K130320

COVIDIEN

FEB - 4 2014

510(k) Summary

Date: 24-Jan-2014

510(k) Submitter/Holder

Covidien llc
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Boulder, CO 80301

Contact

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Name of Device

Device Name:	Bedside Respiratory Patient Monitoring System
Catalog Numbers:	GR101704, GR101704-RR, 10099029
Common Name:	Pulse oximeter
Classification:	Class II
Regulation:	21 CFR § 870.2700 Oximeter
Primary Product Code:	DQA
Secondary Product Code:	BZQ

Purpose of Submission

Bedside Respiratory Patient Monitoring System has undergone an engineering design change associated with the replacement of the printed circuit board assembly that performs oximetry functions for the device. Furthermore, the indications for use have been expanded to specifically claim oximetry accuracy for "both no motion and motion conditions". The purpose of this submission is to demonstrate substantial equivalence of the Covidien Nellcor Bedside Respiratory Patient Monitoring System to the predicate devices as related to these specific changes.

Summaries of clinical and non-clinical testing were provided to support 1) accuracy of oximetry performance, and 2) the expansion in the indications for use to include accuracy in the presence of motion.

Predicate Devices

Bedside Respiratory Patient Monitoring System was compared and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Trade Name:	Bedside Respiratory Patient Monitoring System
Device Common Name:	Oximeter, monitor, breathing frequency
510(k) Number:	K121806 (cleared 9/2012)
Manufacturer:	Covidien, formerly Nellcor, a division of Tyco Healthcare
Trade Name:	Nellcor Puritan Bennett OxiMAX N-595 Pulse Oximeter
Device Common Name:	Monitor, breathing frequency
510(k) Number:	K012891 (cleared 3/2002)
Manufacturer:	Covidien, formerly Nellcor, a division of Tyco Healthcare

Device Description

The Covidien Nellcor Bedside Respiratory Patient Monitoring System is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by use of one of a range of compatible Nellcor OxiMax oxygen transducers (sensors). The Bedside Respiratory Patient Monitoring System displays digital values of SpO_2 and pulse and respiratory rate. Pulse amplitude is displayed by means of a "blip bar" presentation or plethysmographic waveform. The Bedside Respiratory Patient Monitoring System can be powered by an internal power supply operating on AC from a standard electrical utility receptacle (from 80VAC to 264VAC) or alternatively by an integral sealed 7.2V, 83W/hr rechargeable lithium-ion battery.

Intended Use

The Nellcor™ Bedside Respiratory Patient Monitoring System is a portable pulse oximeter intended for prescription use only as a continuous non-invasive monitor of arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport. The OxiMax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The Respiration Rate parameter, when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System and Nellcor™ Respiratory Sensor, is intended for the continuous, non-invasive monitoring of respiration rate in adult patients who are well perfused during no motion conditions, in hospitals and hospital-type facilities.

Technological and Performance Characteristics

The Bedside Respiratory Patient Monitoring System features the same performance characteristics and design, chemical composition, and energy source as the predicate K121806 (9/2012).

The external appearance and hardware of the subject device is exactly the same as that of the primary predicate, utilizing a similar molded plastic exterior case, display, and interface cables.

Design Change

The only significant difference between the subject and primary predicate device is the replacement of the internal printed circuit board assembly (PCBA). The key element of the design change to the subject device is the difference in the analog hardware that was introduced through integration of the new PCBA. These hardware changes are specifically related to the Sample Rate/Interval and T-Mux frequency which were the main drivers for clinical validation of the design change to demonstrate that these differences produced equivalent results in the clinical setting. Results of performance testing has demonstrated that the performance of the Bedside Respiratory Patient Monitoring System has not changed due to the integration of the new PCBA and that the performance of the oximeter is equivalent to that of the primary predicate device.

There are no significant changes to the function or performance of the device other than the expansion in the indications for use to include accuracy in the presence of motion as based upon test methods cleared through K012891 (3/2002).

Usability / Human Factors

Usability of the Bedside Respiratory Patient Monitoring System was evaluated with users in simulated operating environments during original design and testing. These studies consisted of formative and summative studies, which demonstrate the device provides adequate assurance of safety and performance (in regards to human factors/usability aspects) for the patient and operator. No features associated with device usability have changed through design change to the subject device and thus no additional usability testing was performed.

Performance Data

Clinical and non-clinical tests were performed to support the determination of substantial equivalence. Clinical studies were conducted following regulations under Title 21 of the Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions, Part 50 - Protection of Human Subjects and Part 56 Institutional Review Boards.

Non-clinical Summary

Appropriate safety, environmental, performance and functional tests were conducted to ensure that the specifications of the Bedside Respiratory Patient Monitoring System were met.

Verification testing of the performance of the Respiration Rate parameter, when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System and Nellcor™ Respiratory Sensor has been performed. Simulated patient data has been applied to closely mimic clinical free breathing studies on healthy volunteer subjects. Respiration rate accuracy was tested to demonstrate accuracy from 4-40 breaths per minute (BrPM) in the range of 40 -170 beats per minute (BPM) at a fixed O_2 saturation of 97%.

Testing was conducted according to the FDA Guidance documents and consensus standards shown below:

- "Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff" - July 19, 2007
- "Use of Standards in Substantial Equivalence Determinations" – March 12, 2000
- "General principles of Software Validation, Final Guidance for Industry and FDA Staff" – January 11, 2002
- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: ICH Harmonized Tripartite Guideline: Guideline for Good Clinical Practice E6(R1)10 – June 1996
- EN 60601-1:2006- Medical Electrical Equipment - Part 1: General Requirements for Safety and Essential Performance -
- EN 60601-1-4:1999- Medical electrical equipment - Part 1-4 : general requirements for safety - Collateral standard : programmable electrical medical systems
- EN 60601-1-6:2010- Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
- EN 60601-1-8:2006- Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems -
- EN 60601-1-9- Medical electrical equipment Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: requirements for environmentally conscious design
- EN 80601-2-61:2011- Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 60601-1-2: 2007- Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance —Collateral standard: Electromagnetic compatibility — Requirements and tests

Clinical Summary

Clinical testing has been performed on healthy, well perfused adults ranging in skin pigmentation from light to dark, and has demonstrated that the Bedside Respiratory Patient Monitoring System meets the Accuracy Root Mean Square (ARMS), in the 70%-100% SpO_2 range acceptance criteria for both SpO_2 and Pulse Rate in comparison to reference-standard measurements of blood SaO_2 by a CO-Oximeter during motion and non-motion conditions. Testing has also demonstrated accuracy of SpO_2 and Pulse Rate in low saturation conditions and equivalent performance of the Respiration Rate V 1.0 software to that of the cleared predicate.

Clinical validation studies on healthy adult volunteers were conducted to assess the accuracy of the Respiration Rate Software residing on the oximeter. The studies have demonstrated that the accuracy of the Respiration Rate Software algorithm is equivalent to that of the predicate. The studies demonstrated the Respiration Rate Software algorithm calculates respiration rate within a stated accuracy of ± 1 breath per minute, and is shown to be substantially equivalent to the predicate device with respect to Respiration Rate (for adults).

No device related adverse event were observed during the clinical studies.

Substantial Equivalence

In establishing substantial equivalence of the Bedside Respiratory Patient Monitoring System to the predicate devices, Covidien has evaluated the intended use, indications for use, technological characteristics, and elements of risk analysis and risk management. The use of the Bedside Respiratory Patient Monitoring System in patient monitoring environments does not raise any new questions of safety and effectiveness when compared with the predicate devices currently in use.

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

February 04, 2014

Covidien, LLC
Ms. Elizabeth Malo
Senior Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, CO 80301

Re: K130320
Trade/Device Name: Bedside Respiratory Patient Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, BZQ
Dated: November 6, 2013
Received: November 7, 2013

Dear Ms. Malo:

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.

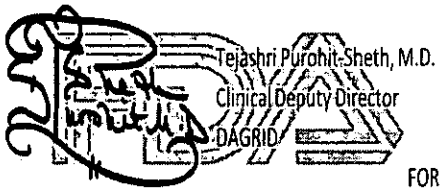
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130320

Device Name: Covidien Nellcor™ Bedside Respiratory Patient Monitoring System and the Covidien Nellcor™ Bedside Respiratory Patient Monitoring System Respiration Rate Software

Indications for Use:

For Covidien Nellcor Bedside Respiratory Patient Monitoring System with Respiration Rate Software:

The Nellcor™ Bedside Respiratory Patient Monitoring System is a portable pulse oximeter intended for prescription use only as a continuous non-invasive monitor of arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport. The OxiMax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The Respiration Rate parameter, when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System and Nellcor™ Respiratory Sensor, is intended for the continuous, non-invasive monitoring of respiration rate in adult patients who are well perfused during no motion conditions, in hospitals and hospital-type facilities.

Prescription Use (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)

K130320

Nayan J. Patel -S
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