extension of his instrumentation and technique that has made bipolar the methodology of choice in neurological, gynecological and other surgical areas. Dr. Malis states that "Since all of the current used to coagulate flows between the two halves of the ball electrodes, there is no current spread to adjacent tissue and, accordingly, no heat spread. Additionally, the bipolar ball electrodes are able to coagulate in bloody, wet or irrigated fields."

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, and therefore, there is very little thermal tissue damage.

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

* The bipolar 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

DEC 19 1997

Mr. Jerry L. Malis
President
Valley Forge Scientific Corporation
136 Green Tree Road
Oaks, Pennsylvania 19456

Re: K973554
Trade Name: Valley Forge Bipolar Ball Tip Electrode
Regulatory Class: II
Product Code: JOS
Dated: September 18, 1997
Received: September 19, 1997

Dear Mr. Malis:

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.

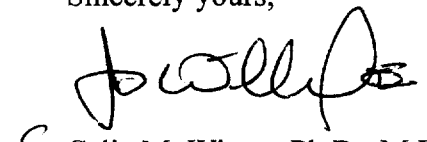
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4595. 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,



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

Enclosure

510(k) Number (if known): K973554

Device Name: Bipolar Ball Electrodes

Indications for Use:

The bipolar ball electrodes are designed for electrosurgical coagulation of soft body tissue in a dry, infiltrated or wet surgical field.

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Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973554