

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA**I. General Information**

- A. Submitted By: Perimed, Inc.
821 West Jericho Turnpike, Suite A
Smithtown, NY 11787
- Contact Person: Kjell Bakken
- B. Device Trade Name: Perimed Transcutaneous PO₂ and PCO₂ Monitor (PF5040)
- Common Name: Transcutaneous Oxygen/Carbon Dioxide Monitor
- Classification Name: 868.2500, Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
868.2500, Monitor, Oxygen, Cutaneous, for Use Other than for Infant not under Gas Anesthesia
868.2480, Monitor Carbon Dioxide, Cutaneous
- C. Predicate Device: Novamatrix TCO₂M Transcutaneous O₂/CO₂ Monitor
- D. Device Description:

The Transcutaneous PO₂ and PCO₂ Monitor (PF5040) is a modular unit which can be installed in the Periflux System 5000 transcutaneous monitoring system. Patient monitoring is accomplished by the application of an electrode to specific sites on the patient after calibration of the unit.

The Periflux System 5000 is a multi-channel, multi-function system capable of hosting several function units including: the Modular Laser Doppler system for blood perfusion and the Transcutaneous PO₂ and PCO₂ Monitor (PF5040) for monitoring oxygen and/or carbon dioxide levels. The Periflux system 5000 can accommodate up to four different function units enabling different types of simultaneous measurements.

E. Indications for Use:

When installed in the Periflux System 5000, the Transcutaneous PO₂ and PCO₂

Monitor (PF5040) is intended to monitor the levels of oxygen and/or carbon dioxide from tissue transcutaneously. The unit provides continuous, non-invasive monitoring of cutaneous oxygen and carbon dioxide.

F. Technological Comparison:

The Novamatrix TCO₂M Transcutaneous Monitor has the same indications for use as the Perimed Transcutaneous PO₂ and PCO₂ Monitor (PF5040) in that both measure and display continuous, noninvasive transcutaneous oxygen and carbon dioxide levels using O₂/CO₂ electrode sensors attached to the patient. They utilize similar types of display and comparable output ranges. Both can be connected to external devices for data analysis. Both automatically compensate for metabolic factors and temperature when monitoring PCO₂.

II. Testing

Testing was performed to demonstrate the safety and performance characteristics of the Transcutaneous PO₂ and PCO₂ Monitor (PF5040). The testing demonstrated that the device met test requirements and performed in accordance with applicable standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

Mr. Kjell Bakken
Perimed, Inc.
4873 Princeton Drive
North Royalton, OH 44133

Re: K990960
Perimed Transcutaneous pO₂/pCO₂ Monitor
Regulatory Class: II (two)
Product Code: 73 LKD and 73 KLK
Dated: June 23, 1999
Received: June 25, 1999

Dear Mr. Bakken:

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.

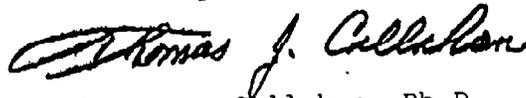
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Kjell Bakken

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

K990960

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Perimed Transcutaneous PO₂ and PCO₂ Monitor (PF5040)

Sponsor Name: Perimed, Inc.

Indications for Use:

When installed in the Periflux System 5000, the Transcutaneous pO₂/pCO₂ Monitor (PF5040) is intended to monitor the levels of oxygen and/or carbon dioxide from tissue transcutaneously. The pO₂ monitor is intended only for use with infants not under gas anesthesia. The unit provides continuous, non-invasive monitoring of cutaneous oxygen and carbon dioxide.

The Periflux System 5000 with the pO₂/pCO₂ module is intended to be used in hospitals and physician's offices. It is intended to monitor transcutaneous pCO₂ in adults and infants with and without gas anesthesia and pO₂ in infants not under gas anesthesia. The system is not intended for use by patients without the supervision of a physician.

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Westhausen

Prescription Use
Over the Counter Use

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

510(k) Number K990960