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JUN 17 2009

16. 510(k) SUMMARY

510(K) SUMMARY of Safety and Effectiveness
(as required by 21 CFR 807.92)

Date:	January 12, 2009
Manufacturer:	Vermed, Inc. 9 Lovell Drive Bellows Falls, VT 05101 Registration Number 1219288
Telephone:	(800) 245-4025
Contact Person:	Marc Fillion VP of Quality & Regulatory Affairs (800) 245-4025, Extension 1205 Fax Number: (802) 463-9228
Device Trade Name:	Tender-Trode® Prewired ECG Electrodes
Common Name:	Disposable ECG Monitoring Electrode
Classification Name:	Electrocardiograph Electrode
Regulatory Reference:	74 DRX
Predicate Device:	Bunny Electrode/Stealth Electrode Pre Wired ECG, Lead-Lok, Inc., K911529
Description:	A conductive solid gel electrode consisting of a conductive adhesive gel, a silver/silver chloride plated ABS eyelet, an adhesive cloth substrate, vinyl label, 24" wire w/.060 dia. female socket and polystyrene release liner.

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Intended Use:

The Tender-Trode® Prewire is a disposable, noninvasive electrode intended to be used for resting ECG monitoring on neonatal and pediatric patients in a hospital setting. These electrodes can be used for short-term or long-term applications, up to 24 hours. The Tender-Trode® prewired electrodes are single-use, non-sterile, disposable and are to be used on intact (uninjured) skin.

Physical/Technical Comparison:

Tender-Trode® Prewired ECG Electrodes are technologically equivalent to the predicate device. Physical and technical characteristics, including materials used in construction, size, intended use and conductive gel are comparable.

Performance Summary:

The device was tested and demonstrated conformance with internationally recognized consensus standards. Test results indicate that this device meets or exceeds the performance specifications as established in EC12:2000 for Disposable ECG Electrodes. In addition, the device was found to meet EC12:2000 AAMI standard for labeling, shelf life, packaging and safety. A certification to conformance with this standard has been provided.

Biocompatibility Testing:

The solid conductive gel underwent skin sensitivity testing as specified in the Tripartite Biocompatibility Guidance for Medical Devices and ISO 10993-1 requirements for skin contact. These tests include Cytotoxicity, Sensitization, and Primary Skin Irritation (test results attached). The materials were found to be non-irritating, non-cytotoxic, and non-sensitizing.

Shelf Life:

Data obtained in accelerated shelf life studies was reviewed and found to substantiate our claimed shelf life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

Vermed, Inc.
c/o Mr. Marc Fillion
VP of Quality & Regulatory Affairs
9 Lovell Drive
Bellows Falls, VT 05101

Re: K090180
Tender-Trode® Prewired ECG Electrodes
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: May 7, 2009
Received: May 8, 2009

Dear Mr. Fillion:

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

K090180

5. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Tender-Trode® Prewired ECG Electrodes

Indications for Use:

The Tender-Trode® Prewired electrode is a disposable, noninvasive electrode that is intended to be used for resting ECG monitoring on neonatal and pediatric patients in a hospital setting. These electrodes can be used for short-term or long-term applications, up to 24 hours. The Tender-Trode® prewired electrodes are single-use, non-sterile, disposable and are to be used on intact (uninjured) 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert B Zuckerman

(Division Sign-Off) 6/17/09

Division of Cardiovascular Devices

510(k) Number K090180