JUL 2 2 2005

K051627

SUMMARY OF SAFETY AND EFFECTIVENESS
G3000 Electrosurgical Device

1. Submitter Information

Valleylab, a Division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301
Contact: Herbert Vinson
Telephone: 303-530-6469

Date summary prepared: June 17, 2005

2. Name of Device

Trade or Proprietary Name: Valleylab G3000 Electrosurgical Device

Common Name: Monopolar electrosurgical device

Classification Name: Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, General and Plastic Surgery

3. Predicate Devices

The G3000 Electrosurgical Device is substantially equivalent in function and intended use to the Valleylab E2516 Electrosurgical Pencil (K813071) and the Valleylab E2517 Power Control Pencil (K861112). All three devices are used for monopolar electrosurgery, allowing the surgeon to actuate the electrosurgical generator from the sterile field using push button controls on the device. All devices are used with conventional electrosurgical electrodes with a 2.4mm (3/32 inch) shaft diameter, such as coated and uncoated blade, needle, ball, LLETZ loop, and arthroscopy electrodes.

4. Device Description

The G3000 Electrosurgical Device is a handheld, single-use device designed to deliver monopolar RF electrosurgical energy to a surgical site to cut and/or coagulate tissue. The G3000 Electrosurgical Device is designed for use only with the Valleylab ForceTriad™ Electrosurgical Generator (510(k) application submitted), and has a connector that will only fit into the ForceTriad™ generator. The G3000 connector is a "smart connector" that allows the ForceTriad™ generator to verify the device type. The device body incorporates "soft touch" material to improve the surgeon's grip.

The surgeon activates the desired electrosurgical mode from the sterile field by using one of three push buttons on the device. Three electrosurgical modes are available:

- Cut – cuts tissue with minimal coagulation / hemostasis
- Hemostasis with Division – divides tissue with controlled hemostasis
- Coag – coagulates bleeding vessels to provide hemostasis

The surgeon can also control the power settings of the electrosurgical generator from the sterile field using a slider control on the device.

The G3000 Electrosurgical Device uses conventional electrosurgical electrodes, such as coated and uncoated blade, needle, ball, LLETZ loops, and arthroscopy electrodes, with a 2.4mm (3/32 inch) shaft diameter. Valleylab initially intends to market the G3000 Electrosurgical Device with Valleylab coated blade electrodes (K955836, K962044), 10 and 15 foot cord lengths, and Valleylab disposable safety holsters (K791639). Alternate configurations with other electrodes are anticipated in the future.

5. Intended Use

The G3000 Electrosurgical Device is a single-use device intended for use in surgical procedures (such as general, urologic, thoracic, plastic and reconstructive, gynecologic, arthroscopic) where the surgeon desires monopolar radio-frequency electrosurgical energy to cut and/or coagulate tissue. The G3000 Electrosurgical Device is intended for use with the Valleylab ForceTriad™ Electrosurgical Generator and conventional monopolar electrosurgical electrodes, such as coated and uncoated blade, needle, ball, LLETZ loop, and arthroscopic electrodes.

There are no specific contraindications associated with the G3000 Electrosurgical Device. General contraindications and warnings related to the use of electrosurgery, as outlined in the user instructions for Valleylab electrosurgical generators, apply to the G3000 Electrosurgical Device.

6. Summary of Technological Characteristics

The G3000 Electrosurgical Device has the same basic technological characteristics as the predicate devices noted above.

7. Performance Data

Performance testing was performed to ensure that the G3000 Electrosurgical Device functions as intended, and meets design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2005

Valleylab, a Division of Tyco Healthcare Group LP
c/o Mr. Herbert Vinson
Senior Regulatory Associate
5920 Longbow Drive
Boulder, Colorado 80301

Re: K051627
Trade/Device Name: Valleylab G3000 Electrosurgical Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 17, 2005
Received: June 20, 2005

Dear Mr. Vinson:

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

510(k) Number (if known): K051627

Device Name: **Valleylab G3000 Electrosurgical Device**

Indications For Use:

The Valleylab G3000 Electrosurgical Device is a single-use device intended for use in open surgical procedures (such as general, urologic, thoracic, plastic and reconstructive, gynecologic, arthroscopic) where the surgeon desires monopolar radio-frequency electrosurgical energy to cut and/or coagulate tissue. The G3000 Electrosurgical Device is intended for use with the Valleylab ForceTriad™ Electrosurgical Generator and conventional monopolar electrosurgical electrodes, such as blade, needle, ball, LLETZ loop, and arthroscopic electrodes.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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