DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 19, 2016

Covidien LLC
Ms. Nancy Sauer
Principal Regulatory Affairs Specialist
5920 Longbow Drive
Boulder, CO 80301

Re: K160290
Trade/Device Name: Valleylab™ REM Polyhesive™ Infant Patient Return Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device & accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 19, 2016
Received: April 21, 2016

Dear Ms. Sauer:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160290

Device Name
Valleylab REM Polyhesive Infant Patient Return Electrode

Indications for Use *(Describe)*

The REM Polyhesive Infant 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.

The product is used for general monopoloar electrosurgery on newborns, infants, and children weighing between approximately 6 and 30 lb.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Number: K160290

Date summary prepared: 5/18/2016

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
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Contact

Nancy Sauer
Principal Regulatory Affairs Specialist
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Name of Device

Trade Name:	Valleylab™ REM Polyhesive™ Infant Patient Return Electrode
Catalog Numbers:	E7510-25, E5710-25DB
Common Name:	Patient Return Electrode
Classification Name:	Electrosurgical device, cutting, coagulation, and accessories
Regulation Number:	21CFR 878.4400
Product Code:	GEI

Predicate Device

The primary predicate device for this submission is the Valleylab™ REM Polyhesive™ Neonatal Patient Return Electrode. This device was cleared for marketing under 510(k) K994428.

Device Description

The Valleylab™ REM Polyhesive™ Infant Patient Return Electrodes are part of a family of patient return electrodes. They are non-sterile, single-use devices used in monopolar surgery to complete the electrical circuit with the generator. Providing a low-impedance path back to the generator through the return electrode helps to prevent unintended RF burns. The infant return electrodes are designed to be compatible with the return electrode monitoring function of compatible Covidien generators.

There are two separate catalog numbers for the infant Polyhesive™ return electrodes. The two models differ only with regard to the length of the cord connecting the return electrode to the generator. One has a 9-foot cord and the other has a 15-foot cord.

Indications for Use

The REM Polyhesive Infant 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.

The product is used for general monopoloar electrosurgery on newborns, infants, and children weighing between approximately 6 and 30 lb.

Technological Characteristics

This is a non-sterile single-use device that includes the following features:

- Conductive resin that adheres to the patient's skin and conducts electrical current away from the patient's body.
- Non-conductive adhesive border that provides a stronger adhesive bond and helps to prevent fluid ingress.
- Two separate pieces of conductive metal foil. The presence of two separate foil sheets is necessary for the Covidien Return Electrode Monitoring (REM) system in the Covidien generators.
- An integral cord that conducts the current from the conductive metal foil back to the generator.

Comparison to the Predicate Device

Similarities

- Same general intended use
- Both are indicated for use in pediatric populations, primarily newborns and infants
- Same materials and design
- Both use the Covidien REM technology for contact quality monitoring.

Differences

The indicated patient weight range is higher for the Valleylab™ REM Polyhesive™ Infant Patient Return Electrode. It is indicated for use in patients weighing between 6 and 30 pounds (2.7 – 13.6 kg), whereas the predicate device is indicated for use in patients weighing between 1 and 6 pounds. Because return electrodes intended for larger pediatric patients are expected to carry more current, the infant return electrode has a larger surface area than the neonatal return electrode.

The impact of these differences was evaluated through testing to show that the Valleylab™ REM Polyhesive™ Infant Patient Return Electrode meets thermal performance requirements for return electrodes indicated for use on patients weighing between 5 and 15 kg.

Sterilization

The Valleylab™ REM Polyhesive™ Infant Patient Return Electrodes are not sterile. Because the products are not delivered in sterile form, the primary packaging is not intended to act as a sterile barrier.

Shelf Life

The packaged Valleylab™ REM Polyhesive™ Infant Return Electrodes have a shelf life of two years. The suitability of this shelf life has been verified in accordance with sub-clause 201.15.101.8 of IEC 60601-2-2: 2009, which requires that the products be aged to within 30 days of their expiration date prior to conducting thermal performance and contact impedance testing.

The primary packaging has also been evaluated to verify the suitability of the two year shelf life. The primary packaging remains intact with no tears, holes, or other degradation and the seal remains intact (seal width maintained and no visual evidence of seal degradation).

Biocompatibility

The products have been evaluated for biocompatibility in accordance with ISO 10993-1: 2009 and the FDA Blue Book Memorandum G95-1. Per the standard, patient return electrodes are classified as intact skin contacting devices with limited duration (< 24 hours) of contact.

The direct patient contact materials are:

- Conductive gel (adhesive polymer matrix, water, electrolytes, blue colorant, and preservative)
- Pressure-sensitive adhesive border
- Silicone-coated paper (can be used to cover adhesive border at the surgeon's discretion)

Two non-patient contacting materials were included in testing because of their potential for affecting the direct patient contact materials.

- Conductive foil-polymer laminate
- Cross-linked foam backing

Production-representative devices made of these materials were subjected to cytotoxicity, sensitization, and primary skin irritation tests. The devices met all of the acceptance criteria for these tests.

Performance

Appropriate performance of the Valleylab™ REM Polyhesive™ Infant Patient Return Electrode was demonstrated by showing that the device meets applicable clauses in the following standards:

IEC 60601-1: 2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-2: 2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-1-2: 2007 and 2014, *Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and Tests.*

Conclusion

The comparison of device characteristics and the review of the performance data support the conclusion that the Valleylab™ REM Polyhesive™ Infant Patient Return Electrode is substantially equivalent to the Valleylab™ REM Polyhesive™ Neonatal Patient Return Electrode.