DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 2, 2014

Leonhard Lang Gmbh
% Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K142803
Trade/Device Name: Skintact® Multifunction Electrodes
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: October 2, 2014
Received: October 3, 2014

Dear Elaine 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K142803

Device Name
Skintact® Multifunction Electrodes

Indications for Use *(Describe)*
Skintact® Multifunction Electrodes are for use on adults and children weighing more than 25 kg for external defibrillation, pacing, monitoring and cardioversion. The device is non-sterile and single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

SECTION 5
510(K) SUMMARY

This 510(k) summary has been prepared in accordance with the requirements of 21CFR 807.92:

SUBMITTER:

Submitted on behalf of:

Company Name:	**Leonhard Lang GmbH**
Address:	**Archenweg 56** **6020 Innsbruck** **Austria**
Telephone:	+43 512 334257
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Contact Person:	**Elaine Duncan, M.S.M.E., RAC** **President, Paladin Medical, Inc.** **PO Box 560** **Stillwater, MN 55082**
Telephone:	715-549-6035
Fax:	715-549-5380

Date prepared: **November 26, 2014**

Device Identification:

TRADE NAME:	**Skintact® 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)**
PRO CODE:	**MKJ**
Regulation No.:	**21CFR 870.5310**
Classification:	**Class III**

SUBSTANTIALLY EQUIVALENT TO:

K072233	Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different devices, Leonhard Lang GmbH, decision date: 10/05/2007
K082090	9131 Defibrillation Electrodes, Cardiac Science Corporation, decision date: 12/12/2008

INDICATIONS FOR USE:
Skintact® Multifunction Electrodes are for use on adults and children weighing more than 25 kg for external defibrillation, pacing, monitoring and cardioversion. The device is non-sterile and single use only.

510(k) Summary-Continued

DESCRIPTION of the DEVICE:
Skintact® Multifunction Electrodes are single use, non-sterile and disposable and are to be used on intact (uninjured) skin. Skintact® Multifunction Electrodes are accessories to defibrillators. Skintact® Multifunction Electrodes are passive devices and do not contain active electronics, software or firmware.

Skintact® Multifunction Electrodes consist of a backing material, conductive layer and conductive adhesive gel. The Multifunction Electrodes are applied on a release liner. This is the same composition like used for devices approved in existing K072233.

The shape of the electrodes has been slightly modified in comparison with K072233. The difference in shape of electrodes is an enhanced total area, but the active area is equivalent like approved in existing K072233.

Also this submission adds additional models of multifunction electrodes compatible with additional models of defibrillators.

An additional type of packaging is offered. This type of packaging is substantially equivalent to reference device approved in existing 510(k) K082090 9131 Defibrillation Electrodes, Cardiac Science Corporation, decision date: 12/12/2008.

Substantial Equivalence Summary [21CFR 807.92(a) (6)]

Skintact® Multifunction Electrodes have the **same indications for use** as Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different devices approved in existing 510(k)s K072233. The indicated limitation of use on children is by age in K072233 but in this submission it is being changed to weight. Children may have variations in weight at the same age and weight is the more important characteristic for safe performance on children.

Indications for Use	
K072233	**This submission**
Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different defibrillators	Skintact® Multifunction Electrode
are for use on adults	are for use on adults
and children	and children
over eight years old	weighing more than 25 kg
for external defibrillation, pacing, monitoring and cardioversion.	for external defibrillation, pacing, monitoring and cardioversion.
The device is non-sterile and single use only.	The device is non-sterile and single use only.

510(k) Summary-Continued

Skintact® Multifunction Electrodes are substantially equivalent to predicate devices:

Comparison	Skintact® Multifunction Electrodes	
	K072233	**This submission**
Description	Hydrogel polymeric self-adhesive electrode pads	
Technical Characteristics / Features	Emergency treatment of cardiac arrest patients	
	for use on adults and children over eight years old	for use on adults and children weighing more than 25 kg
	for short term use (< 24 hours)	
	disposable	
	self-adhesive	
	non-sterile	
Packaging	sealed foil pouch	
	--	additional packaging: Cable out-of-pouch, substantially equivalent to K082090
Testing	Biocompatibility testing	
	Electrical and adhesive performance testing	

Models of Skintact® Multifunction Electrodes:

Model	Compatible with device
DF20N **DF20NC**	**Physio Control** (Medtronic) Lifepak 9 Lifepak 10 Lifepak 12 Lifepak 15 Lifepak 20 Lifepak 500 Lifepak 1000
DF26N **DF26NC**	**Philips Codemaster** Codemaster XL Codemaster XL+ Codemaster 100
DF27N **DF27NC**	**Philips Heartstart** Heartstart FR2(+) Heartstream FR2 Heartstart FR3 Heartstart MRx Heartstart XL Heartstart XL+

510(k) Summary-Continued

Model	Compatible with device
DF28N **DF28NC**	**Zoll** Zoll M, E & R Series Zoll PD 1200 Zoll PD 1400 Zoll PD 1600 Zoll PD 1700 Zoll PD 2000
DF29N **DF29NC**	**Welch Allyn** AED10 AED20 PIC 30 PIC 40 PIC 50
DF55N **DF55NC**	**GE** CardioServ Responder 3000
DF59N **DF59NC**	**Zoll** Zoll AED Plus Zoll AED Pro M Series E Series R Series X Series
DF82I	**Cardiac Science** Powerheart AED G3 Powerheart AED G3 pro Powerheart AED G3 plus

SUMMARY of TESTING:

Performance Data:
Performance testing was conducted according standard *IEC 60601-2-4:2010 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*, relevant clauses. Results are within limits.

Biocompatibility:
Biocompatibility testing has been performed for materials with direct skin contact. Biocompatibility testing confirms the materials are biocompatible and do not introduce new risks.

CONCLUSION:
The introduction of the Skintact® Multifunction Electrodes (and also to be offered for sale under various private label tradenames) does not introduce new issues of safety or effectiveness and the Skintact® Multifunction Electrodes are substantially equivalent to the predicate device. Testing has shown the devices perform as intended and are safe when used according to the instructions for use.