



JUN 12 2012

**510k Summary of Safety and Effectiveness**

**CONMED® Macrolyte® Dispersive Electrode**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. ConMed Electrosurgery is hereby submitting the 510(s) Summary of Safety and Effectiveness for the 510(k) Number \_\_\_\_\_ as of February 8, 2012.

**A. Submitter**

ConMed Electrosurgery  
14603 E. Fremont Ave.  
Centennial, Colorado 80112

**B. Company Contact**

Shawn Riedel  
Vice President, Quality Assurance and Regulatory Affairs  
14603 E. Fremont Ave.  
Centennial, Colorado 80112

Phone: 303-269-8224  
Fax: 303-699-9854  
e-mail: [shawnriedel@conmed.com](mailto:shawnriedel@conmed.com)

**C. Device Name**

|                      |  |
|----------------------|--|
| Trade Name:          | CONMED® Macrolyte® Dispersive Electrode                        |
| Common Name:         | Electrosurgical unit and accessories                           |
| Classification Name: | Electrosurgical Cutting and Coagulation Device and accessories |
| Regulation Number:   | 21 CFR 878.4400 Class II 79 GEI                                |
| Panel:               | General and Plastic Surgery                                    |

**D. Predicate Device Name**

CONMED® Macrolyte® Dispersive Electrode  
ConMed Electrosurgery  
510(k) K100686

**E. Device Description**

The CONMED® Macrolyte® Dispersive Electrode is a single use, non-sterile dispersive electrode with a pre-attached cord. The purpose of the return electrode is to complete the electrosurgical circuit between the generator, the active electrode, and the patient. The CONMED® Macrolyte® Dispersive Electrode is to be used on any patient where full skin

contact and a suitable placement site can be obtained. Use of this product for unintended applications could lead to an unsafe condition.

The surface of the conductive area is covered with a soft, conformable hydro-gel conductive adhesive. The pad also has a non-conductive border adhesive surrounding the entire conductive area to isolate the conductive area from surgical fluids.

There are 9 models of the CONMED® Macrolyte® Dispersive Electrode.

#### **F. Intended Use**

The device is applied to the patient during electrosurgical procedures to provide a path for RF current to leave the patient and return to the generator.

#### **G. Indications for Use**

CONMED® Macrolyte® Dispersive Electrodes are designed for use with electrosurgical generators during electrosurgery and provide a path for, RF energy produced at the active electrode to return to the generator. The CONMED® Macrolyte® Dispersive Electrode is for use with all patient populations providing there is sufficient surface area to ensure full contact of the electrode with the patient's skin.

#### **H. Technological Characteristics**

The technological characteristics of the proposed device are identical to the predicate device. Both devices are intended for single use.

#### **I. Safety Information**

Questions of safety and effectiveness are the same for this device as they are for the predicated devices and other patient return electrodes on the market. There are no new technologies incorporated into the device.

#### **J. Biocompatibility**

The biological safety of selected components of the CONMED® Macrolyte® Dispersive Electrode has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. These were selected on the basis of Part 1 of ISO 10993-1, "Biological Evaluation of Medical Devices."

#### **K. Performance Testing**

Where applicable, specific testing performed was in conformance with the requirements of the following standards:

IEC 60601-2-2:2009 Edition 5.0 2009-02, Medical Electrical Equipment Part 2-2

ISO 10993-5: 1999 Biological Evaluation of Medical Devices – Part 5 Tests for cytotoxicity, in vitro methods

ISO 10993-10: 2002/Amd 1:2006 Biological Evaluation of Medical Devices – Tests for Irritation and delayed-type hypersensitivity



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

Conmed Corporation  
% Mr. Shawn Riedel  
VP, Quality Assurance and Regulatory Affairs  
14603 East Fremont Avenue  
Centennial, Colorado 80112

JUN 12 2012

Re: K120476.

Trade Name: CONMED® Macrolyte® Dispersive Electrode  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: GEI, JOS  
Dated: May 22, 2012  
Received: May 25, 2012

Dear Mr. Riedel:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



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

Enclosure

Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: CONMED® Macrolyte® Dispersive Electrode

---

Indications for Use:

CONMED® Macrolyte® Dispersive Electrodes are designed for use with electrosurgical generators during electrosurgery and provide a path for, RF energy produced at the active electrode to return to the generator. The CONMED® Macrolyte® Dispersive Electrode is for use with all patient populations providing there is sufficient surface area to ensure full contact of the electrode with the patient's skin.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

Page \_\_\_ of \_\_\_

510(k) Number   K120476