tyco
Healthcare

Nellcor
Puritan Bennett

4280 Hacienda Drive
Pleasanton, CA 94588-2719

Tele: 925 463-4000
Fax: 925 463-4420

MAR 7 2002

K012891

510(k) Summary

Submitted by:	Nellcor Puritan Bennett Incorporated 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	Ronald J. Ehmsen, Sc.D. Senior Director, Regulatory Affairs Respiratory Division, Tyco Healthcare Group (925) 463-4371 FAX (925) 463-4020
Date Summary Prepared:	August 27, 2001
Trade Name:	OxiMAX Pulse Oximetry System with N-595 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 Puritan Bennett Inc. N-395 Pulse Oximeter, 510(k) #K991823 2. Nellcor Puritan Bennett Inc. N-395 Pulse Oximeter, With Extended Device Claims, 510(k) #K993637 3. Nellcor Inc. Reflectance Sensor (RS-10), 510(k) #K904039 4. Nellcor N-20PA Portable Pulse Oximeter, 510(k) #K952222

I. Device Description

The OxiMAX Pulse Oximetry System is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by use of one of a range of compatible Nellcor OxiMAX oxygen transducers (sensors). The N-595 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-595 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 integral sealed 6V rechargeable lead-acid battery. The OxiMAX Pulse Oximetry System is intended for prescription use with adult, pediatric and neonatal patients in hospitals, hospital-type facilities, intra-hospital transport, and home environments.

Audible and visual alarms for high/low saturation, pulse rate and pulse search are provided. The N-595 Pulse Oximeter also includes adjustable alarm silence duration and other configurable power-on settings. The N-595 provides an audible low battery warning to alert the user of impending loss of power and consequent loss of monitoring capability. The N-595 Pulse Oximeter has visual indicators for pulse search, motion, 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-595 interfaces with selected multiparameter monitors.

The Nellcor pulse oximetry cable, Model DOC-10, links individual OxiMAX sensors to the N-595 Pulse Oximeter. The N-595 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, OXI-A/N, and OXI-P/I.

II. 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.

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-595 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-595 to write data to and read data from OxiMAX adhesive sensors
- MAX-FAST Adhesive Forehead Reflectance Sensor

The N-595 uses similar SpO2 and Pulse Rate software algorithm, motion-filtering software, and SatSeconds alarm management software as the legally marketed predicate device, N-395, that was cleared under 510(k)s #K991823 and #K993637.

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 the N-595 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-595 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 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

MAR 7 2002

Ronald J. Ehmsen, Sc.D.
Nellcor Puritan Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, CA 94588

Re: K012891
OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter
and OxiMAX Sensors and Cables (aka "Accessories")
Regulation Number: 870.2700, 870.2710
Regulation Name: Oximeter, Ear Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA, 74 DPZ
Dated: December 13, 2001
Received: December 17, 2001

Dear Mr. Ehmsen:

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.

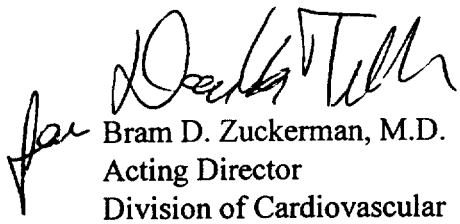
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012891

Device Name: OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter and OxiMAX Sensors and Cables (aka "Accessories")

Indications For Use:

The OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter and OxiMAX Sensors and Cables is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The OxiMAX Pulse Oximetry System 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.

The Nellcor OxiMAX adult oxygen sensor, model MAX-A, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing more than 30 kg.

The Nellcor OxiMAX adult oxygen sensor, model MAX-AL, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing more than 30 kg.

The Nellcor OxiMAX pediatric oxygen sensor, model MAX-P, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 10 and 50 kg.

The Nellcor OxiMAX infant oxygen sensor, model MAX-I, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 3 and 20 kg.

The Nellcor OxiMAX neonatal/adult oxygen sensor, model MAX-N, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for neonates weighing less than 3 kg or adults weighing more than 40 kg.

The Nellcor OxiMAX adult nasal oxygen sensor, model MAX-R, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing more than 50 kg.

The Nellcor OxiMAX adhesive forehead reflectance sensor, model MAX-FAST, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing greater than 40 kg.

The Nellcor OxiMAX OxiCliq adult oxygen sensor, model A, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing more than 30 kg. The OxiCliq-A sensor is for use only with a Nellcor OxiCliq sensor cable, model OC-3.

The Nellcor OxiMAX OxiCliq pediatric oxygen sensor, model P, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 10 and 50 kg. The OxiCliq-P sensor is for use only with a Nellcor OxiCliq sensor cable, model OC-3.

The Nellcor OxiMAX OxiCliq infant oxygen sensor, model I, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 3 and 20 kg. The OxiCliq-I sensor is for use only with a Nellcor OxiCliq sensor cable, model OC-3.

The Nellcor OxiMAX OxiCliq neonatal/adult oxygen sensor, model N, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for neonates weighing less than 3 kg, or adults weighing more than 40 kg. The OxiCliq-N sensor is for use only with a Nellcor OxiCliq sensor cable, model OC-3.

The Nellcor OxiMAX Durasensor adult oxygen sensor, model DS-100A, is indicated for use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing greater than 40 kg.

The Nellcor OxiMAX Dura-Y multisite oxygen sensor, model D-YS, is indicated for use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing greater than 1 kg.

The Nellcor Dura-Y ear clip, model D-YSE, is intended for use only with the Nellcor OxiMAX Dura-Y oxygen sensor, model D-YS, when continuous, noninvasive arterial oxygen saturation and pulse rate monitoring are required. It is indicated for use for patients weighing 30 kg or more, using the ear lobe or pinna as a monitoring site.

The Nellcor PediCheck pediatric spot-check clip, model D-YSPD, is intended for use only with the Nellcor OxiMAX Dura-Y oxygen sensor, model D-YS, when noninvasive, arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 3 kg and 40 kg.

The Nellcor OxiMAX Oxiband pediatric/infant oxygen sensor, model OXI-P/I, is indicated for use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 3 kg and 40 kg.

The Nellcor OxiMAX Oxiband adult/neonatal oxygen sensor, model OXI-A/N, is indicated for use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing less than 3 kg or more than 40 kg.

The Nellcor pulse oximetry cable, model DOC-10, is a 10-foot (3-meter) cable that links a Nellcor oxygen sensor to a compatible Nellcor pulse oximeter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012897

(Optional Format 3-10-98)

000023