MAR 9 2005

K 050364

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Summary of Safety & Effectiveness

This 510 K Summary is being submitted in accordance with the requirements of 1990 and 21CFR807.92.

General Information

Date Prepared:	March 7, 2005
Submittor:	Valley Forge Scientific Corp. P. O. Box 1179 Oaks, PA 19456
Contact:	Jerry Malis, M.D. (610) 666-7500 Fax (610) 666-7565

General Provisions

Trade name	Malis Bipolar 2000 Electrosurgical System
Classification:	Electro Surgical Device
Predicate Device:	K955346, VFS 300
Classification:	Class II
Performance Standard:	Pursuant to Section 1990 CFR 870.92, no performance standards have been established for this device.
Intended Use:	The Malis 2000 Electrosurgical Generator is indicated for use in micro, macro and endoscopic bipolar cutting and coagulation of tissue and sealing of blood vessels in all areas of surgery.

Device Description:

The Malis 2000 Bipolar Electrosurgical System includes the generator, a Bipedal footswitch for operating the cutting and coagulation functions, a connecting cable to allow the use of a MALIS irrigator with the MALIS 2000 generator. The unit incorporates the use of a LCD panel to make it easier for the surgeon to see the setting.

Substantial Equivalence:

Item	*Existing Device* K 955346 VFS 300 Bipolar Electro-surgical Generator	*Modified Device* Malis 2000 Bipolar Electro-surgical Generator
Intended Use	The Valley Forge Scientific Malis Bipolar Generator is indicated for use in surgical procedures for cutting tissue and coagulating blood vessels.	The Valley Forge Scientific Malis Bipolar Generator is indicated for use in surgical procedures for cutting tissue and coagulating blood vessels.
Control Circuitry	Digital	Digital
Method of Operation	Delivery of RF power for cutting and coagulating.	Delivery of RF power for cutting and coagulating.
RF Output Range	5 watts to 300 watts	5 watts to 300 watts
Blend Cut/Coag	Three (3) levels	Three (3) levels
Activation	By Footpedal	By footpedal and finger operated instruments.
Output power controls	Up/down rocker switches	Rotary Switches
Power Display for Outputs	Segmental digital indicators	LED Display Screen
Sterilization	Non sterile	Non sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 - 2005

Jerry L. Malis, M.D.
President
Valley Forge Scientific Corporation
P.O. Box 1179
Oaks, Pennsylvania 19456

Re: K050364
Trade/Device Name: Malis Bipolar 2000 Electrosurgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 8, 2005
Received: February 14, 2005

Dear Dr. Malis:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting 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): K050364

Device Name

Valley Forge Scientific MALIS ™ 2000 Bipolar Electrosurgical Generator.

Indications for Use

The MALIS 2000 Bipolar Electrosurgical system is indicated for use in micro, macro and endoscopic bipolar cutting and coagulation of tissue and sealing of blood vessels in all types of surgery.

Prescription Use: X AND/OR Over-the-Counter Use: _____
(Per 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)

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

510(k) Number K050364