DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 2, 2014

Covidien
Ms. Mia Ware
Senior Regulatory Affairs Product Specialist
6135 Gunbarrel Ave.
Boulder, CO 80301

Re: K141542
Trade/Device Name: Nellcor Portable SpO_2 Patient Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 28, 2014
Received: September 4, 2014

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 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" (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 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)*

K141542

Device Name
Nellcor™ Portable SpO_2 Patient Monitoring System

Indications for Use *(Describe)*
The Nellcor Portable SpO_2 Patient Monitoring System is indicated for prescription use only for spot check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It 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, mobile, and home environments.

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.

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510(K) SUMMARY

Applicant Name and Address:	Covidien LP. 6135 Gunbarrel Ave Boulder, CO 80301 Phone: (303) 305-2750 Fax: (303) 305-2212
Establishment Registration Number:	2936999
Device Name(s):	**Nellcor™ Portable SpO_2 Patient Monitoring System**
Classification:	Class II
Classification Name:	Oximeter (74DQA) (per 21 CFR §870.2700)
Product Code:	DQA
Date Prepared:	06/09/2014
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:	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 predicate device(s) to which the Nellcor™ Portable SpO_2 Patient Monitoring System is claiming substantial equivalence are as follows:

Trade Name:	OxiMAX NPB-40 Pulse Oximeter	N-600X Pulse Oximeter
510(k) Number:	K051352 (cleared on 8/11/05)	K123581 (cleared on 05/09/2013)
Applicant:	Nellcor Puritan Bennett, Incorporated	Covidien LP
	4280 Hacienda Drive Pleasanton, CA 94588-8604	6135 Gunbarrel Ave Boulder, CO 80301

Purpose of this 510(k):

This 510(k) submission is to obtain market clearance for the Nellcor Portable SpO_2 Patient Monitoring System, a line extension of the Nellcor pulse oximeters with OxiMAX technology.

General Description:

The Nellcor Portable SpO_2 Patient Monitoring System is a modification of the OxiMax NPB-40 and N-600X Pulse Oximetry Systems. It is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate using Nellcor pulse oximetry sensors with OxiMAX technology, and the oximetry sensor cable. The monitor displays digital values of SpO_2 and Pulse Rate. Pulse Amplitude is displayed by means of a "blip bar" presentation or plethysmographic waveform. The Nellcor Portable SpO_2 Patient Monitoring System is powered by four AA batteries.

Proposed Nellcor Portable SpO_2 Patient Monitoring System Indications for Use:

The Nellcor Portable SpO_2 Patient Monitoring System is indicated for prescription use only for spot check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It 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, mobile, and home environments.

Summary of Technical Characteristics

The Nellcor Portable SpO2 Patient Monitoring System is a line extension of the Nell-1 family of pulse oximeters. It is technologically identical to the predicate devices. It has the same oximetry PCBA and software as N-600X and has the same hand-held portable form factor and performs within the same specifications as the NPB-40. The clinical performance when used with adult, pediatric and neonatal patients is the same as in the N-600X pulse oximeter and was established with that oximeter in K060576 and K123581. The Nellcor Portable SpO2 Patient Monitoring System is intended to be used with the same Nellcor SpO2 sensors that are commercially available and used with the predicate devices. Based on the results of the non-clinical validation studies, Covidien has established that the Nellcor Portable SpO2 Patient Monitoring System is substantially equivalent to the predicate devices.

Non-clinical/bench-testing data

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, and testing incorporating simulated motion performed to validate the pulse rate accuracy of in the range of 20 -250 beats per minute during motion using a functional tester.

Discussion of clinical data

Clinical data submitted in K060576, and K123581 is applicable to the Nellcor Portable SpO_2 Patient Monitoring System. Because there are no changes to the performance, technology, and intended use of the device, the clinical data submitted as part of the premarket notifications for the predicate devices also applies to the Nellcor Portable SpO_2 Patient Monitoring System.

Conclusions

The technological characteristics of the Nellcor Portable SpO_2 Patient Monitoring System and the results of non-clinical and clinical tests do not raise new questions of safety or effectiveness when compared to the legally marketed predicate devices.