510(k) Summary

For

FEB - 5 2010

TCM TOSCA/CombiM Monitoring System

Manufacturer:

Radiometer Medical ApS
Company Address: Åkandevej 21,
DK-2700 Brønshøj, Denmark

Contact Information:

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Jana S. Hellm

Date of Preparation: August 31, 2009

TCM TOSCA/CombiM Monitoring System

Device Name/Classification

- Trade name:
  (21 CFR 868.2480, product code LKD, DQA, DPZ)
- Trade name:
  (21 CFR 868.2500, product code LKD, KLK, LPP)

Identification of Predicate Device
TOSCA500 Monitoring System, K063434
MicroGas 7650 rapid, K003943
TCM 4/40 Monitoring System, K043003

Instrument Description
The **TCM TOSCA monitoring system** and the **TCM CombiM monitoring system** are based on the TCM 4/40 Monitoring System (K043003) which consist of a basic unit that has touch screen and two modules. One module for the combined $tcpO_2/tcpCO_2$ monitoring and one for SpO_2. . Both new modules have an integrated calibration unit

Both Sensors can be used with either earclip- or a conventional fixation ring application system. In addition the CombiM also comes with a double adhesive ring.

The software of the TCM 4/40 basic unit has been updated (to version 3.01) and two new modules have been developed to enable the use of the sensor technology from the TOSCA500 Monitoring System (K063434) and from the MicroGas 7650 rapid (K003943).

Thereby the SpO_2 and $tcpCO_2$ can be measured using the new TCM TOSCA module and the combined $SpO_2/tcpCO_2$ sensor of the TOSCA500 system.

The $tcpO_2$ and $tcpCO_2$ can be monitored using the new TCM CombiM module and the combined $tcpO_2/tcpCO_2$ sensor of the MicroGas 7650 rapid system. A new single $tcpCO_2$ sensor can also be used with this module.

Device Intended Use

TCM TOSCA/CombiM Monitoring system
The TCM CombiM Monitoring Systems is intended for continuous monitoring of transcutaneous Carbon Dioxide ($tcpCO_2$), oxygen ($tcpO_2$) partial pressure in neonates, pediatrics and adults not under gas anesthesia.

The TCM TOSCA Monitoring Systems is intended for continuous monitoring of transcutaneous Carbon Dioxide ($tcpCO_2$), oxygen saturation of arterial haemoglobin (SpO_2) and pulse rate in pediatrics and adults.

TCM TOSCA/CombiM Monitoring System

Medical device to which equivalence is claimed:

TOSCA500 Monitoring System, K063434
MicroGas 7650 rapid, K003943
TCM 4/40 Monitoring System, K043003

Please do refer to enclosed drawing showing the inter relationship with the new device and the predicate devices.

Comparison to Predicate Device:

Table 1 Comparison of features for TCM CombiM and Predicate Device

TCM CombiM compared to TCM4

Area	TCM4	TCM CombiM	Substantial
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 TCM CombiM monitoring system is intended for continuous transcutaneous monitoring of carbon dioxide (tcpC02) and oxygen (tcp02) partial pressures. It is indicated for use on neonates, pediatrics and adults not under gas anesthesia	YES
Gas Measurement parameters	$tcpO_2$,$tcpC0_2$	$tcpO_2$,$tcpC0_2$	YES
Basic unit HW (CPU + controller)	TCM 4/40 ETX Basic Unit	TCM 4/40 ETX Basic Unit	YES
Module	TCM 4/40 Module	TCM CombiM Module	YES*1
Operating system	Microsoft CE 5.0	Microsoft CE 5.0	YES
Basic unit SW	V3.0	V3.0	YES

TCM TOSCA/CombiM Monitoring System

Table 2 Comparison of features for TCM TOSCA and Predicate Device

TCM TOSCA compared to TCM40

Area	TCM40	TCM Tosca	Substantial
Indications for use	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.	The TCM TOSCA monitoring system is intended for continuous transcutaneous monitoring of carbon dioxide (tcpC02) partial pressures, oxygen saturation of arterial hemoglobin (Sp02) and pulse rate. It is indicated for use on pediatrics and adults not under gas anesthesia.	YES*1
Gas Measurement parameters	*$tcpO_2$, $tcpCO_2$*	$tcpCO_2$	YES*1
SpO_2 *Technology*	Nellcor OEM	Massimo OEM	YES*2
Basic unit HW (CPU + controller)	TCM 4/40 ETX Basic Unit	TCM 4/40 ETX Basic Unit	YES
Module	TCM 4/40 Module	TCM CombiM Module	YES*3
Operating system	Microsoft CE 5.0	Microsoft CE 5.0	YES
Basic unit SW	V3.0	V3.0	YES

TCM TOSCA / Tosca 500

Area	Tosca 500	TCM Tosca	Substantial
Sensor technology	Tosca 92	Tosca 92	YES*1

Conclusion

The products listed in the tables are substantially equivalent based on their indications for use and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Jana Hellmann
Vice President,Regulatory Affairs/Quality Assurance
Radiometer Medical ApS
Åkandevej 21
Brønshøj, DK-2700
DENMARK

FEB – 5 2010

Re: K093154
Trade/Device Name: TCM TOSCA/CombiM Monitoring System
Regulation Number: 21 CFR 868.2480
Regulation Name: Cutaneous Carbon Dioxide ($PcCO_2$) Monitor
Regulatory Class: II
Product Code: LKD, DQA, DPZ, KLK, LPP
Dated: January 21, 2010
Received: January 25, 2010

Dear Ms. Hellmann:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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

510(k) Number (if known): N/A

Class II Devices:

Device Names: TCM TOSCA/CombiM Monitoring System

Indication for Use:
The TCM CombiM Monitoring Systems is intended for continuous monitoring of transcutaneous Carbon Dioxide ($tcpCO_2$), oxygen ($tcpO_2$) partial pressure in neonates, pediatrics and adults not under gas anesthesia.

The TCM TOSCA Monitoring Systems is intended for continuous monitoring of transcutaneous Carbon Dioxide ($tcpCO_2$), oxygen saturation of arterial haemoglobin (SpO_2) and pulse rate in pediatrics and adults.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K093154

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: _____