K991649

MAY 21

LINDE MEDICAL SENSORS AG

Appendix 4

510(k) Summary

MicroGas 7650 Transcutaneous Monitor - Summary of Safety and Effectiveness

Company:
Address: Linde Medical Sensors AG
Austrasse 25
4051 Basel - Switzerland
Telephone: 011 41 61 278 82 07
Telefax: 011 41 61 278 81 81

Contact Person:
Jean-Pierre Palma (Regulatory Affairs)

Trade Name:
MicroGas 7650 Transcutaneous Monitor

Common Name:
Cutaneous Blood Gas Monitor

Intended Use:
The Linde Transcutaneous Monitor is intended to measure the partial pressure of oxygen and carbon dioxide that passes through the cutaneous layer of the skin of an infant who is not under gas anesthesia by a sensor attached to the surface of the infant's skin.

Description of the Device:
Detailed description of the device is contained in the MicroGas 7650 Operator's Manual located in Appendix 2 of this document.

Clinical and Non-Clinical Tests of Equivalency:
The MicroGas 7650 is exactly the same device as the MicroGas 7650 distributed by Kontron Instruments under PMA P810037. Both devices are manufactured by Linde Medical Sensors AG of Basel, Switzerland.

Because there are no differences other than labeling between the Linde MicroGas 7650 and the Kontron MicroGas 7650, no additional clinical or non-clinical tests were performed or submitted in the premarket notification. Refer to PMA number P810037 for this data.

Dr. Patrick Eberhard
R&D Manager
May 17, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1999

Mr. Jean-Pierre Palma
Linde Medical Sensors AG
Austrasse 25
CH-4051 Basel
SWITZERLAND

Re: K991644
MicroGas 7650 Transcutaneous Monitor
Regulatory Class: II (two)
Product Code: 73 KLK
Dated: May 11, 1999
Received: May 13, 1999

Dear Mr. Palma:

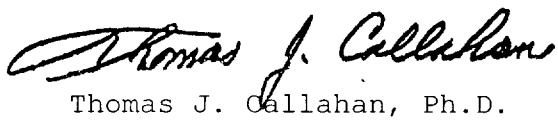
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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"(21 CFR 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991644

Device Name: MicroGas 7650 Transcutaneous Monitor

Indications For Use:

The Linde Transcutaneous Monitor is intended to measure the partial pressure of oxygen and carbon dioxide that passes through the cutaneous ___ layer of the skin of an infant who is not under gas anesthesia by a sensor attached to the surface of the infant's skin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Arthur A. Cavalieri

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)