

K980171

FEB 27 1998

APPENDIX V

Summary of Safety and Effectiveness

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The **DermaSense** PLUS Dispersive Electrode has the same intended use as the currently marketed predicate devices. The Dispersive Electrode has technological characteristics that are substantially equivalent to the predicate devices. The device design, device materials, nominal specifications and performance standards are either identical or substantially equivalent. The Dispersive Electrode has the same mode of operation as the predicate devices.

COMPANY AND CONTACT PERSON

Horizon Medical, Inc.
1719 South Grand Avenue
Santa Ana, CA 92705

Philip L. Ritger
Technical Director
(714) 259-5200

DEVICE NAME

DermaSense™ PLUS Dispersive Electrode

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

1. Valleylab, Inc. REM® PolyHesive® II Patient Return Electrode
2. ConMed Corporation ThermoGard™ PLUS ABC® Dual Dispersive Electrode

DESCRIPTION OF DEVICE

DermaSense PLUS Dispersive Electrode is a disposable, single use device commonly referred to in the industry as a neutral electrode, patient plate, or return electrode. A split, dual conductive plate design allows this device to be used with Return Electrode Monitor (REM) systems found on most electrosurgical generators being marketed today.

STATEMENT OF INTENDED USE

DermaSense PLUS Dispersive Electrode is a disposable, single use, neutral electrode which provides a return path for high frequency electrical current to the electrosurgical generator. No electrosurgical effect, e.g., cutting and removal of tissue or coagulation, is intended at this electrode.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

1. The Valleylab REM PolyHesive II Patient Return Electrode is a disposable, single use, neutral electrode which provides a return path for high frequency electrical current to the electrosurgical generator..
2. The ConMed ThermoGard PLUS ABC Dual Dispersive Electrode is a disposable, single use, neutral electrode which provides a return path for high frequency electrical current to the electrosurgical generator..

STATEMENT OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

For the Horizon and predicate devices, the dispersive electrodes are single use, non-sterile devices for use in monopolar electrosurgical applications. The electrodes are split, dual plate designs which are Return Monitor compatible. All of the devices are comprised of an electrode body and cable assembly.

All of the electrodes are comprised of an acrylic adhesive coated thermoplastic film or closed cell polyethylene foam border with a hydrogel conductive adhesive layer covering an aluminum metallized or laminated plastic film on a closed cell polyethylene foam backing.

The Horizon and predicate devices meet the ANSI/AAMI HF-18 and IEC 601-2-2 industry performance standards.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Philip L. Ritger
Technical Director
Horizon Medical, Inc.
1719 South Grand Avenue
Santa Ana, California 92705-4808

FEB 27 1998

Re: K980171
Trade Name: DermaSense Plus Dispersive Electrode
Regulatory Class: II
Product Code: GEI
Dated: January 15, 1998
Received: January 20, 1998

Dear Mr. Ritger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

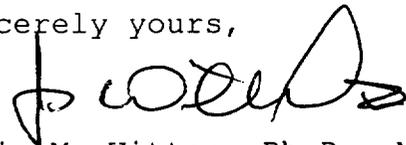
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Ritger

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


R Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980171

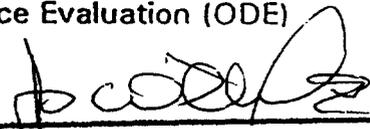
Device Name: DERMASENSE PLUS DISPERSIVE ELECTRODE

Indications For Use:

A NEUTRAL ELECTRODE AT WHICH NO SURGICAL EFFECT IS INTENDED WHICH PROVIDE A RETURN PATH FOR ELECTRICAL CURRENT TO GENERATOR.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980171

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)