**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

August 22, 2014

Reflectance Medical, Inc.
% Nandini Murthy
Regulatory Consultant
116 Flanders Road, Suite 1000
Westborough, Massachusetts 01581

Re: K141496
Trade/Device Name: Multi-parameter Mobile Careguide 4100 Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD, CBZ
Dated: June 4, 2014
Received: June 6, 2014

Dear Nandini Murthy,

This letter corrects our substantially equivalent letter of August 4, 2014.

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.

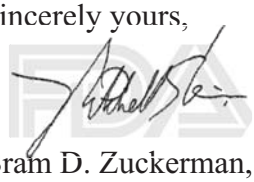
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 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): _____

Device Name: ___Multi-Parameter Mobile CareGuide™ 4100 Oximeter___

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 4100 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 4100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party or Reflectance supplied device, which would interface with the Multi-Parameter Mobile CareGuide 4100 Oximeter via a powered USB connection. The Multi-Parameter Mobile CareGuide 4100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional inside and outside a hospital. The Multi-Parameter Mobile CareGuide 4100 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 4100 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 4100 Oximeter has not been demonstrated in disease states.

| Prescription Use __X__<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

# SECTION 5

## 510(k) SUMMARY

## SUMMARY OF SAFETY AND EFFECTIVENESS FOR Multi-Parameter Mobile CareGuide™ 4100 Oximeter

### Submitter Information


| | |
|---|---|
| Name: | Reflectance Medical, Inc. (RMI) |
| Address: | 116 Flanders Road, Suite 1000<br>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: | August 1, 2014 |

### Device Name

| | |
|---|---|
| Trade name of New Device: | Multi-Parameter CareGuide™ Oximeter |
| Model Number: | 4100 |
| 510(k) Holder/Submitter: | Reflectance Medical, Inc. (RMI) |
| 510(k) Number: | N/A |
| Applicable product codes: | MUD, 21 CFR 870.2700 Oximeter and<br>CBZ, 21 CFR 868.1170 Analyzer, Hydrogen-Ion (Ph) |
| Classification Panel: | Cardiovascular |

### Predicate Devices

| | |
|---|---|
| Predicate Device #1: | CareGuide Oximeter |
| Trade name of Device: | CareGuide™ Oximeter |
| Model #: | 1100 |
| 510(k) holder/Submitter: | Reflectance Medical, Inc. |

510(k) Number: K113656
Predicate Device #2: CareGuide Oximeter
Trade name of Device: Mobile CareGuide™ Oximeter
Model #: 2100
510(k) holder/Submitter: Reflectance Medical, Inc.
510(k) Number: K122645

Predicate Device #3: CareGuide Oximeter
Trade name of Device: Multi-Parameter Mobile CareGuide™ Oximeter
Model #: 3100
510(k) holder/Submitter: Reflectance Medical, Inc.
510(k) Number: K130079

Predicate Device #4: CareGuide Oximeter
Trade name of Device: Multi-Parameter Mobile CareGuide™ Oximeter
Model #: 3100 with Tablet
510(k) holder/Submitter: Reflectance Medical, Inc.
510(k) Number: K133923

## Device Description

The Multi-Parameter Mobile CareGuide 4100 has the following technical characteristics in common with the CareGuide family of predicate devices.

| **Characteristics** | **Reflectance Medical Multi-Parameter Mobile CareGuide 4100 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 4100 is a noninvasive optical sensor that determines two separate medical parameters and reports them out for display to the user in real-time. Light sources in the sensor illuminate the skin with near infrared (NIR) light. NIR light passes through the skin and fat with only some loss to be primarily absorbed by small blood vessels in the muscle tissue. Light which is not absorbed is scattered back and analyzed by the spectroscopic

detector, also contained in the sensor. The microprocessor in the sensor converts the reflected light to an absorbance spectrum which is then analyzed by two separate algorithms, also stored in the sensor's microprocessor. The two algorithms calculate muscle oxygen saturation (SmO2), and muscle pH (pHm).

The sensor is attached to the patient using the CareGuide Disposable. One Disposable is used per patient, but the CareGuide Sensor is reusable. To use, the adhesive liner is removed from the Disposable and, with the sensor clipped into the Disposable, is adhered to the patient's skin over either the deltoid, calf or thigh muscle.

When the sensor is first placed on the patient, software checks to make sure the LEDs are functioning properly and then the sensor automatically performs an optimization routine which sets up the spectral data collection parameters for the individual patient. Once conditions are established the sensor begins collecting spectra and reporting parameter values.

The Multi-Parameter Mobile CareGuide 4100 measures and provides for output of SmO2 and pHm data. The Multi-Parameter Mobile CareGuide 4100 communicates with either a 3rd party display or monitoring device, or RMI-supplied tablet, which is compliant with the Mobile CareGuide communications protocol. SmO2 and pHm values suitable for display and trending are sent via the Mobile CareGuide communications protocol to the display device as well as error information and device states.

## Indications for Use

The Multi-Parameter Mobile CareGuide™ 4100 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 4100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party or Reflectance supplied device, which would interface with the Multi-Parameter Mobile CareGuide 4100 Oximeter via a powered USB connection. The Multi-Parameter Mobile CareGuide 4100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional inside and outside a hospital. The Multi-Parameter Mobile CareGuide 4100 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 4100 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 4100 Oximeter has not been demonstrated in disease states.

## Rationale for Substantial Equivalence

The Multi-Parameter Mobile CareGuide 4100 Oximeter is substantially equivalent to the Reflectance Medical CareGuide predicate devices by intended use and design.

- The Mobile CareGuide 4100 Oximeter is identical to the predicate family in technological optical principles. They all use the identical NIR Spectroscopy hardware and software, using multiple wavelengths in the range 700-900 nm to measure tissue oxygen saturation and pH.
- The Multi-Parameter Mobile CareGuide 4100 Oximeter has a reusable sensor, disposable and sensor check functionality equivalent to the predicates.
- The Multi-Parameter Mobile CareGuide 4100 Oximeter provides identical data to be displayed as numeric values or trend.
- The Intended Use is the same as the predicate.
- Therefore, the Multi-Parameter Mobile CareGuide 4100 Oximeter is substantially equivalent to the predicates in terms of the proposed intended use and technology.
- There are no new or open questions of safety and effectiveness.

## Summary of Safety and Effectiveness Data

Testing demonstrates that the Multi-Parameter Mobile CareGuide 4100 Oximeter is a safe and effective oximeter meeting all relevant FDA recognized standards and internal testing as listed in Table 1.

**Table 1 Standards and Internal Testing**

| **Standard # or Internal Test** | **Description** |
|---|---|
| IEC60825-1 Ed 2.0 (2007) | Safety of laser products - Part 1: Equipment classification, and requirements |
| IEC 60601-1-1: 2005 | Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems |
| IEC 60601-1-2: 2007-03 | Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests |
| ISO 10993-5 2009 | Biological evaluation of medical devices-Part 5: Test for *in vitro* cytotoxicity |
| ISO 10993-10 2010 | Biological evaluation of medical devices-Part 10: Tests for irritation and delay-type hypersensitivity |
| AAMI TIR 12:2010 | Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers |
| AAMI TIR 30:2003 | A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices |

| **Standard # or Internal Test** | **Description** |
|---|---|
| ISTA 1A | Series Non-Simulation Integrity Performance Test Procedure: Packaged-Products 150 lb (68 kg) or Less |
| Internal Tests | Device Verification and Validation tests such as Vibration and shock, Auto-start, Sensor optimization and background checks and verification of minor updates to the CareGuide 4100 algorithm |

The test results in this submission demonstrate that the Multi-Parameter Mobile CareGuide 4100 Oximeter meets the expected performance requirements for an Oximeter. The accuracy, functionality and safety of the Multi-Parameter Mobile CareGuide 4100 Oximeter is the equivalent to the predicate device.

## Conclusion

The Multi-Parameter Mobile CareGuide 4100 Oximeter is equivalent to predicate devices in terms of technology (NIR Spectroscopy) and intended use. The Multi-Parameter Mobile CareGuide 4100 Oximeter does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Multi-Parameter Mobile CareGuide 4100 Oximeter is substantially equivalent to the predicate device.