510(K) SUMMARY

NBM-200MP PULSE OXIMETRY DEVICE

510(k) Number K124041

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OCT 17 2013

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Date Prepared: September 25, 2013

Trade Name: NBM-200MP Pulse Oximeter and Hemoglobin Monitor

Device Common or Usual Names: Pulse Oximeter

Classification Name: Oximeter

Classification: 21 CFR § 870.2700 (Product Code DQA)
21 CFR § 864.7500 (Product code GLY)

Predicate Device: The NBM-200MP Pulse Oximeter and hemoglobin Monitor device is substantially equivalent to a combination of the following predicate devices:

- NBM 200MP Pulse Oximeter (K091564) manufactured by OrSense Ltd. The new NBM-200MP is a pulse oximeter device, similar to the previously cleared NBM-200MP pulse oximeter device.
- Rainbow SET Radical/Rad 57t Co-Oximeter (K080238) manufactured by Masimo Corp. SET Radical/Rad 57t is a pulse oximeter and hemoglobin monitoring device, similar to the NBM-200MP pulse oximeter and hemoglobin monitoring device.
- Rainbow SET Pronto Pulse Co-Oximeter (K091057) manufactured by Masimo Corp. SET Pronto is a pulse oximeter and hemoglobin monitor device, similar to the NBM-200MP pulse oximeter and hemoglobin monitor device.
- Rainbow SET RadCheck Pulse Co-Oximeter (K082052) manufactured by Masimo corp. RadCheck is a pulse oximeter and hemoglobin monitor device, similar to the NBM-200MP pulse oximeter and hemoglobin monitor device.
- Rainbow SET Radical 7R Pulse Co-Oximeter (K100428) manufactured by Masimo corp. Radical 7R is a pulse oximeter and hemoglobin monitor device, similar to the NBM-200MP pulse oximeter and hemoglobin monitor device.

Device Description: OrSense NBM-200MP device is a pulse oximetry and hemoglobin monitoring device, measuring SpO_2, pulse rate, hemoglobin and estimated Hematocrit. In addition to a regular operating mode, it also includes an "occlusion spectroscopy" mode, which is activated during low-perfusion conditions for oximetry (SoO_2) and for Hb measurements. The sensor probe pneumatic cuff is placed around a

finger and briefly inflates and deflates; the resulting changes in blood optical behavior within the finger are measured and analyzed to provide accurate measurements of SoO_2 during low-perfusion conditions and Hemoglobin values at predetermined time intervals. The monitor should not be used under any circumstances as a substitute for an approved lab blood analyzer.

Intended Use / Indication for Use:

The NBM-200MP is a portable Hemoglobin and oximetry monitor. It non-invasively monitors and displays Hemoglobin (Hb), estimated Hematocrit (Hct), functional saturation of arterial oxygen hemoglobin (SpO_2), temporary occluded blood oxygen saturation (SoO_2), pulse rate (PR) and plethysmogram waveform.

For oximetry (SpO_2/SoO_2), the NBM-200MP permits continuous patient monitoring with adjustable alarm limits, as well as visible and audible alarm signals. SoO_2 is intended for use in low perfusion conditions and under any conditions that will cause poor signal quality.

The NBM-200MP periodically displays Hemoglobin (Hb) and estimated Hematocrit (Hct) values and it can also be used for spot measurements. The monitor estimates Hct via a calculation based on the Hb measurement for normal hemoglobin values (i.e. 11 to 17 g/dl) only and abnormal values will not be displayed. It is intended for use by trained medical personnel, with adult individuals, in clinical and non-clinical settings (e.g. hospitals, hospital-type facilities, mobile environments, clinics, physician offices and ambulatory surgery centers).

Technological Characteristics

The new OrSense NBM-200MP Pulse Oximeter and hemoglobin Monitoring device has the same basic technological characteristics as the predicate devices. All the devices consist of a microprocessor controlled portable monitor base unit and a cable-connected finger attached sensor. The new device is identical in hardware to the original NBM-200MP device (K091564), and they both use an inflatable cuff inside the sensor housing employing pneumatic tissue manipulation.

The measurement, as common for all pulse oximetry devices, is a function of how the light wavelength is absorbed and scattered. The sensor consists of the light source (red and infrared LEDs), and the photodetector, an electronic device that produces an electrical current proportional to incident light intensity.

The new device includes the parameters of the original NBM-200MP: SpO_2, SoO_2 and pulse rate, and adds a periodic or spot measurement of hemoglobin concentration and estimated Hematocrit. Similarly, the Masimo predicate devices measure SpO_2, pulse rate and total hemoglobin concentration (SpHb) and the Radical 7R (K100428) calculates and displays hematocrit (SpHct). The Rad 57t (K080238) and Radical 7R devices perform continuous measurements of SpHb while the RadCheck (K082052) and Pronto (K091057) devices perform spot-check measurements.

The oximetry measurement procedure is identical to that of the original NBM-200MP.

The Hb values are derived from the signals generated by the 'occlusion spectroscopy' procedure and Hct values are estimated from the Hb values.

Performance Standards:

This 510(k) submission was written in accordance with the FDA's "Draft Guidance for Industry and FDA Staff- Pulse Oximeters- Premarket Notification Submissions [510(k)s], 19 July 2007. The design of the NBM-200MP device conforms to the following voluntary standards:

- ISO9919:(2005) Standard: Medical Electrical Equipment- Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use
- IEC/EN-60601-1: Medical Electrical Equipment; Part 1: General Requirements for Safety. Second edition (1990), including amendments #1(1993), #2(1995) and #13(1996).
- IEC/EN 60601-1-2: Medical Electrical Equipment; Part 1-2: Collateral Standard: Electromagnetic Compatibility- Requirements and Tests (2001)
- IEC/EN 32604:2006 – Software
- ISO14971:2007 – Risk Management to Medical devices

Test Data: The NBM-200MP device has been subjected to extensive safety, performance testing, and validation before release. Final testing of the NBM-200MP device included various performance tests and software validation tests, designed to ensure that the device met all its functional specifications. Tests have been performed to ensure the device complies with industry and safety standards. Tests included Biocompatibility, Bench Performance Testing (Simulator testing), Safety testing, Environmental testing, and Clinical testing.

The safety of the cuff inflation/deflation mechanism, with regard to potential skin ischemia under low blood pressure conditions, was analyzed by comparison of the device duty cycle to a predicate device, by compliance with the relevant sections of a standard for automatic non-

invasive blood pressure monitoring equipment (IEC 60601-2-30 (1999) standard, and by clinical testing as reported below.

All tests passed and demonstrated substantial equivalence with predicates and compliance with the relevant standards.

Clinical Data Summary:

The following clinical data was submitted:

1. Clinical studies as submitted for K091564
2. Clinical study results for assessment of Hb accuracy over the range of 6.5 -17.1 g/dl
3. Clinical study results for assessment of the repeatability and reproducibility of the device performance
4. Supplemental study for demonstration of the device performance in continuous trending

The NBM-200MP was tested at three sites in Israel, and a supplemental study was performed at one site in the U.S.

Demographic details about the trial sites are presented in the table below.

NBM-200MP Clinical Trial Sites

Site	Site Name	Medical condition	Age (y)	Enrolled
1	Assaf Harofeh Medical Center	Non-healthy (Hematology)	19-21	359 (176F, 183M)
2	Rabin Medical Center	Pregnant women	21-54	212 (212F)
3	Chaim Sheba Medical Center	Healthy and non-healthy	18-90	100 (66F, 34M)
4	Zabloki Veterans Affairs Medical Center	Healthy	19-42	27 (14F, 13M)

For the accuracy studies at the Israeli sites 1-3, testing consisted of two non-invasive Hb measurements with the NBM-200MP. Results were compared to routine Hb measurements from an automated blood analyzer (Coulter LH750) using venous whole blood samples. For the reproducibility study, 33 subjects were tested at site 3 (Sheba MC) 3 times on two fingers by 3 operators and with 3 NBM units.
The study population was comprised of 82% Caucasian, 12% Hispanic, 5.5% African or African-American and 0.5% Asian or Mediterranean.

In the supplemental study (site 4) the variability of measured Hb during a 2-hour period was tested in resting, healthy, young volunteers. A second protocol for the study performed in 12 of the subjects included a hemodilution procedure to demonstrate the continuous operation of NBM over a wide dynamic range of Hb values. At this site a Radiometer OSM3 was used for reference.

Overall results in the Hb study:

- Mean difference (bias) of -0.13 g/dl
- Standard deviation of the difference: 0.96 g/dl
- Root mean square error (RMSE): 0.97 g/dL
- 95% limits of agreement: [-2.01, 1.76 g/dl]
- Reproducibility SD of the NBM is 0.5 g/dl; the CV is 4.2%.

Clinical data were collected to assess the Hb accuracy over the range of 6.5 to 17.1 g/dl. For simplicity reasons, we specified the measurement range of the device as 7 to 17 g/dl.

No adverse events or subject discontinuation related to the use of the NBM-200MP were reported during the multi-center studies.

Oximetry study (K091564):

A clinical study of induced hypoxia in consenting healthy individuals was performed to validate SpO2 and SoO2 accuracy in comparison to reference measurements of blood SaO2 by a co-oximeter. The study was performed in compliance with the requirements of ISO9919:(2005) Standard. The device was tested on 10 healthy individuals.

Results:

- In the NBM-200MP pulse mode, based on 388 pairs of data points, the error (rms) obtained was 2.5%, with 0.95 correlation and 0.2% bias.
- In the occlusion mode there were 438 data pairs, with 2.2% error, 0.96 correlation and 0.05% bias.

No adverse events were reported.

Substantial Equivalence:

The NBM-200MP pulse oximeter device is similar to currently distributed pulse oximeter devices intended for measurement and monitoring of SpO_2, Hb and pulse rate.

Conclusions: The conclusions drawn from the above Performance Testing and comparison to predicate devices is that the NBM-200MP pulse oximetry and hemoglobin monitoring device is substantially equivalent to the predicate devices listed above.

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

October 17, 2013

OrSense, Limited
C/O Mr. Mark A. Heller, Consultant
Goodwin Procter, Limited Liability Partnership
901 New York Avenue, North West
WASHINGTON DC 20001

Re: K124041
Trade/Device Name: NBM-200MP Pulse Oximeter and Hemoglobin Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, GLY
Dated: September 25, 2013
Received: September 25, 2013

Dear Mr. Heller:

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.

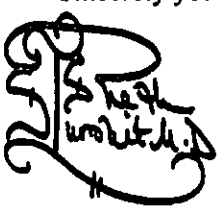
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K124041

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Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D)	OR	Over-The-Counter Use___ (Optional Format Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nayan J. Patel -S
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