MAR 19 2010

510(K) SUMMARY

NBM-200MP PULSE OXIMETRY DEVICE

510(k) Number K K091564

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Date Prepared: March 2010

Trade Name: NBM-200MP pulse oximeter

Device Common or Usual Names: Pulse Oximeter

Classification Name: CFR Classification section 870.2700 (Product code DQA)

Classification: Class II medical Device

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

- SET Rad-8 Pulse Oximeter (K053269) manufactured by Masimo corp. SET Rad-8 is a pulse oximeter device, similar to the NBM-200MP pulse oximeter device.
- CRIT-SCAN (K910077) manufactured by In-Line Diagnostics. CRIT-SCAN is a non-invasive hematocrit measuring device, using a pneumatic cuff technology for periodic inflation and deflation around a finger. Similarly, the NBM-200MP pulse oximeter device is also using a pneumatic cuff technology for temporary inflation and deflation around a finger.
- BMEYE NEXFIN_HD (K072049) manufactured by BMEYE B.V. (The Netherlands). BMEYE NEXFIN_HD is a non-invasive monitor that enables the continuous assessment of a patient's cardiovascular function and blood pressure, using a pneumatic cuff technology which exerts continuously changing external pressure around a finger. Similarly, the NBM-200MP pulse oximeter device is also using a pneumatic cuff technology for temporary inflation and deflation around a finger.

Device Description: OrSense NBM-200MP device is a pulse oximetry device, measuring SpO_2 and Pulse Rate. In addition to a regular operating mode, it also includes an "occlusion spectroscopy" mode, which is activated during low-perfusion conditions. A pneumatic cuff placed around a finger temporarily inflates and deflates; the resulting changes in blood behavior within the occluded finger are measured and analyzed to provide accurate measurements of blood oxygen saturation during low-perfusion conditions.

Intended Use / Indication for Use:

The NMB-200MP is a portable Oximetry monitor which may be used in low perfusion conditions. It non-invasively and

continuously monitors and displays arterial blood oxygen saturation (SpO2), temporary occluded arterial blood oxygen saturation (SoO2), pulse rate (P.R.) and plethysmogram waveform.

Temporary occluded arterial blood oxygen saturation (SoO2) is intended for use under any conditions that will cause poor signal quality. It is not intended for use under motion conditions.
It may be used on adult patients in the hospital or clinical environments.
The NBM-200MP permits continuous patient monitoring with adjustable alarm limits for oximetry, as well as visible and audible alarm signals.
The NBM-200MP is NOT intended for home use.

ContraIndications:

- Patients with significant deformity, swelling, irritation, degenerative changes or edema of the fingers or hand
- Patients with localized infection, ulceration or skin lesions involving the fingers
- Placing the sensor on a finger that has restricted blood flow e.g. tourniquet or pressure cuff

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)

Test Data:

The NBM-200MP device has been subjected to extensive safety, performance testing, and validation before device 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 cycling 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. 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 accuracy (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.

2. To evaluate the safety of the inflation/deflation mechanism, the device was clinically tested in an Intensive Care Unit environment. The device was tested on 32 patients in a general ICU (including patients with pneumonia, pancreatitis, GI Bleeding, cervical trauma, diabetes, sepsis and septic shock, post surgery, with cancer, receiving blood transfusion, respiratory failure, liver failure, and arrhythmias). The OrSense device was attached to patients and operated in continuous cyclic occlusion mode for varying durations, from 3 to 24 hours. The tested patients included patients receiving high Noradrenalin doses, low oxygenation states, and low blood pressures. The range of blood pressure ranged from severe hypotension to hypertension.

The investigators observed the fingers (on which cuffs were placed and inflated/deflated during monitoring) for any changes

Results: No device-related adverse events were reported. There were no reports of marks, or any significant differences in color/shape, on the fingers. This, even in those patients with markedly reduced perfusion states, and after the longest durations of operation.

Substantial Equivalence: The NBM-200MP pulse oximeter device is similar to currently distributed pulse oximeter devices intended for measurement and monitoring of SpO_2 and Pulse Rate.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAR 19 2010

Re: K091564
Trade/Device Name: NBM-200MP Pulse Oximetry Device
Regulation Number: 21CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 7, 2010
Received: March 11, 2010

Dear Mr. Stein:

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):_____

Device Name: NBM-200MP Pulse Oximetry device

Indications for Use:

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The NBM-200MP is NOT intended for home use.

Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D) C)

OR

Over-The-Counter Use___ (Optional Format Subpart

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

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

510(k) Number: K091564

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