K994428

MAR - 7 2000

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

## I. Submitter Information

Valleylab
5910 Longbow Drive
Boulder CO 80301

Contact: Robert C. Moore, Senior Regulatory Affairs Associate

Telephone: (303) 530-6241
Fax: (303) 530-6313

## II. Date Prepared

February 1, 2000

## III. Name of Device

| | |
|---|---|
| Proprietary Name: | E7512 Neonatal REM PolyHesive™ II Neonatal Patient Return Electrode |
| Common Name: | Patient Return Electrode |
| Classification Name: | Electrosurgical Cutting and Coagulation Device and Accessories |

## IV. Predicate Devices

Valleylab E7507 Return Electrode (K813072)
Valleylab VL7600 Return Electrode (K953737)
ConMed 440-2400 MacroLyte® Premie Dispersive Electrode (K855084)

## V. Device Description

The E7512 Neonatal REM PolyHesive™ II Neonatal Patient Return Electrode is a single use, non-sterile dispersive electrode with a preattached cord, the purpose of which is to complete the electrosurgical circuit between the generator, the active electrode, and the patient. It is

specifically designed for use on newborn and prematurely born patients whose small size creates a limited area for pad placement and makes placement of other, larger-size pads difficult.

## VI. Intended Use

The E7512 Neonatal REM PolyHesive™ II Neonatal Patient Return Electrode is intended for use in surgical procedures in which electrosurgical equipment is used on newborn or prematurely born infants of approximately 1 to 6 lbs.

## VII. Summary of Technological Characteristics

The E7512 Neonatal REM PolyHesive™ II Neonatal Patient Return Electrode is comparable to the Valleylab E7507 REM PolyHesive™ II Patient Return Electrode (K813072), the Valleylab VL7600 REM™ Patient Return Electrode (K953737), and the ConMed 440-2400 Premie Pad (K855084), both legally marketed devices, except for the following characteristics:

- The E7512 is smaller in size that the Valleylab E7507 and the Valleylab VL7600.
- The E7512 features the Return Electrode Monitoring system (REM™) which the ConMed 440-2400 does not.
- The E7512 features an optional-use adhesive border. Both the Valleylab E7507 and the ConMed 440-2400 have an integral adhesive border, the use of which is not optional. The Valleylab VL7600 has no adhesive border.

## VIII. Performance Data

Performance testing has been performed to verify that the device functions as intended and that design specifications and applicable consensus standards have been met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2000

Mr. Robert C. Moore, Jr., RAC
Senior Regulatory Affairs Associate
Valleylab
5920 Longbow Drive
Boulder, Colorado 80301-3299

Re: K994428
Trade Name: E7512 Neonatal REM Polyhesive II Patient Return
Regulatory Class: II
Product Code: GEI
Dated: December 29, 1999
Received: December 30, 1999

Dear Mr. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K994428

DEVICE NAME: E7512 Neonatal REM Polyhesive II NeonatalPatient Return Electrode

**INDICATIONS FOR USE:**

The E7512 Neonatal REM PolyHesive™ II Neonatal Patient Return Electrode is a single use, non-sterile dispersive electrode with a preattached cord. The electrode adheres to the patient over its entire surface. Its purpose is to complete the electrosurgical circuit between the generator, the active electrode, and the patient.

Indications for use are general monopolar electrosurgery on newborn or prematurely born patients of between approximately 1 and 6 lbs.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994428