K103186

SECTION 5

FEB 8 2011

510(K) SUMMARY

SUBMITTER

Submitted on behalf of:	**Company Name:**	**Leonhard Lang GmbH**
	Address:	Archenweg 56 6020 Innsbruck Austria
	Telephone:	++ 43 / 512 / 33 4 25 7
	Fax:	++ 43 / 512 / 39 22 10
	Registration Number:	8020045
	Owner/Operator Number:	8020045
	by:	**Elaine Duncan**, MS.M.E., RAC President, Paladin Medical, Inc. PO Box 560 Stillwater, MN 55082 Telephone: 715-549-6035 Fax: 715-549-5380
Contact Person:	**Elaine Duncan** (see address above)	
Date prepared:	October 28, 2010	
Trade Name:	Skintact® Radiotransparent Multifunction Electrodes *(and also to be offered for sale under various private label tradenames)*	
Common Name:	Defibrillation Electrodes	
Classification Name:	Dc-defibrillator, low-energy, (including paddles)	
Regulation:	Defibrillators, Automatic, External, 21 CFR § 870.5310	
Regulatory Class	This device is Class III	
Device Panel and Product Code:	74 Cardiovascular, MKJ, MLN	

Reason for 510(k) Submission: additional feature "radiotransparent"

Substantial Equivalence: Skintact® Radiotransparent Multifunction Electrodes are substantially equivalent to the stated predicate devices:

K072233 Leonhard Lang Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different devices

K014209 PadPro 2001, 2001-S, 2001-C, 2001-EPS Multifunction Electrodes

Description of device: All Skintact® Multifunction Electrodes are self-adhesive, non-sterile, single use disposable electrodes. Multifunction electrodes can be used for defibrillation, pacing, cardioversion and monitoring. These multifunction electrodes have the additional feature "radiotransparent" which allows these electrodes to stay on the patient when moving through different departments.

Indications for use: Skintact® Radiotransparent Multifunction Electrodes are for use on adults and children over 8 years old or weighing more than 25 kg in external defibrillation, pacing, monitoring and cardioversion. The device is non-sterile and single use only.

Basis for Equivalence - performance testing: Biocompatibility testing was conducted and passed ISO 10993 for intact skin. The performance data of Skintact® Radiotransparent Multifunction Electrodes and predicate device (K072233) met specifications as established in ANSI/AAMI DF80:2003 and IEC/EN 60601-2-4:2003. The introduction of Skintact® Radiotransparent Multifunction Electrodes (*and also to be offered for sale under various private label tradenames)* does not introduce new issues of safety or effectiveness and Skintact® Radiotransparent Multifunction Electrodes are substantially equivalent to the predicate devices K072233 and K014209.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 8 2011

Paladin Medical®, Inc.
c/o Ms. Elaine Duncan
President
P.O. Box 560
Stillwater, MN 55082-0560

Re: K103186
Skintact® Radiotransparent Multifunction Electrodes
Regulation Number: 21 CFR 870.5310
Regulation Name: Defibrillators, Automatic, External
Regulatory Class: Class III
Product Code: MKJ
Dated: January 18, 2011
Received: January 20, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: K103186

Device Name: Skintact® Radiotransparent Multifunction Electrodes

Indications For Use: Skintact® Radiotransparent Multifunction Electrodes are for use on adults and children over eight years old or weighing more than 25 kg for external defibrillation, pacing, monitoring and cardioversion. The device is non - sterile and single use only.

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

(PLEASE DO NOT WRITE BELOW 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 K103186