JUL 10 2014

510(k) Summary of Safety and Effectiveness

ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrodes

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92. ConMed Corporation is hereby submitting the 510(k) Summary for 510(k) number _____ as of March 11, 2014

A. Submitter

ConMed Corporation
525 French Road
Utica, N.Y. 13502
Registration Number: 1320894

B. Company Contact

Sandy LeClair
Regulatory Affairs Specialist
ConMed Corporation
525 French Road
Utica, N.Y. 13502
Phone: 315-624-3435
Fax: 315-624-3225
Email: sandyleclair@conmed.com

Alternate Contact
Lisa Anderson
Regulatory Affairs Manager
ConMed Corporation
525 French Road
Utica, N.Y. 13502
Phone: 315-624-3371
Fax: 315-624-3225
Email: lisaanderson@conmed.com

C. Device Name

Trade Name:	The ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrodes
Common Name:	Dispersive Electrodes
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400
Class:	II
Product Code:	GEI
Panel:	General and Plastic Surgery

D. Predicate Device

ThermoGard® and ThermoGard® Plus ABC Dispersive Electrodes
ConMed Corporation
510(k) # K972628
Product Code: GEI
Regulation Number: 878.4400

E. Device Description

The ConMed ThermoGard® and ThermoGard® Plus ABC 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 ThermoGard® and ThermoGard® Plus ABC Dispersive Electrode is designed for use with electrosurgical generators equipped with either continuity monitors or contact quality monitoring systems. The ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrode is composed of a non-conductive border adhesive surrounding the entire conductive gel area to ensure full contact with the patient's skin, and a pre-attached cordset.

F. Intended Use of Device

Both the proposed and predicate devices have the same intended use. The ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrode is used for the dispersion and return to the electrosurgical generator of therapeutic energy

(RF) introduced to the patient at the active electrode during electrosurgical procedures.

G. Technological Characteristics

The proposed devices are equivalent to the predicate devices in their technological characteristics and performance. Both are designed for use with electrosurgical generators equipped with either continuity monitors or contact quality monitoring systems.

Both devices are designed to disperse and return therapeutic (RF) energy from the patient back to the electrosurgical generator during electrosurgical procedures.

Both devices demonstrate compliance with applicable sections of AAMI / ANSI ES60601-1:2005/(R) 2012 and C1:2009/(R)2012 A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and IEC 60601-2-2 Edition 5.0: 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. Materials analysis demonstrates the ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrode materials comply with the requirements of ISO 10993-1:2009 Biological Evaluation of Medical Devices Evaluation and Testing within a Risk Management Process.

The proposed devices differ from the predicates with minor design changes affecting dimensions, construction, and patient contacting materials.

H. Non-Clinical Testing

Design testing was performed to verify that none of the changed features would affect equivalence. New patient contacting materials were tested per ISO 10993 and verified to be biocompatible.

I. Substantial Equivalence

The differences between the predicate device and the proposed device do not raise any new issues of safety or efficacy. Supporting documentation per this premarket submission confirms that the proposed ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrodes are substantially equivalent in design, manufacturing materials, intended use, and technical characteristics to the

predicate ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrodes.

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

July 10, 2014

ConMed Corporation
Ms. Sandy LeClair
Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K140658
Trade/Device Name: Thermogard & Thermogard Plus ABC dispersive electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 15, 2014
Received: April 21, 2014

Dear Ms. LeClair:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

David Krause -S

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)*

K140658

Device Name
ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrodes

Indications for Use *(Describe)*
The ConMed ThermoGard® and ThermoGard® Plus ABC Dispersive Electrodes are used for the dispersion and return to the electrosurgical generator of therapeutic (RF) energy introduced to the patient at the active electrode during electrosurgical procedures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.