JUL 19 2013

SECTION 5

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS FOR Multi-Parameter Mobile CareGuide™ 3100 Oximeter

Submitter Information

Name:	Reflectance Medical, Inc. (RMI)
Address:	116 Flanders Road, Suite 1000 Westborough, MA 01581 USA
Telephone Number:	508.366.4700
Registration Number:	NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)
Contact Person:	Dr. Babs Soller
Telephone Number:	508.366.4700, Ext 223
Fax Number:	508.366.4770
Email:	Babs.Soller@reflectancemedical.com
Date Prepared:	June 12, 2013

Device Name

Trade name of New Device:	Multi-Parameter CareGuide™ Oximeter
Model Number:	3100
510(k) Holder/Submitter:	Reflectance Medical, Inc. (RMI)
510(k) Number:	N/A
Proposed Additional product codes:	CBZ, 21 C.F.R. § 868.1170, Anesthesiology
Classification Panel:	Anesthesiology

Predicate Devices

Predicate Device #1:	Multi Parameter Catheter
Trade name of Device:	Paratrend™ Multi parameter Sensor and Satellite Monitor System with Paratrend 7 Plus multi-parameter catheter
Model #:	7
510(k) holder/Submitter:	Diametrics Medical Limited

510(k) Number:	K970906
Product codes:	CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2:	Terumo Khuri
Trade name of device:	Terumo Khuri™ Myocardial pH Monitoring System
Model #:	N/A
510(k) holder/Submitter:	Terumo Cardiovascular Systems Corporation
510(k) Number:	K020967
Product codes:	CBZ, 868.1170, Anesthesiology

Predicate Device #3:	Masimo multi-parameter oximeter
Trade name of Device:	Rainbow SET™ Radical 7 Co-oximeter
510(k) holder/Submitter:	Masimo Corporation
510(k) Numbers:	K080238, K061204
Product Codes:	DQA, 21 CFR 870.2700, Anesthesiology JKS, 21 CFR 862.3220, Clinical Toxicology DPZ, 21 CFR 870.2710, Cardiovascular (K080238)

Predicate Device #4:	CareGuide
Trade Name of Device:	Mobile CareGuide Oximeter
Model #:	1100, 2100
510(k) Holder/Submitter:	Reflectance Medical Inc.
510(k) Number:	K113656, CareGuide 1100 K122645, CareGuide 2100
Product code:	MUD, 21 CFR 870.2700, Cardiovascular

Device Description

The Multi-Parameter Mobile CareGuide 3100 Oximeter sensor uses Near Infrared (NIR) Spectroscopy to calculate muscle oxygen saturation (SmO_2) and muscle pH (pHm).

Characteristics	**Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter**
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor and disposable pad
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO_2) and muscle pH (pHm)

The Multi-Parameter Mobile CareGuide 3100 Oximeter is a multiple parameter oximeter. The sensor contains algorithms that calculate SmO_2 and pHm from collected spectra and communicates the current SmO_2 and pHm results to a 3rd party display or patient monitor through a proprietary protocol. The Multi-Parameter Mobile CareGuide 3100 Oximeter reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with either a USB connection or CAN connection to the 3rd party display/patient monitor. The sensor is identical to the predicate (K122645) Mobile CareGuide 2100 Oximeter hardware containing six major components: (1) light sources to illuminate the skin; (2) a spectroscopic detector to analyze the reflected spectra back from the subject; (3) a microprocessor to control the optical components; (4) a microprocessor to perform the spectral analysis and generate the calculated SmO2 and pHm; (5) one of two different communications components to transmit in CAN or USB format; (6) a battery to power all components. The Multi-Parameter Mobile CareGuide 3100 Oximeter uses the same disposable element as the Mobile CareGuide 2100 Oximeter, a disposable sleeve that isolates the sensor optical elements from the patient's skin.

Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or

therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.

Rationale for Substantial Equivalence

This device's oximetry feature has been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter. The remaining component of the device is pH (21 CFR 868.1170)-.

The Multi-Parameter CareGuide 3100 has the same intended use as one of the identified predicates, the Terumo Khuri Regional pH monitor (K020967).

There is no change in how the User would use the information generated by the Multi-Parameter Care Guide 3100 relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter CareGuide 3100 nor any of the predicate devices identified by RMI provide diagnostic output.

The Multi-Parameter CareGuide 3100 has the same principle of operation (an optical technological platform that relies on light absorption) as the Paratrend 7 Sensor (pH) (K970906) predicate device. The Multi-Parameter Mobile CareGuide 3100 includes a sensor and monitor and, outputs a numeric trend like these predicate devices.

While the optical technology used in the Multi-Parameter CareGuide 3100 is not identical to that of the Paratrend monitor, the accuracy of the CareGuide 3100 is comparable to that predicate device. Much like the testing strategy used by other multi-parameter monitors, accuracy of the CareGuide 3100 was established via a bridging study, comparing CareGuide 3100 values against direct blood measurements using a laboratory analyzer.

The Multi-Parameter CareGuide 3100 also has the same technological characteristics as the previously cleared RMI devices, the CareGuide 1100 (K113656) and the Mobile CareGuide 2100 (K122645).

- The principle of operation of the Multi-Parameter Mobile CareGuide 3100 Oximeter is identical to that of the predicate CareGuide devices. They use the exact same NIR spectroscopic platform to measure tissue oxygen saturation and muscle. The same software quantitative algorithm for SmO2 is used in both devices.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter is equivalent to the Mobile CareGuide 2100 predicate in reusable components. Both devices use the exact same sensor hardware: main sensor CPU board, battery, optical board (light sources, spectrometer and microprocessor), CAN/USB interfaces, plastic housing and cables.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter is equivalent to the CareGuide predicates in disposable components. Both devices use the exact same disposable sheath ("Ray") and disposable sensor check device ("Cradle").

- The Multi-Parameter Mobile CareGuide 3100 Oximeter has the identical underlying LED light source as the CareGuide predicates, with the exact same range of wavelength (700-900 nm).

Summary of Safety and Effectiveness Data

Testing demonstrates that the Multi-Parameter Mobile CareGuide 3100 Oximeter is a safe and effective oximeter meeting all relevant consensuses and FDA recognized standards. The test results in this submission demonstrate that the Multi-Parameter Mobile CareGuide 3100 Oximeter meets the expected performance requirements for an Oximeter, and is therefore equivalent to the predicate relative to safety and mechanical properties. The accuracy and safety of the Multi-Parameter Mobile CareGuide 3100 Oximeter is the same as the predicate device.

Conclusion

The Multi-Parameter Mobile CareGuide 3100 Oximeter is equivalent to predicate device in terms of technology (NIR Spectroscopy) and intended use. The Multi-Parameter Mobile CareGuide 3100 Oximeter does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Multi-Parameter Mobile CareGuide 3100 Oximeter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 19, 2013

Reflectance Medical, Inc.
c/o Ms. Nandini Murthy
116 Flaunders Road, Suite 1000
Westborough, MA 01581

Re: K130079
Trade/Device Name: Multi-Parameter Mobile CareGuide 3100 Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD CBZ
Dated: June 13, 2013
Received: June 18, 2013

Dear Ms. Nandini Murthy:

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 contact 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. 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,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K130079

Device Name: Multi-Parameter Mobile CareGuide™ 3100 Oximeter

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.07.19 08:19:45 -04'00'