NOV 2 8 2003

# 510(k) Summary
# for the
## MALIS™ Irrigation Module 1000

K033499

*Valley Forge Scientific Corp.*
*136 Green Tree Rd., Suite 100, P.O. Box 1179*
*Oaks, PA. 19456*

**Contact Person:** Jerry L. Malis, President
Phone Number: 610-666-7500
Fax Number: 610-666-7565

**Date Prepared:** 10/30/03

**Proprietary Name:** MALIS™ Irrigation Module 1000
**Common Name:** Irrigation Device for Bipolar Coagulation and Cutting
**Classification Name:** Electrosurgical Cutting and Coagulation Accessory

**Device Classification:** This device is Class II per Class II per 21 CFR § 878.4400 – Electrosurgical Cutting and Coagulation Device and Accessories

**Predicate Device:** MALIS™ Irrigation System (K854413)

**Intended Use:** The MALIS™ Irrigation Module 1000 is indicated for use with irrigating bipolar forceps with the CODMAN® / MALIS™ generators.

**Device Description:** The MALIS™ Irrigation Module 1000 is an irrigation control system for use with the MALIS™ CMC-III Bipolar Electrosurgical Systems and the Synergy MALIS™ Precision System. This system provides controlled flow of irrigating fluid across the tips of bipolar irrigating forceps.

**Performance Data:** Verification and validation tests were conducted on the on both the system and its software. Electrical safety testing was also conducted. All testing passed.

**Substantial Equivalence:** The modified system, the MALIS™ Irrigation Module 1000, is substantially equivalent to the predicate MALIS™ Irrigation System (K854413) in terms of intended use, function, technical specifications, and operating principles. The safety and efficacy of the MALIS™ Irrigation Module 1000 is therefore substantiated by its similarity to the original device, MALIS™ Irrigation System (K854413).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2003

Mr. Jerry L. Malis
President
Valley Forge Scientific Corporation
136 Green Tree Road, Suite 100
P.O. Box 1179
Oaks, Pennsylvania 19456

Re: K033499
Trade/Device Name: MALIS™ Irrigation Module 1000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 3, 2003
Received: November 6, 2003

Dear Mr. 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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

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

Enclosure

510(k) Number (if known): K033499

Device Name

MALIS™ Irrigation Module 1000

Indications for Use

The MALIS™ Irrigation Module 1000 is indicated for use with irrigating bipolar forceps with the CODMAN® / MALIS™ generators.

(Please do not write below this line - continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Melkerson

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

(510(k) Number K033499