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510(K) Summary

E Surgical, LLC
1990 N. California Blvd., Suite 1040
Walnut Creek, CA 94596
925-280-8388 Phone
925-280-1788 Fax
Contact: Hans Richter, RA/QA Director

AUG 31 2007

I. Trade Name: E Surgical
Electrodesurgical Infant Patient Return Electrode, Dual Plate with Cord.

II. Common Name: Electrosurgical Infant Patient Return Electrode

III. Classification: 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories

IV. Product Code: GEI

V. Indications for Use:
A Single use, non sterile dispersive electrode with or without a pre-attached cord to adhere to the infant patient over the entire pad surface to complete the electrosurgical circuit between the generator, the active electrode, and the patient.

VI. Predicate Device: Valleylab, Inc., VL 7510-25 Infant REM Polyhesive II Patient Return Electrode. 510 (K) #K060255

VII. Device Description: The E Surgical Infant Patient Return Electrode Dual Plate is a single use, non-sterile disposable electrode with and without a pre-attached cord. The use is to complete an electrical circuit during electro surgery between the generator, the active electrode, and an infant patient.

VIII. Summary of Technological Characteristics: The E Surgical Infant Patient Return Dual Electrode is comparable to the Valleylab, Inc.'s VL E7510-25 Dual Pad, REM compatible electrode, a legally marketed device. The E Surgical pad is furnished with a 9'2" cord. The pad has a hydrogel adhesive for conductivity with an acrylic border to prevent invasion of fluids. Both pad designs are compatible with return electrode monitoring generator systems.

IX. Performance Data: The E Surgical Pad complies with the ANSI/AAMI HF-18 standard Electrosurgical Device for Dispersive Electrode Thermal Safety and Contact Impedance. The Pad design is proven safe by compliance to biocompatibility standard ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2007

E Surgical, LLC
% Mr. Hans J. Richter
RA/QA Director
1910 N. California Boulevard
Suite 1040
Walnut Creek, California 94596

Re: K071080
Trade/Device Name: E Surgical Electrosurgical Infant Patient Return Electrode, Dual Plate With Cord
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 17, 2007
Received: August 21, 2007

Dear Mr. Richter:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: E Surgical Electrosurgical Infant Patient Return Electrode, Dual Plate With Cord.

Indications for Use:

A Single use, non-sterile dispersive electrode with a pre-attached cord used to adhere to the Infant patient over the entire pad surface to complete the electrosurgical circuit between the generator, the active electrode, and the patient.

Prescription Use __X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

510(k) Number K071080