MAY 9 2013

K123581

3. 510(K) SUMMARY

Applicant Name and Address:	Covidien llc. 6135 Gunbarrel Ave Boulder, CO 80301 Phone: (303) 305-2750 Fax: (303) 305-2212
Establishment Registration Number:	2936999
Device Name(s):	**OxiMax N-600X Pulse Oximeter with OxiMax Sensors and Cables (aka "Accessories")**
	Covidien Nellcor Bedside SpO_2 Patient Monitoring System
	Covidien Nellcor Bedside Respiratory Patient Monitoring System
Classification:	Class II
Classification Name:	Oximeter (74DQA) (per 21 CFR §870.2700)
Product Code:	DQA
Date Prepared:	11/27/2012
510(k) Contact Person and Phone Number:	Mia M. Ware Sr. Regulatory Affairs Specialist Covidien - Respiratory and Monitoring Solutions 6135 Gunbarrel Ave. Boulder, CO 80301 Phone: (303)305-2750 Fax: (303) 305-2212
Name and Address of Manufacturing Site(s)	
Establishment Registration Number:	8020893
Registered Establishment Name:	Covidien (formerly: Nellcor Puritan Bennett Ireland, Ltd)
Address:	Michael Collins Road, Mervue, Galway, IRELAND
Establishment Registration Number:	30003591740
Registered Establishment Name:	Mediana Co. LTD
Address:	Wonju Medical Industry Park, 1650-1, Donghwa-ri, Munmak-eup, Wonju-si, Gangwon-do, Korea

Predicate Devices:
The Nellcor OxiMax N-600X Pulse Oximeter, Nellcor Bedside SpO_2 Patient Monitoring System, and Nellcor Bedside Respiratory Patient Monitoring System claim to be substantially equivalent to the following legally marketed predicate device:

1. Nellcor Puritan Bennett Model N-595 Pulse Oximeter, cleared under 510(k) # K012891 on 03/07/2002.

Purpose of this 510(k):

This submission is to expand the indications for use for the OxiMAX pulse oximeters using the Nell-1 oximetry board (including the N-600X, Nellcor Bedside Respiratory Patient Monitoring System, and Nellcor Bedside SpO_2 Patient Monitoring System) to include SpO_2 and Pulse Rate accuracy during motion and no motion conditions.

Summaries of clinical and non-clinical testing were provided to support 1) the expansion in the indications for use to include accuracy in the presence of motion, and 2) modifications to the device(s) labeling to incorporate the results of clinical trials described in peer-reviewed publications regarding the use of Nellcor pulse oximeters and sensors intended to screen newborn patients for critical congenital heart disease (CCHD). FDA Guidance for Industry and FDA Staff - Bundling Multiple Devices or Multiple Indications in a Single Submission was used in the preparation of this Traditional 510(k) submission.

General Description:

The OxiMAX family of pulse oximeters (including the N-600X, Nellcor Bedside Respiratory Patient Monitoring System, and Nellcor Bedside SpO_2 Patient Monitoring System) provides continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.
The N-600X, Nellcor Bedside Respiratory Patient Monitoring System, and Nellcor Bedside SpO_2 Patient Monitoring System are designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate using OxiMAX pulse oximetry sensors and the DOC-10 cable.

Current N-600X Indications for Use (cleared via K083325 on 03/09/2009):

The N600x Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

The N-600X Pulse Oximeter is intended for use with neonatal, pediatric, and adult patients, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments.

The N-600X with SPD feature is intended for use on adults to detect patterns of desaturation that are indicative of repetitive reductions in airflow through the upper airway and in to the lungs.

Current Nellcor Bedside Respiratory Patient Monitoring System Indications for Use (cleared via K121806 on 09/28/2012) :

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 (SpO_2) and pulse rate of adult, pediatric, and neonatal patients 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 to be used for the continuous non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

Current Nellcor Bedside SpO_2 Patient Monitoring System Indications for Use (cleared via K120773 on 06/10/2012):

The Nellcor Bedside SpO_2 Patient Monitoring System is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Nellcor Bedside SpO_2 Patient Monitoring System is intended for prescription use only with neonatal, pediatric, and adult patients, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, and intra-hospital transport.

Proposed N-600X Indications for Use:

The Nellcor OxiMAX N-600X Pulse Oximetry System with N-600X Pulse Oximeter and OxiMAX Sensors and Cables is indicated for prescription use only for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-600X Pulse Oximeter is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, intra hospital transport, and home environments.

The N-600X with SPD feature is intended for use on adults to detect patterns of desaturation that are indicative of repetitive reductions in airflow through the upper airway and into the lungs.

Proposed Nellcor Bedside Respiratory Patient Monitoring System 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 (SpO_2) 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 to be used for the continuous non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

Proposed Nellcor Bedside SpO_2 Patient Monitoring System Indications for Use:

The Nellcor Bedside SpO_2 Patient Monitoring System is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Nellcor Bedside SpO_2 Patient Monitoring System is intended for prescription use only with neonatal, pediatric, and adult patients, during both no motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, and intra-hospital transport.

Summary of Technical Characteristics

The Nellcor Bedside Respiratory Patient Monitoring System, Bedside SpO_2 Patient Monitoring System and the OxiMAX N-600X Pulse Oximetry System, the Nell-1 family of pulse oximeters, are technologically identical. They have the same oximetry PCBA and software. This submission includes clinical data and clinical reports to expand the indications for use and labeling claims for the Nell-1 pulse oximeters. The N-600X Pulse Oximetry System, the representative model of the Nell-1 family of pulse oximeters, is substantially equivalent to the N-595 Pulse Oximeter, the predicate device in this submission, as evidenced in 510(k) K060576. The test method used to demonstrate performance during motion as described in the motion testing Clinical Trial Protocol uses the same definition of standard motion as was used in the invasive hypoxia clinical study which validated the accuracy in the presence of motion of the N-595 Pulse Oximeter, the predicate device. Based on the results of the studies, Covidien has established that the Nell-1 family of pulse oximeters including N-600X, Nellcor Bedside Respiratory Patient Monitoring System, and Nellcor Bedside SpO_2 Patient Monitoring Systems, are substantially equivalent to the predicate device.

Tests Performed to Support Determination of Substantial Equivalence

Non-clinical/bench-testing data

The performance testing section of this submission references the previous **Non-clinical data** submitted in previously cleared 510(k)s K060576, K120773, and K121806. Additional testing incorporating simulated motion performed to validate the pulse rate accuracy of N-600X in the range of 25 -250 beats per minute during motion using a functional tester, is provided for review.

Discussion of clinical data

Device Description:

In order to support this claims expansion, Covidien performed an invasive hypoxia study on healthy, well perfused adults using the N-600X as the representative for the Nell-1 family of pulse oximeters including N-600X, Nellcor Bedside Respiratory Patient Monitoring System, and Nellcor Bedside SpO2 Patient Monitoring Systems. In accordance to ISO 80601-2-61, an invasive hypoxia study was carried on healthy, well-perfused adults. Data was collected at targeted oxygen saturation plateaus during periods of motion. The SpO2 data was compared against SaO2 values from a CO-Oximeter. Pulse rate data was compared against ECG values.

Sensors Tested:

Performance claims during motion was demonstrated on the OxiMAX sensors, the same sensors as submitted and cleared in the 510(k) for the N-595 pulse oximeter,

Study Results and Adverse Events:

The Nell-1 family of pulse oximeters, including N-600X, Nellcor Bedside Respiratory Patient Monitoring System, and Nellcor Bedside SpO_2 Patient Monitoring Systems has been validated for accuracy in the presence of motion in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-oximeter and ECG monitor. There were no adverse events or complications observed in the invasive hypoxia studies.

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

May 09, 2013

Ms. Mia M. Ware
Senior Regulatory Affairs Specialist
Covidien Limited Liability Company
6135 Gunbarrel Avenue
BOULDER CO 80301

Re: K123581
Trade/Device Name: Nellcor OxiMAX N-600X Pulse Oximetry System
Nellcor Bedside SpO_2 Patient Monitoring System
Covidien Nellcor Bedside Respiratory Patient Monitoring System and
The Covidien Nellcor Bedside Respiratory Patient Monitoring
System Respiration Rate Software
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 10, 2013
Received: April 11, 2013

Dear Ms. Ware:

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,

Kwame O. Ulmer -S FDA for

Anthony D. Watson, B.S., M.S., M.B.A.
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

510(k) Number: K123581

Device Name: Nellcor OxiMAX N-600X Pulse Oximetry System

Indications for Use:

The Nellcor OxiMAX N-600X Pulse Oximetry System with N-600X Pulse Oximeter and OxiMAX Sensors and Cables is indicated for prescription use only for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-600X Pulse Oximeter is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, intra hospital transport, and home environments.

The N-600X with SPD feature is intended for use on adults to detect patterns of desaturation that are indicative of repetitive reductions in airflow through the upper airway and into the lungs.

Prescription Use___X___ AND/OR Over-the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K123581

Indications for Use

510(k) Number: K123581

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 (SpO_2) 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 to be used for the continuous non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

Prescription Use___X___ AND/OR Over-the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

510(k) Number: K123581

Indications for Use

510(k) Number: K123581

Device Name: Nellcor Bedside SpO_2 Patient Monitoring System

Indications for Use:

The Nellcor Bedside SpO_2 Patient Monitoring System is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Nellcor Bedside SpO_2 Patient Monitoring System is intended for prescription use only with neonatal, pediatric, and adult patients, during both no motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, and intra-hospital transport.

Note:

- Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital type facilities.
- Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.
- Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

Prescription Use___X___ AND/OR Over-the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123581