

## 510(k) Summary of Safety and Effectiveness

### ConMed™ ECG Monitoring Electrodes

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

#### A. Submitter

ConMed Corporation  
525 French Road  
Utica, NY 13502  
Registration Number: 1320894

AUG 07 2009

#### B. Company Contact

Sandy Coveleski  
Regulatory Affairs Specialist  
ConMed Corporation  
525 French Road  
Utica, NY 13502

Phone: 315-624-3435  
Fax: 315-624-3225  
e-mail: sandy\_coveleski@mail.conmed.com

#### C. Device Name

Trade Name:	ConMed™ ECG Monitoring Electrodes
Common Name:	Electrocardiograph Electrode
CLASSIFICATION NAME:	Cardiovascular Devices
Proposed Class/Device:	Class II
Product Code:	DRX
Regulation Number:	21 CFR 870.2360
Panel:	870 Cardiovascular

**D. Predicate Devices**

ConMed 2710 CLEARTRACE<sup>2</sup>LT Monitoring ECG Electrode  
ConMed Corporation  
510(k) # K954388

2700 Cleartrace Radiotranslucent Monitoring ECG Electrode  
ConMed Andover Medical, Inc  
510(k) # K944849

ECG Electrode  
ConMed Andover Medical, Inc  
510(k) # K944655

1800 Monitoring ECG Electrode And 1870 Diaphoretic Monitoring ECG  
Electrodes  
ConMed Andover Medical, Inc  
510(k) # K945836

1700 Monitoring ECG Electrode  
ConMed Andover Medical, Inc  
510(k) # K946273



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-0609  
Silver Spring, MD 20993-0002

AUG 07 2009

ConMed Corporation  
c/o Ms. Sandra Coveleski  
Regulatory Affairs Specialist  
525 French Road  
Utica, NY 13502

Re: K091856  
Trade/Device Name: ConMed ECG Monitoring Electrode  
Regulatory Number: 21 CFR 870.2360  
Regulation Name: Electrocardiograph Electrode  
Regulatory Class: Class II (Two)  
Product Code: DRX  
Dated: July 14, 2009  
Received: July 15, 2009

Dear Ms. Coveleski:

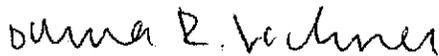
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0120. 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,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known) K091856

Device Name: ConMed™ ECG Monitoring Electrodes

Indications for use:

The **ConMed™ ECG Monitoring Electrodes** are pre-gelled, single patient use, disposable electrocardiographic electrodes for use as an accessory to ECG equipment for long term or short term monitoring and diagnostic procedures with regular or diaphoretic adhesives.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

and/or

Over-the-counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE  
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Anna R. Volmer*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K091856