NOV 2 1 2006

K063161

510(k) Summary

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**
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
DATE PREPARED: October 13, 2006

Trade Name: Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 gel
Common Name: Electrosurgical Grounding Plates
Classification Name: Electrosurgical Grounding Plates

SUBSTANTIALLY EQUIVALENT TO: Skintact® Cool Contact Electrosurgical Grounding Plates will now be offered with **new gel NH 04**, in otherwise the grounding plates are equivalent to the materials of construction used in the Skintact® Cool Contact Electrosurgical Grounding Plates (the manufacturer's predicate device) cleared via 510(k) [K030362]. The Skintact® Cool Contact Electrosurgical Grounding Plates with new NH 04 gel include also a range of electrodes with different geometry and area. The area is also equivalent to the Skintact® Cool Contact Electrosurgical Grounding Plates (the manufacturer's predicate device) cleared via 510(k) [K030362]. Based upon these similar features and conformance with the recognized standard ANSI/AAMI HF 18:2001, the Leonhard Lang **Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 gel** are substantially equivalent.

DESCRIPTION of the DEVICE: Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 gel *(and as also to be offered for sale under various private label tradenames)* are self-adhesive, non-sterile, single use disposable electrodes, available in a comprehensive range of shapes and sizes (adult and pediatric), standard and split, with or without lead wires.

INDICATIONS FOR USE: Skintact® Cool Contact Electrosurgical Grounding Plates are designed for use with electrosurgical generators for cutting and coagulation of human tissue.

SUMMARY of TESTING: Biocompatibility testing confirms the materials are biocompatible and do not introduce any new risks. The following testing showed no adverse results: Cytotoxicity; Skin Irritation; Sensitization. The **ANSI/AAMI HF 18:2001** "Electrosurgical devices" was used to define the requirements for Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 gel. All performance and safety tests are according to ANSI/AAMI HF 18:2001 and were conducted by Leonhard Lang GmbH, Archenweg 56, 6020 Innsbruck, Austria, and Dr. Michael Verius and Dr. Ralf Huttary, Univ. Klinik für Radiodiagnostik, Anichstraße 35, 6020 Innsbruck, Austria. The testing conducted was: Maximum safe temperature rise; Electrode contact impedance; Electrode adherence: Pull test, Conformability test, Fluid tolerance test. All Skintact® Cool Contact Grounding Plates are packaged in water-vapor-proofed, heat-sealed, non-transparent, aluminized pouches. Leonhard Lang has 20 years of experience with this packaging and has met requirements for 24 months shelf-life. No differences were required for packaging the Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 gel compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Leonhard Lang, GmbH
% Paladin Medical, Inc.
Elaine Duncan, M.S.M.E., RAC
President
P.O. Box 560
Stillwater, Minnesota 55082-0560

NOV 2 1 2006

Re: K063161
Trade/Device Name: Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 gel
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 7, 2006
Received: November 8, 2006

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) 276-0115. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)

Device Name: Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 gel

Indications for Use:

Skintact® Cool Contact Electrosurgical Grounding Plates are designed for use with electrosurgical generators for cutting and coagulation of human tissue.

Prescription Use ___X___ OR Over -The-Counter Use _____

(Optional Format 1-2-96)

(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 General, Restorative and Neurological Devices

510(k) Number K060161