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

March 5, 2015

Covidien
Jamie Thomas
Senior Regulatory Affairs Specialist
6135 Gunbarrel Ave.
Boulder, CO 80301

Re: K141518
Trade/Device Name: Nellcor™ Bedside Respiratory Patient Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, BZQ
Dated: January 30, 2015
Received: February 2, 2015

Dear Ms. Thomas,

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141518

Device Name

Nellcor™ Bedside Respiratory Patient Monitoring System

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, provided is the 510(k) summary for the Nellcor™ Bedside Respiratory Patient Monitoring System.

SUBMITTER INFORMATION:

Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Contact:	Jamie Thomas Sr. Regulatory Affairs Specialist
Phone:	303-305-2315
Fax:	303-305-2212

Date of Preparation:	June 6, 2014

DEVICE NAME:

Trade Name(s):	Nellcor™ Bedside Respiratory Patient Monitoring System
Common/Usual Name:	Pulse Oximeter
Classification Names:	Class II, Anesthesiology
CFR Reference:	21 CFR 870.2700
Product Code:	DQA, BZQ

PREDICATE DEVICES:

Covidien Nellcor™ Bedside Respiratory Patient Monitoring System	K121806
Covidien Nellcor™ Bedside Respiratory Patient Monitoring System	K123581
Covidien Nellcor™ Bedside Respiratory Patient Monitoring System	K130320

DEVICE DESCRIPTION:

The subject device is the Nellcor™ Bedside Respiratory Patient Monitoring System (oximeter) which contains the Nellcor™ Respiration Rate Parameter (RR Version 2.0 Application device). The oximeter is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and respiratory rate by use of one of a range of compatible Nellcor OxiMax oxygen transducers (sensors). The oximeter displays digital values of SpO_2 and pulse and respiratory rate. The oximeter device features the same technological characteristics as the predicate, which is the exact same system featuring a system software upgrade.

The oximeter features the optional Nellcor™ Respiration Rate (RR) Software Application for use on the finished oximeter device. Covidien is submitting this traditional 510(k) submission as the result of a design change to the RR software device residing on the oximeter. The design change to the RR Software Application involves a modification to the principles of operation of the RR software algorithm.

The RR software application is intended for continuous non-invasive monitoring of respiration rate in adult patients, and it is calculated by an RR algorithm residing on the monitor which derives patient respiratory rate in breaths per minute based upon oximetry photoplethysmography data that is received from the oximetry sensor on the patient. The software parameter was cleared by the FDA through traditional 510(k) premarket notification (K111933) as the Nellcor Respiration Rate Software, Version 1.0 on March 15, 2012. Version 2.0 (V2.0) of the Respiration Rate (RR) software is an upgraded design of the original cleared software.

INDICATIONS FOR 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 motion and no 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 Nellcor™ Respiration Rate parameter, when used in conjunction with the Nellcor™ Bedside Respiratory Patient Monitoring System and Nellcor™ Adult Respiratory Sensor, is intended for the continuous, non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

TECHNOLOGICAL CHARACTERISTICS SUMMARY & SUBSTANTIAL EQUIVALENCE STATEMENT:

The subject device, is the Nellcor™ Bedside Respiratory Patient Monitoring System (oximeter) which contains the Nellcor™ Respiration Rate Software Version 2.0 Application (RR software device), has the same intended use (Adults), general design (continuous, non-invasive indication of respiration rate) and fundamental scientific technology (indicator of central ventilatory drive) as the predicate device Nellcor™ Bedside Respiratory Patient Monitoring System K130320, K123581 and K121806.

The Respiration Rate Software uses photoplethysmography to calculate respiration rate, both of which are indicators of central ventilator drive. The respiration rate measurement range for the Respiration Rate Software is 4-40 breaths/minute, and is indicated for adults only. Both the subject and predicate devices have an accuracy of ±1 breaths/minute for the adult population.

PERFORMANCE DATA SUMMARY:

Non-clinical performance data summary

The appropriate safety, environmental, performance and functional testing was conducted to ensure that the specifications of the Nellcor Respiration Rate Software and Nellcor™ Adult Respiratory Sensor were met.

The performance testing section of this submission includes verification and validation reports for pulse oximetry performance in accordance with FDA Guidance document: “Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff”. Non-clinical testing in this submission includes, but is not limited to, ISO 80601-2-61:2011 and IEC 60601-1:2005 test reports, Oximetry performance verification, Human Factors Summative Usability validation, testing incorporating simulated motion performed to validate pulse rate accuracy across the operating

range of 20 to 250 beats per minute, and testing incorporating simulated motion performed to validate respiration rate accuracy across the operating range of 4 to 40 breaths per minute.

The simulated motion data used to assess respiration rate performance was collected from monitored patients on the general care floor which represents the intended populations and includes extreme boundaries of patient characteristics and artifact. Specifically, this simulation assesses respiration rate accuracy in the presence of motion artifact under conditions of low pulse rate (5th percentile) and low perfusion (5th percentile) and low respiratory variations for all of frequency, amplitude and baseline modulations (all 10th percentile) and validates the respiration rate accuracy across the range of 4 to 40 breaths per minute.

The results of this testing demonstrate that the Nellcor™ Bedside Respiratory Patient Monitoring System has a respiration rate measurement range of 4 to 40 breaths per minute with an accuracy of ±1 breath per minute, and is substantially equivalent to the predicate device with respect to Respiration Rate (for adults).

Clinical Summary

Clinical validation studies on healthy adult volunteers and on subjects from the hospital general care floor were conducted to assess the accuracy of the Respiration Rate Software algorithm. The studies demonstrated the accuracy of the Respiration Rate Software algorithm was as good as the predicate. The studies demonstrated the Respiration Rate Software algorithm calculates respiration rate within a stated accuracy of ±1 breath per minute over a range of 4-32 breaths per minute and is shown to be substantially equivalent to the predicate device.

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

Conclusions

The information provided in this 510(k) demonstrates the Nellcor™ Bedside Respiratory Patient Monitoring System is substantially equivalent to the predicate devices with respect to performance.