K023920

JAN 16 2003

510(k) Summary

SUBMITTED ON BEHALF OF:

Company Name:	**Leonhard Lang GmbH**
Address:	**Archenweg 56** **6010 Innsbruck** **Austria**
Telephone:	**++ 43 / 512 / 33 4 25 7**
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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: November 21, 2002

Trade Name:	Skintact® ECG Tab Electrode
Common Name:	Disposable ECG Electrodes
Classification Name:	Electrocardiograph (ECG) electrode

SUBSTANTIALLY EQUIVALENT TO: Skintact® ECG Tab Electrodes with LecTec LT 4900 gel are substantially equivalent to the Tracet Ag 4000 electrodes by LecTec Corporation. Leonhard Lang has predicate ECG electrodes (same procode) of different materials and construction design cleared in previous 510(k) submissions such as K 023503 and K 982521.

DESCRIPTION of the DEVICE: Skintact® ECG Tab Electrodes *(and as also to be offered for sale under various private label tradenames)* will be offered with LecTec LT 4900 gel. Skintact® ECG Tab Electrodes with LecTec LT 4900 gel are self-adhesive, non-sterile, single use disposable electrodes for diagnostic resting ECG. ECG Tab electrodes are composed of a PET tape, Ag/AgCl ink and a conductive gel, at each case 10 electrodes are applied on a one-sided siliconized transparent PET card, 10 cards are packaged in a pouch.

INDICATIONS FOR USE:

Skintact ECG electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording. Skintact ECG electrodes are non-sterile and are to be used on intact (uninjured) skin. (NO CHANGE to ORIGINAL INDICATION for USE previously cleared by Leonhard Lang.)

SUMMARY of TESTING:

Biocompatibility testing confirms the materials are biocompatible and do not introduce any risks. The following testing showed no adverse results: Cytotoxicity; Skin Irritation; Sensitization.

The **ANSI/AAMI EC 12:2000 "Disposable ECG electrodes"** was used to define the requirements for Skintact ECG Tab Electrodes with LecTec LT 4900 gel. All electrical tests are according to ANSI/AAMI EC 12:2000. The testing conducted was: AC impedance; DC offset voltage; Defibrillation overload recovery; Combined offset instability and internal noise; Bias current tolerance. The shelf life of the electrodes was tested in real-time aging.

Leonhard Lang has experience for about 20 years of using the current packaging and this ensures all requirements for the 24 months shelf-life of the electrodes.

The comparison with the predicate device and the data from the ECG Tab electrodes with LecTec LT 4900 gel shows similar results. The difference is negligible in the limits defined in ANSI/AAMI EC12:2000. Therefore the electrical performance of the predicate device and ECG Tab electrodes with LecTec LT 4900 gel is equivalent.

Clinical data: Three ECG tracings using LecTec LT 4900 gel electrodes were provided. Each tracing contains more than 10 seconds of data. The data demonstrate that ECG Tab electrodes with LecTec LT 4900 gel provide a reliable signal tracing of consistent high quality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2003

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

Re: K023920
Skintact® ECG Tab Electrodes with LecTec LT 4900 gel
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: November 21, 2002
Received: November 25, 2002

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 (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for 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) K023920

Device Name: Skintact ECG Tab Electrodes

Indications for Use:

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Skintact ECG electrodes are non-sterile and are to be used on intact (uninjured) skin.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over -The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023920