December 15, 2017

Covidien
Mia Carroll
Principal Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K172482
Trade/Device Name: Nellcor™ USB Pulse Oximetry Monitor Interface Cable
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 15, 2017
Received: August 16, 2017

Dear Mia Carroll:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tara A. Ryan -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

005_Indications for Use

510(k) Number: K172482

Device Name: Nellcor™ USB Pulse Oximetry Monitor Interface Cable

Indications for Use:

The Nellcor™ USB Pulse Oximetry Monitor Interface Cable is indicated for prescription use only for spot check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) 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 and hospital-type facilities.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

006_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™ USB Pulse Oximetry Monitor Interface Cable
Classification:	Class II
Classification Name:	Oximeter (74DQA) (per 21 CFR §870.2700)
Product Code:	DQA
Date Prepared:	06/30/2017
510(k) Contact Person and Phone Number:	Mia M. Carroll Principal 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: **Registered Establishment Name:** **Address:**	Registration Number: 3026961 TYCO ELECTRONICS 10025 S.W. Freeman Court Wilsonville , OR 97070

Predicate Devices:

The predicate device(s) to which the Nellcor™ USB Pulse Oximetry Monitor Interface Cable is claiming substantial equivalence are as follows:

Trade Name:	N-600X Pulse Oximeter
510(k) Number:	K141518 (cleared on 05/09/2013)
Applicant:	Covidien LP
	6135 Gunbarrel Ave Boulder, CO 80301

Purpose of this 510(k):

This 510(k) submission is to obtain market clearance for the Nellcor™ USB Pulse Oximetry Monitor Interface Cable, a line extension of the Nellcor pulse oximeters with OxiMAX technology.

General Description of Subject Device:

The Nellcor™ USB Pulse Oximetry Monitor Interface Cable is a modification of the OxiMax N-600X Pulse Oximetry Systems. When connected to a qualified host display monitor, 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. The cable provides digital values of SpO_2 and Pulse Rate, which are displayed on the host monitor. Pulse Amplitude is displayed by means of a "blip bar" presentation or plethysmographic waveform. The Nellcor™ USB Pulse Oximetry Monitor Interface Cable is connected via USB2 and is powered by the host monitor.

Mechanism of Action for the Nellcor USB Pulse Oximetry Monitor Interface Cable

The Nellcor™ USB Pulse Oximetry Monitor Interface Cable (the "monitoring cable") is a cable with Oximetry PCBA "engine" embedded in the sensor connector to provide external Oximetry-in-the-cable solution for devices with USB connectivity. The cable uses pulse oximetry to measure functional oxygen saturation in the blood. The cable is powered by and achieves its mechanism of action through connection to a host system. To connect the monitoring cable to a host monitoring system, insert the monitoring cable's USB connector into a compatible USB port on the host system. Then connect the Nellcor SpO2 sensor to the port in the sensor connector end of the cable.

Principle of Operation for the Nellcor USB Pulse Oximetry Monitor Interface Cable

Pulse oximetry is based on two physical principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography). A monitoring system determines SpO2 by passing red and infrared light into a vascular bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the sensor serve as light sources; a photo diode serves as the photo detector.

Since oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. The monitoring cable uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitoring cable bases its SpO2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of non-pulsatile absorbers such as tissue, bone, and venous blood.

Power

The cable is powered by USB connection to a compatible host monitor.

Standards used for performance testing include:

Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
1-85	ISO	80601-2-61 First edition 2011-04-01	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
2-156	AAMI ANSI ISO	10993-1:2009/(R)2013	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
19-8	IEC	60601-1-2 Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
19-4	AAMI ANSI	ES60601-1:2005/(R)2012 and A1:2012,	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
19-1	IEC	60601-1-2 Edition 3: 2007-03	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
5-89	IEC	60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5-76	IEC	60601-1-8 Edition 2.1 2012-11	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

13-79	IEC	62304 Edition 1.1 2015-06	Medical device software - Software life cycle processes
5-40	ISO	14971 Second edition 2007-03-01	Medical devices - Application of risk management to medical devices
5-90	ISO	15223-1 Second Edition 2012-07-01	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
5-116	ISO	7010 Second edition 2011-06-01	Graphical symbols - Safety colours and safety signs - Registered safety signs [Including AMENDMENT 1 (2012) through AMENDMENT 7 (2016)]

Biocompatibility Testing

The Nellcor™ USB Pulse Oximetry Monitor Interface Cable could have incidental contact with the patient during monitoring. Because of this, the following Biocompatibility testing was performed and is included in report RE00094646:
- cytotoxicity test per ISO 10993-5:2009
- Skin Irritation and Skin Sensitization Test per ISO 10993-10:2009.

Software and Electrical components of the subject device:

Functionally, the Nellcor USB Pulse Oximetry Monitor Interface Cable consists of the following electrical subsystems:
- USB Connector Cable to Host
- Isolation module
- SpO2 Module - measures the oxygen saturation and contains pulse oximetry software.

Host Monitoring System Requirements:

The monitoring cable provides oximetry reporting to any host monitoring system that provides the following features:
- USB Standard A female receptacle supporting USB 2.0 Full-Speed
- Operating system compatible with the monitoring cable's Client-Side Virtual COM Port Driver
- User interface software that can update the displayed monitoring cable information
- User interface software providing a GUI to display SpO2 and pulse rate as reported by the monitoring cable
- User interface software providing a GUI that allows a user to send commands to the monitoring cable

The technological characteristics of the subject device compared to the predicate device that demonstrates substantial equivalence:

Name/510(K) Number	**Subject Device: Nellcor USB Pulse Oximetry Monitor Interface Cable** **K172482**	**Predicate Device: Nellcor OxiMAX N-600X Pulse Oximeter with SPD** **K141518**	**Impact of Differences**
Characteristics			
Web site	www.nellcor.com	www.nellcor.com	N/A
Indication for use	The Nellcor™ USB Pulse Oximetry Monitor Interface Cable is indicated for prescription use only for spot check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) 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 and hospital-type facilities.	The Nellcor OxiMAX N-600X Pulse Oximetry System 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.	The indication for use for the subject device is limited within the use of the predicate device. The Nellcor™ USB Pulse Oximetry Monitor Interface Cable doesn't include mobile transport (EMS) and home environments in the indicated areas of use.
Environment of Use	Hospitals, hospital-type facilities.	Same	N/A
Measurement parameter	Oxygen saturation, Pulse rate	Same	N/A
Sensor compatibility	Use only Nellcor-approved sensors	Same	N/A
Intended Patient Population	Adult, Pediatric, Neonate	Same	N/A
Performance Specifications			
SpO_2 Technology	Spectrophotometry and plethysmography	Same	N/A
SpO_2 Algorithm	Comparison of red/infrared modulation %	Same	N/A

Name/510(K) Number	**Subject Device: Nellcor USB Pulse Oximetry Monitor Interface Cable** **K172482**	**Predicate Device: Nellcor OxiMAX N-600X Pulse Oximeter with SPD** **K141518**	**Impact of Differences**
Characteristics			
SpO_2 measurement range (%)	1% to 100% (Requirement and testing is done at 0 to 100%).	Same	N/A
SpO_2 measurement accuracy specification			
• Without motion – Adults	70-100% ±2 digits	Same	N/A
• Without motion - Neonates	70-100% ±2 digits	Same	N/A
• With motion – Adults, Neonates	70-100% ±3 digits	Same	N/A
• Low Perfusion	70-100% ±2 digits	Same	N/A
• LoSat	60% to 80%±3 digits	Same	
Pulse rate measurement range(BPM) and accuracy			
• Without Motion (Adult and Neonate)	20 to 250 BPM ±3 digits	Same	N/A
• With Motion	20 to 250 BPM ±5 digits	Same	N/A
• Low Perfusion	20 to 250 bpm ±3 digits	Same	N/A
Compliance	ISO 80601-2-61:2011	ISO9919:2005	No impact to substantial equivalence because the ISO 80601-2-61:2011 standard has superseded ISO9919:2005 since 2011 and is the current FDA recognized pulse oximetry particular standard.

Summary of Technical Characteristics

The Nellcor™ USB Pulse Oximetry Monitor Interface Cable is a line extension of the Nellcor family of pulse oximeters. It is technologically identical to the predicate devices. It has the same oximetry software and performs within the same specifications as N-600X. The clinical performance when used with adult, pediatric and neonatal patients meets the same acceptance criteria as in the N-600X pulse oximeter clinical evaluations submitted in K060576 and K141518. The Nellcor™ USB Pulse Oximetry Monitor Interface Cable is intended to be used with the same Nellcor SpO2 sensors that are

commercially available and used with the predicate device. Based on the results of the non-clinical validation studies, Covidien has established that the Nellcor™ USB Pulse Oximetry Monitor Interface Cable 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 in low perfusion conditions, Host connectivity and performance verification, Human Factors Summative Usability validation, and testing incorporating simulated motion performed to validate the pulse rate accuracy across the measurement range during motion.

Discussion of clinical data

Prospective Clinical data is submitted in *Section 021_Performance Testing - Clinical* for the Nellcor™ USB Pulse Oximetry Monitor Interface Cable. Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia blood studies spanning the 60-100% saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a diverse range of skin pigmentations. Pulse oximeter SpO2 readings were compared to SaO2 values of drawn blood samples measured by hemoximetry. Data from 12 healthy volunteers were included in the analysis. SpO2 values were continuously recorded from each instrument while inspired oxygen was controlled to produce five steady state plateaus at target saturations. Arterial blood samples are periodically taken from an indwelling arterial catheter at each plateau resulting in a total of approximately 30 samples per subject. Each arterial sample is drawn while SpO2 data were simultaneously collected and marked for direct comparison to reference-standard measurements of blood SaO2 by a CO-oximeter. End tidal CO2, respiratory rate, and respiratory pattern were continuously monitored throughout the study through CO2 sampling line connected to the patient monitor.

Motion performance was validated during a controlled hypoxia blood study over an SaO2 span of 70% to 98.9%. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. All accuracies are expressed as ±1 SD.

Conclusions

The technological characteristics of the Nellcor™ USB Pulse Oximetry Monitor Interface Cable 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.

-End of Section 006_510(k) Summary-