510(k) Summary – TCM4/40 Monitoring Systems

Submitter: Radiometer Medical ApS
Address: Åkandevej 21, DK-2700 Brønshøj, Denmark
Phone: +45 3827.3827
Fax: +45 3827.2736
Contact Person: Pierre Pelletier

Trade Name: TCM4/40 Monitoring Systems
Common name: Transcutaneous $pO_2/pCO_2/SpO_2$/pulse monitoring system
Classification Names: 21CFR§868.2500: Monitor, Oxygen, Cutaneous
21CFR§868.2480: Monitor, Carbon Dioxide, Cutaneous
21CFR§870.2700: Oximeter
Predicate Devices: TCM400 Monitoring System
TCM3 Monitoring System
OxiMAX N-550 Pulse Oximetry System
TOSCA PCO_2, SpO_2 and Pulse Rate Monitoring System
Perimed Transcutaneous PO_2 and PCO_2 Monitor (PF5040)
MicroGas 7650 Transcutaneous Monitor
Siemens Transcutaneous TpO_2/CO_2 Gas Module

Device Description

The TCM4/40 Monitoring Systems essentially consist in a monitor unit, a combined oxygen/carbon dioxide interface module along with the combined electrodes assembly and (for the TCM40 only) an oxygen saturation/pulse module with a selection of three sensors.

Intended use

The TCM4 Monitoring System is intended for continuous transcutaneous monitoring of oxygen and carbon dioxide partial pressures. It is indicated for use on neonates, pediatrics, and adults not under gas anesthesia.

The TCM40 Monitoring System is intended for continuous transcutaneous monitoring of oxygen and carbon dioxide partial pressures as well as of oxygen saturation of arterial hemoglobin and pulse rate. It is indicated for use on neonates, pediatrics, and adults not under gas anesthesia.

Technological characteristics

The monitoring unit (including software, cabinet, touch screen, electronic controls, power supply and battery) is an adaptation of Radiometer's TCM400 Monitoring System, with only one combined $tcpO_2/tcpCO_2$ electrode and (for the TCM40 only) one pulse/SpO_2 sensor (the TCM400 has up to 6 separate $tcpO_2$ electrodes). The combined $tcpO_2/tcpCO_2$ electrode is identical to the electrode used in Radiometer's previous generation TCM3 Monitoring System. The pulse/SpO_2 sensors are identical to the sensors used with Puritan Nellcor Bennett's OxiMAX N-550 Pulse Oximetry System.

Safety and performance evaluation studies

In order to ensure TCM4/40 Monitoring Systems is safe and effective for its intended use, it has been designed and tested to the requirements of the following standards:

- IEC-60601-1:1988
  Medical electrical equipment - Part 1: General requirements for safety
- IEC-60601-1-2:2001
  Medical Electrical Equipment - Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC-60601-2-23:1999
  Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment
- IEC-60601-3-1:1996
  Medical Electrical Equipment Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment
- EN-865:1997
  Pulse oximeters - Particular requirements
- IEC-60601-1-8:2003
  Medical electrical equipment - Part 1-8: General requirements for safety Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Based upon the extensive use of consensus standards covering all aspects of safety and performance, no clinical evaluation was deemed necessary to assess the product performance levels.

Conclusions from safety and performance evaluation studies

Compliance with the requirements in the above-named safety and performance standards demonstrates that the TCM4/40 Monitoring Systems are state-of-the-art transcutaneous oxygen/carbon dioxide monitors and pulse oximeters that have the necessary safety mechanisms and performs up to the requirements of the relevant international consensus standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 - 2005

Mr. Pierre Pelletier
Regulatory Affairs Manager
Radiometer Medical ApS
Åkandevej 21, Brønshøj
Denmark DK-2700

Re: K043003
Trade/Device Name: TCM4/40 Monitoring Systems
Regulation Number: 21 CFR 868.2480
Regulation Name: Cutaneous Carbon Dioxide ($PcCO_2$) Monitor
Regulatory Class: II
Product Code: LKD, LPP, KLK, DQA
Dated: January 20, 2005
Received: January 24, 20045

Dear Mr. Pelletier:

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.

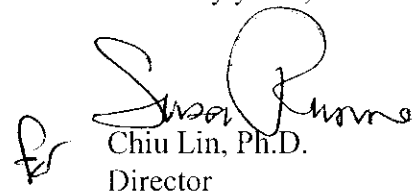
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K043003

Device Name: TCM4/40 Monitoring Systems

Indications for Use:

The TCM4 Monitoring System is intended for continuous transcutaneous monitoring of oxygen and carbon dioxide partial pressures. It is indicated for use on neonates, pediatrics, and adults not under gas anesthesia.

The TCM40 Monitoring System is intended for continuous transcutaneous monitoring of oxygen and carbon dioxide partial pressures as well as of oxygen saturation of arterial hemoglobin and pulse rate. It is indicated for use on neonates, pediatrics, and adults not under gas anesthesia.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K043003