K083825

510(k) Summary

Submitted by:	Covidien, (formerly Nellcor Puritan Bennett Inc.) 6135 Gunbarrel Avenue Boulder, CO 80301
Company Contact:	Scott Dickerhoff Director, Regulatory Affairs Phone: (303) 305-2382 Fax: (303) 305-2212
Date Summary Prepared:	November 3, 2008
Trade Name:	OxiMax N-600x Pulse Oximeter with SPD
Common/Usual Name:	Pulse Oximeter, Sensors and Cables
Classification Name:	Oximeter (74DQA) (per 21 CFR §870.2700) Patient Transducer and Electrode Cable (including connector) (74DSA) (per 21 CFR §870.2900)
Substantially Equivalent Devices:	1. OxiMax Pulse Oximetry System with N-600x Pulse Oximeter, K060576 2. Lifescreen Apnea, K042745

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I. Device Description

This section describes the N-600x Pulse Oximeter with SPD. The N-600x with SPD is comprised of the N-600x Pulse Oximeter with SPD software and a variety of OxiMax Adult Sensors and cables that have been previously cleared.

The Saturation Pattern Detection (SPD) is a software option which is compatible with the N-600x. The software option is intended to add an advanced SpO2 trend analysis feature. SPD will detect patterns in the saturation trend that are associated with a reduction in airflow and provide annunciation. The SPD feature mines information that is present in the SpO2 trend history stored in the monitor and alerts the caregiver to patterns in that trend. The SPD feature is a means of evaluating the SpO2 information being collected by the oximeter, analogous to the threshold or SatSeconds™ alarm features currently available on the predicate device. The addition of the SPD feature to the predicate device does not affect the device hardware.

II. Intended Use

The *OxiMax N-600x* pulse oximeter is intended for prescription use only with neonatal, pediatric, and adult patients who are well or poorly perfused in hospitals, hospital-type facilities, intra-hospital transport, and home environments. The saturation pattern detection with OXIMAX™ SPD™ technology (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.

III. Technological Characteristics

The OxiMax Pulse Oximetry System measures functional oxygen saturation non-invasively via a light signal interacting with tissue, by utilizing the time-varying changes in tissue optical properties that occur with pulsatile blood flow. Red and infrared light-emitting diodes (LEDs) are utilized as light sources. A photodiode acting as a photodetector senses the signal strengths of the two wavelengths of light, which vary with the amount of light transmitted through the tissue. The N-600x Pulse Oximeter receives this electrical information from the sensor and processes the information by use of an algorithm to provide real time values of SpO2, pulse rate and pulse amplitude.

IV. Tests Performed to Support Determination of Substantial Equivalence

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.

V. Conclusions

The technological characteristics of the OxiMax N-600x Pulse Oximetry System with SPD 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Scott D. Dickerhoff
Director, Regulatory Affairs
Covidien
6135 Gunbarrel Avenue
Boulder, Colorado 80301

MAR - 9 2009

Re: K083325
Trade/Device Name: N-600x Pulse Oximeter with Oximax SPD™ Alert
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 20, 2009
Received: February 23, 2009

Dear Mr. Dickerhoff:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number:

Device Name: N-600x Pulse Oximeter with Oximax SPD™ Alert

Indications for Use:

The N600x Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) 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.

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)

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

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