K060576

AUG 14 2006

510(k) Summary

Submitted by:	Nellcor Puritan Bennett Incorporated 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	Patrick Garvey Regulatory Affairs Manager Phone: (925) 463-4479 Fax: (925) 463-4020
Date Summary Prepared:	October 10, 2005
Trade Name:	OxiMax Pulse Oximetry System with N-600x Pulse Oximeter and OxiMax Sensors and Cables (aka "Accessories")
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. Nellcor OxiMax Pulse Oximetry System with N-595 Pulse Oximeter, 510(k) #K012891 2. Nellcor N-200 Pulse Oximeter, 510(k) #K863784 & K022819

I. Device Description

The OxiMax N-600x Pulse Oximeter is a modification OxiMax Pulse Oximetry System with N-595 Pulse Oximeter and OxiMax Sensors and Cables. The N-600x is 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. The N-600x Pulse Oximeter displays digital values of SpO_2 and Pulse Rate. Pulse Amplitude is displayed by means of a "blip bar" presentation or plethysmographic waveform. The N-600x can be powered by an internal power supply operating on AC from a standard electrical utility receptacle (manually switchable from 115V to 230V) or alternatively by an internal 6V rechargeable sealed lead-acid battery. The OxiMax N-600x Pulse Oximeter is intended for prescription use with adult, pediatric and neonatal patients in hospitals, hospital-type facilities, intra-hospital transport, and home environments.

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Audible and visual alarms for high/low saturation, pulse rate and pulse search are provided. The N-600x Pulse Oximeter also includes adjustable alarm silence duration and other configurable power-on settings. The N-600x provides a back-up piezo alarm that sounds if a high-level audible alarm has not been responded to within 45 seconds. The piezo alarm will also activate in the event of a primary alarm failure. The N-600x provides an audible low battery warning to alert the user of impending loss of power and consequent loss of monitoring capability. The N-600x Pulse Oximeter has visual indicators for pulse search, interference, power mode (i.e., battery or AC), alarm silence and alarm features. There is also a serial port (EIA-232 and RS-422 interface) that provides ASCII output of real-time data. Via the serial port, the N-600x interfaces with selected multiparameter monitors.

The Nellcor pulse oximetry cable, Model DOC-10, links individual OxiMax sensors to the N-600x Pulse Oximeter. The N-600x and DOC-10 are intended for use only with the OxiMax family of sensors. These OxiMax sensors each contain a memory chip carrying information about the sensor which the oximeter needs for correct operation, including in-sensor data, Advanced Signal Evaluation, lot code and data set revision, and sensor model. These OxiMax sensors include the following models: OxiMax MAX-A, MAX-AL, MAX-P, MAX-I, MAX-N, MAX-R, MAX-FAST, OxiCliq-A, OxiCliq-P, OxiCliq-I, OxiCliq-N, DS-100A, D-YS, D-YSE, D-YSPD, SC-A, SC-NEO, SC-PR, OXI-A/N, OXI-P/I, and NeoMax.

II. Intended Use

The Nellcor OxiMax Pulse Oximeter N-600x is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate.

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 SpO_2, pulse rate and pulse amplitude.

OxiMax technology encompasses:

- OxiMax Advanced Digital Signal Processing for reading through motion artifact and low perfusion
- Advanced Signal Evaluation providing the user information on sensor placement
- SatSeconds Alarm Management
- OxiMax Sensor Technology, including in-sensor data, allows the N-600x to write data to and read data from OxiMax adhesive sensors

The N-600x uses SpO2 and Pulse Rate software algorithms, interference-filtering software, and SatSeconds alarm management similar to the software in the legally

marketed predicate device cleared under K012891, with minor changes that do not raise new questions of safety or efficacy.

The Nellcor brand sensors containing OxiMax technology are compatible with the N-600x, other Nellcor oximeters and instruments containing Nellcor OxiMax oximetry, or with instruments licensed to use Nellcor sensors (Nellcor-compatible instruments). OxiMax Sensor Technology, including in-sensor data, allows the N-600x to write data to and read data from OxiMax adhesive sensors allowing patient history, namely SpO2 and pulse rate alarm events, to travel with the patient, and enabling quick patient assessment upon transfer to a new point of care. The N-600x provides on-screen viewing of in-sensor patient data including SpO2 and pulse rate trend of events.

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 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. Patrick Garvey
Regulatory Affairs Manager
Nellcor Puritan Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, California 94588-2719

Re: K060576
Trade/Device Name: The Nellcor® OxiMax® N-600x Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 7, 2006
Received: August 8, 2006

Dear Mr. Garvey:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Chiu Lin, Ph.D.
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 (if known): _____

Device Name: The Nellcor® OxiMax® N-600x Pulse Oximeter

Indications For Use:

The Nellcor OxiMax N-600x Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The Nellcor OxiMax 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. For prescription use only

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Nichol for Ann Graham

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

510(k) Number K060576

(Optional Format 3-10-98)

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