

510(K) SUMMARY

JUL 29 2014

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

Submitted on behalf of:

Company Name: **Leonhard Lang GmbH**
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Contact Person: **Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082**
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Date prepared: **July 25, 2014**

Device Identification:

TRADE NAME: **Skintact® Neutral Electrodes for Neonates**
(and also to be offered for sale under various private label tradenames)
COMMON NAME: **Neutral Electrodes**
CLASSIFICATION NAME: **Electrosurgical cutting and coagulation device and accessories**
PRO CODE: **GEI**
Regulation No.: **21CFR 878.4400**
Classification: **Class II**

SUBSTANTIALLY EQUIVALENT TO:

K063161 **Leonhard Lang Skintact® Cool Contact Electrosurgical Grounding Plates, Leonhard Lang GmbH with NH04 Gel, decision date: 11/21/2006**

K030362 **Leonhard Lang Skintact® Cool Contact Electrosurgical Grounding Plates, Leonhard Lang GmbH, decision date: 04/14/2003**

K994428 **E7512 Premie REM PolyHesive II Patient Return Electrode, Valleylab Inc., decision date: 03/07/2000**

INDICATIONS FOR USE:

Skintact® Neutral Electrodes for Neonates are designed for use with electrosurgical generators for cutting and coagulation of human tissue of newborn or prematurely born patients of between approximately 1 and 11 lbs (0.45 kg and 4.99 kg).

Traditional 510(k): Skintact® Neutral Electrodes for Neonates

510(k) Summary-Continued

DESCRIPTION of the DEVICE:

Skintact® Neutral Electrodes for Neonates are single use, non-sterile and disposable and are to be used on intact (uninjured) skin.

Skintact® Neutral Electrodes for Neonates consist of a backing material, conductive layer and conductive adhesive gel. The Neutral Electrodes for Neonates are applied on a release liner. The only change in construction materials is a slight modification of the conductive hydrogel. This modification was carried out to adapt the gel to the skin of neonates. Skintact® Neutral Electrodes for Neonates are accessories to surgery devices.

Skintact® Neutral Electrodes for Neonates are passive devices and do not contain active electronics, software or firmware. Skintact® Neutral Electrodes for Neonates are packaged in water-vapour-proofed, heat-sealed, non-transparent, aluminized pouches.

SUMMARY of TESTING:

Performance and Standards:

Performance testing was conducted according standard EN60601-2-2:2009 *Medical electrical equipment -Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009)*, relevant clauses.

EN60601-2-2:2009, 201.15.101.5 - NE thermal performance- including comparative thermal performance testing against predicate product.

EN60601-2-2:2009, 201.15.101.6 - NE contact impedance

EN60601-2-2:2009, 201.15.101.7 - NE adhesion

Release test with electrodes aged at +23°C for 43 days and Shelf life test with accelerated aged electrodes at increased temperature of +75°C for 43 days.

According EN60601-2-2:2009, 201.15.101.8. Results are within limits.

Biocompatibility and Sterility:

Biocompatibility testing has been performed for materials with direct skin contact.

Biocompatibility testing confirms the materials are biocompatible and do not introduce new risks. Skintact® Neutral Electrodes for Neonates are NON-STERILE so there was no sterility testing required.

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

Skintact® Neutral Electrodes for Neonates have the **same indications for use** as Skintact® Cool Contact Electrosurgical Grounding Plates approved in existing 510(k)s K030362 and K063161, expanded with the addition of target group "neonates" like approved in existing 510(k) K994428.

Comparison of Indications for Use				
--	K030362, K063161	This submission	K994428	--
similar	Skintact® Cool Contact Electrosurgical Grounding Plates	Skintact® Neutral Electrodes for Neonates	The E7512 Neonatal REM PolyHesive™ II Neonatal Patient Return Electrode	similar
SAME	are designed for use with electrosurgical generators for cutting and coagulation of human tissue.	are designed for use with electrosurgical generators for cutting and coagulation of human tissue	is single use, non-sterile dispersive with a preattached cord. The electrode adheres to the patient over its entire surface. Its purpose is to complete the electrosurgical circuit between the generator, the active electrode, and the	similar

Traditional 510(k): Skintact® Neutral Electrodes for Neonates

510(k) Summary-Continued

			patient. Indications for use are general monopolar electrosurgery on	
--	--	of newborn or prematurely born patients of between approximately 1	newborn or prematurely born patients of between approximately 1	SAME
--	--	and 11 lbs.	and 6 lbs.	similar

The patient weight range of Skintact® Neutral Electrodes for Neonates is indicated according standard **EN60601-2-2:2009 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009)**

Skintact® Neutral Electrodes for Neonates are substantially equivalent to predicate devices

Comparison	K030362 K063161	Skintact® Neutral Electrodes for Neonates	K994428
Technical Characteristics / Features	single patient use		
	disposable		
	self-adhesive		
	non-sterile		
	for use on adults and children	for use on neonates (newborn or prematurely born)	
Packaging	sealed foil pouch		unknown
Testing	Based on biocompatibility testing and electrical and adhesive performance testing of the electrodes the devices are safe and effective when used according instructions for use.		
Construction	<ul style="list-style-type: none"> ➤ Backing material ➤ Conductive layer ➤ Conductive adhesive hydrogel ➤ Cover material 		

CONCLUSION:

The introduction of the Skintact® Neutral Electrodes for Neonates (and also to be offered for sale under various private label tradenames) does not introduce new issues of safety or effectiveness and the Skintact® Neutral Electrodes for Neonates are substantially equivalent to the predicate device. Biocompatibility testing confirms the materials are biocompatible and do not introduce new risks.



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

July 29, 2014

Leonhard Lang GmbH
Ms. Elaine Duncan, M.S.M.E, RAC
President, Paladian Medical Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K140500

Trade/Device Name: SkinTact[®] Neutral Electrodes for Neonates
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 26, 2014
Received: June 30, 2014

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 contact 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>. 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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140500

Device Name: Skintact® Neutral Electrodes for Neonates

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S