K072233

510(k) Summary

OCT 5 2007

SUBMITTED ON BEHALF OF:

Company Name: Leonhard Lang GmbH
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6020 Innsbruck
Austria
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By: **Elaine Duncan**, MS.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
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CONTACT PERSON: Elaine Duncan

DATE PREPARED: August 8, 2007

Trade Name: **Skintact® Multifunction Electrodes with DH02 gel available with different connectors compatible with different defibrillators**

Common Name: Defibrillation Electrodes

Classification Name: DC-defibrillator, low-energy, (including paddles)

Substantially equivalent to Predicate Device

Skintact® Multifunction Electrodes with DH02 gel available with different connectors compatible with different defibrillators are equivalent to **Skintact® Multifunction electrodes with DH02 Gel** (cleared in existing 510(k) K041883) There are no changes to the materials used in the construction. Test results are provided which show that this change does not introduce any new issues of safety and performance.

Device description

Skintact® Multifunction Electrodes with DH02 gel available with different connectors compatible with different defibrillators (*and as also to be offered for sale under various private label tradenames*) consist of a foam backing, a laminated metallic substrate and conductive adhesive gel DH02 [all materials cleared in existing 510(k) K041883]. **Skintact® Multifunction Electrodes with DH02 gel available with different connectors compatible with different defibrillators** are packaged in pairs in water-vapor-proof, heat-sealed, non-transparent, aluminized pouches, non-sterile and single-use.

Indications for use

Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different defibrillators 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.

Comparison of Characteristics

There are no technological or material differences between the The **Skintact® Multifunction Electrodes with DH02 gel available with different connectors compatible with different defibrillators** and the predicate device.

Data Used in Determination of Substantial Equivalence

Bench testing demonstrated that the performance of the **Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different defibrillators** meets its specifications.

Summary of Testing

Performance Testing:

Skintact® Multifunction Electrodes with DH02 gel available with different connectors compatible with different defibrillators met the same requirements as those of the predicate. Performance and safety tests were conducted according to **ANSI/AAMI DF80:2003** and **IEC/EN 60601-2-4:2003** and were conducted by SGS (All test reports are available for access at: Leonhard Lang GmbH, Archenweg 56, 6020 Innsbruck, Austria).
All **Skintact® Multifunction Electrodes with DH02 gel available with different connectors compatible with different defibrillators** are packaged in pairs in water-vapor-proofed, heat-sealed, non-transparent, aluminized pouches. Leonhard Lang has met requirements for 30 months shelf-life.

Biocompatibility testing:
All materials were cleared in 510(k) K041883: Results of updated testing for skin irritation and sensitization testing are included. (Cytoxicity tests were not repeated since previous submission.)

Conclusion
Skintact® Multifunction Electrodes with DH02 gel available with different connectors compatible with different defibrillators does not introduce new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 " 2007

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

Re: K072233
Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different defibrillators
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: September 6, 2007
Received: September 10, 2007

Dear Ms. Duncan:

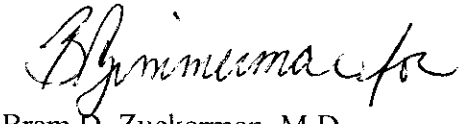
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

510(k) Number (if known)

Device Name: **Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different defibrillators**

Indications for Use:

Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different defibrillators 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 ____X____ OR Over -The-Counter Use _____

(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 Cardiovascular Devices
510(k) Number k071233