

JAN 22 2010

1093080

Page 1 of 4

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:** TreyMed, Inc.
N56 W24790 N Corporate Circle
Sussex, WI 53089
262-820-1294 phone
262-820-1295 fax
www.treymed.com
E-mail: rhr@treymed.com

Contact Person: Robert H. Ricciardelli

Position/Title: President

Date of Preparation: September 25, 2009

Trade Name: Metaphor Metabolic Monitor

Common/Classification Name: Computer, Oxygen Uptake; Pulse Oximeter; Analyzer, Gas, Carbon-Dioxide, Gaseous-phase; Analyzer, Gas, Oxygen, Gaseous-phase; Analyzer, Gas, Nitrous-Oxide, Gaseous-phase; Spirometer, Monitoring;

Product Code(s): The following Class II classifications appear to apply:
BZL 21 CFR § 868.1730
DQA 21 CFR § 870.2700
CCK 21 CFR § 868.1400
CCL 21 CFR § 868.1720
CBR 21 CFR § 868.1700
BZK 21 CFR § 868.1850

Class: Class II

(3) **Predicate Device(s):**

K051092 Datex-Ohmeda S/5 Compact Airway Module (Model Family E-CAIOVX), GE HealthCare

K955432 MedGraphics CPX/D with Breeze EX software; Medical Graphics Corporation

- K982487** Meteor Hand Held Respiratory Mechanics Monitor, TreyMed, Inc. (formerly CardioPulmonary Technologies, Inc.)
- K083705** BCI WW1020 SPECTRO2 Pulse Oximeter, Smiths Medical PM, Inc. (formerly BCI)
- K090722** Shape-HF Cardiopulmonary Exercise Testing System, Shape Medical Systems, Inc.

Reason for Submission: New Device

(4) Description of Device:

The Metaphor Metabolic Monitor integrates the functions of a sidestream respiratory gas monitor (CO₂, O₂, N₂O), and pulmonary mechanics monitor (pressure, flow, and volume). These features allow the Metaphor to measure Oxygen uptake ($\dot{V}O_2$) and Carbon Dioxide production ($\dot{V}CO_2$) to objectively and noninvasively assess breath by breath metabolic function during rest or exercise.

The system is comprised of two main elements:

- Metaphor PC software host application running on a dedicated touch screen computer terminal, which presents computed physiological monitoring parameters, including metabolic measurements, as graphic and numeric data. This application manages the user interface, including alarms, and it interfaces to the BXB_DAS.
- The BXB_DAS embedded measurement platform – this subsystem contains the sensor technology to perform the gas, pressure, and flow measurements, and integrates a 510(k) cleared third party pulse oximeter module. The BXB_DAS subsystem interfaces with single patient use EZ-Flow sensors and SpO₂ sensors.

(5) Intended use:

Respiratory gas measurements are useful in critical care monitoring scenarios. Pulmonary mechanics measurements are useful in ventilated patients. Metabolic measurements are useful to determine the rate of energy expenditure in a variety of clinical scenarios, as described below.

Indications for Use:

The Metaphor uses the direct measurement of Oxygen uptake ($\dot{V}O_2$) and Carbon Dioxide production ($\dot{V}CO_2$) to objectively and noninvasively assess breath by breath metabolic function during rest or exercise. The Metaphor can assess energy expenditure to support nutritional assessment. Optional

measurement of Nitrous Oxide (N₂O) is available for enhanced accuracy of the CO₂ measurement in the presence of N₂O.

The Metaphor is a comprehensive pulmonary mechanics monitor which can display graphic and numeric data in patients who are mechanically ventilated or breathing spontaneously.

The Metaphor pulse oximetry function provides continuous SpO₂ and pulse rate measurements in neonatal through adult populations with appropriate probes.

The Metaphor provides adjustable visible and audible alarms. The device is not intended for use as a transport monitor.

Prescription Device.

(6) Technological Characteristics:

The Metaphor utilizes similar measurement methods as the referenced predicate devices:

- Flow detection based on differential pressure measurement
- Sidestream gas sampling
- CO₂ and N₂O gas monitoring via infrared optical measurement
- O₂ monitoring using electrochemical cell
- Integration of a listed subsystem for pulse oximetry
- WIN PC-based control program

As described above, the Metaphor implements a PC based monitor application with the TreyMed BXB_DAS (breath by breath data acquisition subsystem) to perform and display the measurements.

The Metaphor Metabolic Monitor has the same technological characteristics as the referenced combination of 510(k) listed devices:

- The Metaphor integrates the same flow measurement technology and EZ-Flow sensor technology as two predicate devices (Meteor, Shape-HF), and the same measurement principle (differential pressure). The Metaphor uses the EZ-Flow sensor.
- The Metaphor, Shape-HF and BCI WW1020 devices use identical oximetry technology, the BCI technology.
- Metaphor reports metabolic parameters similar to CPX/D and Shape-HF, including VO₂ and RQ, employing similar technical means.
- Metaphor provides respiratory gas monitoring parameters (CO₂, O₂, optional N₂O) similar to the Datex CAiOVX using similar means.

(b) (1) **Non-Clinical Tests Submitted:**

The Metaphor Metabolic Monitor was tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, shock and vibration, and environment (temperature and humidity). The device passed the tests.

Materials utilized in patient contact surfaces were reviewed for conformance with biocompatibility requirements. The materials met the requirements.

System level tests of the Metaphor Metabolic Monitor included testing in support of requirements for respiratory gas monitors, pressure/flow measurement testing, and extended range bench testing of metabolic measurements, including, where possible, comparison testing. Pulse oximeter simulation tests were performed to demonstrate successful integration. Alarms testing was performed. The device satisfied performance criteria.

The Metaphor Metabolic Monitor PC software and BXB_DAS subsystem embedded software were verified to requirements and validated to meet intended use. Risk, hazard and failure mode analysis was performed and residual risks were determined to be acceptable.

(2) **Clinical Tests Submitted:**

(none)

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, the testing demonstrates that the Metaphor Metabolic Monitor is as safe and effective as, and functions in a manner equivalent to the predicate devices.



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

Mr. Robert H. Ricciardelli
President
TreyMed, Incorporated
N56 W24790 North Corporate Circle
Sussex, Wisconsin 53089

JAN 22 2010

Re: K093080
Trade/Device Name: Metaphor Metabolic Monitor
Regulation Number: 21 CFR 868.1730
Regulation Name: Oxygen Uptake Computer
Regulatory Class: II
Product Code: BZL, DQA, CCK, CBR, CCL, BZC
Dated: January 18, 2010
Received: January 19, 2010

Dear Mr. Ricciardelli:

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 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.

Page 2 - Mr. Ricciardelli

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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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):

Device Name: TreyMed, Inc. Metaphor Metabolic monitor

Indications for use:

The Metaphor uses the direct measurement of Oxygen uptake ($\dot{V}O_2$) and Carbon Dioxide production ($\dot{V}CO_2$) to objectively and noninvasively assess breath by breath metabolic function during rest or exercise. The Metaphor can assess energy expenditure to support nutritional assessment. Optional measurement of Nitrous Oxide (N_2O) is available for enhanced accuracy of the CO_2 measurement in the presence of N_2O .

The Metaphor is a comprehensive pulmonary mechanics monitor which can display graphic and numeric data in patients who are mechanically ventilated or breathing spontaneously.

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The Metaphor provides adjustable visible and audible alarms. The device is not intended for use as a transport monitor.

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician or other licensed practitioner.

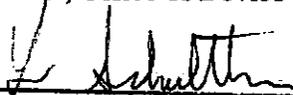
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use _____
(21 CFR 807 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

Page 1 of 1

510(k) Number: K093080