K041883

SEP - 7 2004

510(k) Summary

Date Summary Prepared: July 9, 2004

Submitter's name and address:

Company Name:	Leonhard Lang GmbH
Address:	Archenweg 56 6020 Innsbruck Austria
Telephone:	++ 43 / 512 / 33 4 25 7
Fax:	++ 43 / 512 / 39 22 10

Contact Person:

Elaine Duncan, MS.M.E., RAC	
President, Paladin Medical, Inc.	
PO Box 560	
Stillwater, MN 55082	
Telephone:	715-549-6035
Fax:	715-549-5380

Device Name

Proprietary Name:	Skintact® Multifunction Electrodes
Common Name:	Defibrillation Electrodes
Classification Name:	Electrocardiograph (multifunction) electrodes

Substantially Equivalent to: The Skintact® Multifunction Electrodes are substantially equivalent to the Philips HeartStart Defibrillation Pads (model DP2). Philips Medical Systems, formerly Heartstream, cleared the HeartStart Defibrillation Pads (model DP2) under K955628, a bundled submission including defibrillator and accessories.

Device Description: Skintact® Multifunction Electrodes are self-adhesive, non-sterile, single use disposable electrodes. Skintact® Multifunction Electrodes consist of a foam backing, a laminated metallic substrate and conductive adhesive gel DH 02. Several shapes and sizes are offered, in accordance with standards. Skintact® Multifunction Electrodes are packaged in pairs with color-coded cabling within water-vapor-proof, heat-sealed, non-transparent, aluminized pouches.

Indication for Use: The Skintact® Multifunction Electrodes are for use on adults and children over 8 years for external defibrillation, pacing, monitoring and cardioversion. The device is non-sterile and single use only.

Summary of Comparison and Testing to Demonstrate Equivalence: Biocompatibility tests in accordance with ISO 10993 have been performed on the hydrogel. The testing confirms that the gel is biocompatible and does not introduce any risks. Testing to evaluate the performance of the Skintact® Multifunction Electrodes in accordance with internationally recognized standards demonstrated that the performance of the Skintact® Multifunction Electrodes meet specifications and are suitable for use with the monophasic and biphasic defibrillators. Skintact® Multifunction Electrodes are packaged in the same packaging used by Leonhard Lang GmbH in many previously approved products with demonstrated 24 month shelf-life. In addition, the Skintact® Multifunction Electrodes were tested in accelerated aging, confirming the shelf-life of 24 months for DH02 gel and materials. Skintact® Multifunction Electrodes used for adult defibrillation (and children over 8 years) and pacing have a minimum active (gel) area of 82 cm^2 and the total area of the two electrodes is at least 164 cm^2, thus meeting the standard requirements. Other comparisons demonstrated that the Skintact® Multifunction Electrodes do not introduce new risks and are substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2004

Paladin Medical, Inc.
c/o Elaine Duncan, M.S.M.E., RAC
President
P.O. Box 560
Stillwater, MN 55082-0560

Re: K041883
Trade name: Skintact® Multifunction Electrodes
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: July 09, 2004
Received: July 12, 2004

Dear Ms. Duncan:

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 (301) 594-4648. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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):

Device Name: Skintact® Multifunction Electrodes

Indications For Use:

The Skintact® Multifunction Electrodes are for use on adults and children over eight years old for external defibrillation, pacing, monitoring and cardioversion. The device is non-sterile and single-use only.

Prescription Use __✓_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for BDZ

vision Sign-Off)
ision of Cardiovascular Devices

)(k) Number K041883