OCT 26 1999

15. **510(k) Summary;** K982521

Date:	October 29, 1997
Manufacturer:	Leonhard Lang GmbH Archenweg 56 A-6020 Innsbruck Austria
Telephone: **Fax:**	+43 512 33425-7 +43 512 392210
Contact Person:	Burrhus Lang, President
Device Trade Names:	Skintact ECG Electrodes S&W ECG electrodes
Common Name:	Disposable ECG monitoring electrode
Classification Name:	Electrocardiograph electrode
Regulatory Reference:	74 DRX
Predicate Device:	Skintact AG Electrodes
Description:	Skintact ECG electrodes are self-adhesive, non-sterile, single use disposable ECG electrodes. All include a silver/silver chloride sensing element, a stainless steel stud and a conductive gel. These conductive elements are held in place on the patient's skin by a carrier tape coated with a pressure sensitive medical grade adhesive.
Intended Use:	Skintact ECG electrodes are intended for use in general electrocardiographic procedures where ECG monitoring is

	deemed necessary and is ordered by a physician.
Physical/Technical Comparison:	Skintact ECG electrodes are equivalent to the predicate device. Physical and technical characteristics, including, design, materials used, safety and efficacy characteristics and intended use of Skintact ECG electrodes and the predicate device are either identical or comparable.
Performance Summary:	The electrical performance of Skintact ECG electrodes meets the requirements of the voluntary standard ANSI/AAMI EC12/1991 "Disposable ECG Electrodes". In addition Skintact ECG electrodes meet the requirements of ANSI/AAMI EC12/1991 for labeling, shelf life, packaging and safety.
Biocompatibility Testing:	The biological safety of Skintact ECG electrodes has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The tests were selected on the basis of ISO 10993-1 "Biological Evaluation of Medical Devices - Part1: Guidance on selection of tests".
Shelf Life:	Data obtained in real time shelf life studies was reviewed and found to substantiate the claimed shelf life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 1999

Leonhard Lang GmbH
c/o Carole Stamp
Third Party Official
TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K982521
Skintact™ ECG Electrodes, S&W ECG Electrodes
Regulatory Class: II (two)
Product Code: DRX
Dated: October 8, 1999
Received: October 12, 1999

Dear Ms. Stamp:

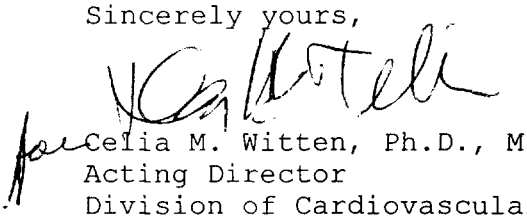
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

10. **Statement of Indications for Use**

510(k) Number (if known): K982521

Device Name: Skintact ECG electrodes

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 recordings.

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 CRRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982521

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)