510(k) Summary
for the
Malis Bipolar Disposable Electro-Surgical Pens

K042604

OCT 2 2 2004

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: September 21, 2004
Proprietary Name: Valley Forge Scientific Malis™ Bipolar Disposable Electro-Surgical Pens
Common Name: Bipolar Disposable Electro-Surgical Pens
Classification Name: Electrosurgical Cutting and Coagulation Accessory

Device Classification: This device is Class II per CFR § 878.4400- Electrosurgical Cutting and Coagulation Instruments

Predicate Devices:

K910510	Valley Forge Scientific Corp.	K896626	Conmed Corp.
K955764	Valley Forge Scientific Corp.	K982742	New Deantronics
K973554	Valley Forge Scientific Corp.	K982884	New Deantronics
K932345	Conmed Corp.	K850297	Birtcher Corp.

Intended Use: The Valley Forge Scientific Malis™ Bipolar Disposable Electro-Surgical Pen is indicated for use with the Valley Forge Scientific 300 Bipolar System.

Device Description: Plastic disposable finger operated bipolar electro-surgical instruments with either blade, ball or loop tips.

Performance Standards: Pursuant to Section 514 of the FD&C Act and 21 CFR 888, no performance standards have been established for this device

Substantial Equivalence:

The Valley Forge Scientific Malis bipolar instruments are similar in use to Bovie-type mono-polar instruments which have been marketed for the past 25-30 years (prior to May 28, 1976). Both the mono-polar and the bipolar instruments depend on an electro-surgical generator to deliver RF current to the tips of the instruments for cutting and coagulation.

The difference between the two methods can be found in the fact that with the mono-polar systems, the current passes from an active electrode through the patient to a grounding pad. The bipolar method eliminates the electrical current being passed through the patient and the use of grounding pads and their inherent safety hazards. Bipolar technology also permits the surgeon to work in a wet or irrigated surgical field without current shunting.

The physical construction of both the mono-polar and bipolar instruments are essentially identical. The switch mechanisms on both are liquid sealed with buttons molded in place.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2004

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

Re: K042604
Trade/Device Name: Valley Forge Scientific MALIS™ Bipolar Disposable Hand-Switching Electro-Surgical Pencil, Loops, and Ball
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 21, 2004
Received: September 24, 2004

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 (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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

INDICATIONS FOR USE

510(k) Number (if known): K042604

Device Name

Valley Forge Scientific MALIS ™ Bipolar Disposable Hand-Switching Electro-Surgical Pencils, Loops, and Ball.

Indications for Use

Electro-Surgical accessories: Hand-Switching Pen for the removal of tissue and control of bleeding in surgical procedures using high frequency (RF) current.

Prescription Use: ✓ 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)

Miriam C. Provost

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

510(k) Number K042604