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K052186

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Healthcare

Nellcor

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510(k) Summary

Submitted by:	Nellcor Puritan Bennett, Inc. 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	James Patrick Garvey II, RRT, RAC Regulatory Affairs Manager (925) 463-4479 - Phone (925) 463-4020 - FAX
Date Summary Prepared:	July 5, 2005
Product Name:	Nellcor OxiMax Pulse Oximetry Sensors, models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST
Common Name:	Oxygen Sensor
Classification:	Patient Transducer and Electrode Cable (including connector) (74DQA) per 21CFR §870.2700
Legally Marketed (Unmodified) Device:	Nellcor OxiMax Pulse Oximetry Sensors, models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST (cleared via K012891, March 07, 2002 and K021089, June 19, 2002)

DEVICE DESCRIPTION

Nellcor OxiMax Pulse Oximetry Sensors, models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST are designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate in conjunction with a Nellcor pulse oximeter. Nellcor OxiMax Pulse Oximetry Sensors, models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST are intended for prescription use with adult, pediatric and neonatal patients in hospitals, hospital-type facilities, intra-hospital transport, and home environments.

These OxiMax sensors each contain a memory chip carrying information about the sensor which the oximeter needs for correct operation including sensor model, Advanced Signal Evaluation, and data set revision. The memory chip is also cable of storing including in-sensor data when connected to an OxiMax-capable monitor, and lot code.

INTENDED USE

The OxiMax Pulse Oximetry System is indicated for the 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, hospital-type facilities, intra-hospital transport, and home environments. These devices are for prescription use only.

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 photo detector senses the signal strengths of the two wavelengths of light, which vary with the amount of light transmitted through the tissue. The 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.

Nellcor brand sensors containing OxiMax technology are compatible with the N-595, other Nellcor oximeters and instruments containing Nellcor oximetry, or with instruments licensed to use Nellcor sensors (Nellcor-compatible instruments). OxiMax Sensor Technology, including in-sensor data, allows OxiMax-cable oximeters 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.

TESTS PERFORMED TO SUPPORT DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Clinical tests were performed to support accuracy specifications for SpO2 performance. 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.

CONCLUSION

The device characteristics and results of clinical testing demonstrate that the revision to the labeling does 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

NOV 10 2005

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

Re: K052186
Trade/Device Name: Nellcor® OxiMax® Pulse Oximetry Sensors, Models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-1 and MAX-FAST
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: October 14, 2005
Received: October 17, 2005

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.

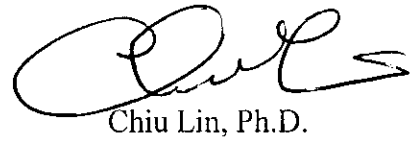
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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: OxiMax Pulse Oximetry Sensors, models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST

Indications For Use:

The Nellcor OxiMax Pulse Oximetry Sensors, models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST are indicated for single patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients in the sizes indicated in the respective sensor directions for use.

Prescription Use: Yes (per 21 CFR 801.109)

(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
(ODE) Number: K052186