NOV 24 1999

K993637

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER: Nellcor Puritan Bennett Inc.
A subsidiary of Mallinckrodt Inc.

DATE: October 27, 1999

COMMON NAME: Pulse Oximeter

PROPRIETARY NAME: N-395 Pulse Oximeter with extension of Motion Performance Claims to cover three additional oximetry sensors

CONTACT:
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A subsidiary of Mallinckrodt Inc.
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CLASSIFICATION: Class II per 21 CFR 870.2700/74DQA
Oximeter

PREDICATE DEVICES: Predicate devices are as follows:

1. N-3000 Pulse Oximeter, Nellcor Puritan Bennett Inc., K955642
2. Model 2000 Pulse Oximeter, Ivy Biomedical Systems, Inc., K982255

I. DEVICE DESCRIPTION

The N-395 Pulse Oximeter is manufactured by Nellcor Puritan Bennett Inc., in GALWAY, Ireland.

The N-395 is a Class II Oximeter, per 21 CFR Part 870.2700. This device is designated as Class I, Type BF equipment, per IEC 601-1.

The N-395 Pulse Oximeter 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 Puritan Bennett oxygen transducers (sensors). The N-395 displays digital values of SpO_2 and Pulse Rate. Pulse Amplitude is displayed by means of a "blip bar" presentation. The N-395 can be powered by an internal power supply operating on AC from a standard electrical utility receptacle (manually switchable from 100V to 240V) or alternatively by an integral sealed 6V rechargeable lead-acid battery. The N-395 is intended for prescription

use with adult, pediatric and neonatal patients in hospitals, hospital-type facilities and intra-hospital transport environments.

Audible and visual alarms for high/low saturation, pulse rate and pulse search are provided. The N-395 also includes adjustable alarm silence duration and other configurable power-on settings. The N-395 provides an audible low battery warning to alert the user of impending loss of power and consequent loss of monitoring capability. The N-395 Pulse Oximeter has visual indicators for pulse search, motion, power mode (i.e. battery or AC) and alarm silence in addition to alarm features.

In addition to the above mentioned device features, the instrument has been designed to satisfy the needs of both the user and the patient. A convenient carrying handle is incorporated into the case. There is also a serial port (EIA-232 and RS-422 interface) that provides ASCII output of real-time data every two seconds. This data can be printed on serial printers. There is also an interface for nurse call systems through the rear connector. The device is also Flash ROM upgradable.

The N-395 Pulse Oximeter measures functional oxygen saturation by calculating the light absorption of tissue, bone and blood in the sampling light beam path during the pulsatile cycle. Red and infrared LED's are utilized as light sources. A photodiode acting as a photodetector senses the signal strengths of the two wavelengths of light, which vary inversely with the amount of light transmitted through the tissue. The N-395 receives this electrical information from the sensor and processes the information by use of an oximetry algorithm to provide real time values of SpO_2, Pulse Rate and Pulse Amplitude.

The N-395 uses a **similar** SpO_2 and Pulse Rate software algorithm to process the information from the sensor as the predicate device, **N-3000**, cleared under **K955642**.

In addition, the N-395 possesses motion-filtering software that reduces the effects of patient/sensor motion, enabling the N-395 to *read through* motion artifact to provide valid SpO2 and Pulse Rate readings for many types of motion.

Also included is an alarm management software technique, known as *SatSeconds* which allows the caregiver to set the N-395 to accept desaturations below a specified threshold without alarming if those desaturations are of short duration or small magnitude.

This submission requests clearance for a labeling modification to the original N-395, cleared under K991823, to extend Motion Performance Claims to three additional oximetry sensors, as follows:

N-395 Motion Performance Device Claims:

1. The N-395 features OXISMART®XL advanced digital signal processing which enables the N-395 to read *through* motion artifact to deliver accurate saturation and pulse rate values.

2. The N-395 reads through challenging motion conditions giving valid SpO2 and Pulse Rate readings for many types of motion.

Note 1:"Challenging motion" is of a nature and of sufficient magnitude to cause the N-3000 to be in Pulse Search at least 40% of the time.
Note 2: Under "challenging motion" conditions, the N-395 produces a 20% improvement in motion performance compared to the N-3000
Note 3: The N-3000 detects and indicates motion.
Note 4: Motion performance claims verified for Adult and Neonatal patients using D-25 and N-25 sensors.

Applicability:
Models D-25, N-25, D-25L, D-20, I-20, Nellcor *OXISENSOR II* Oximetry Sensors.

Nellcor Puritan-Bennett Inc., asserts that:

a) the intended use of the N-395 Pulse Oximeter, as described in its labeling, has not changed from that of the device cleared under K991823 and,

b) the fundamental scientific technology of the N-395 Pulse Oximeter has not changed from that of the device cleared under K991823.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Mr. David A.C. Green
Nellcor Puritan Bennett Inc.
2200 Faraday Avenue
Carlsbad, CA 92008-7208

Re: K993637
N-395 Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: October 27, 1999
Received: October 28, 1999

Dear Mr. Green:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Christy Foreman for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

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510(k) Number (if known): K993637

Device Name: N-395 Pulse Oximeter

Indications For Use:

The N-395 Pulse Oximeter is indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. For use with neonatal, pediatric and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities and intra-hospital transport environments. For prescription use only.

N-395 Motion Performance Device Claims:

Applicability:
Models D-25, N-25, D-25L, D-20, I-20, Nellcor *OXISENSOR II* Oximetry Sensors.

The N-395 features OXISMART®XL advanced digital signal processing which enables the N-395 to read *through* motion artifact to deliver accurate saturation and pulse rate values.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Christy Foreman

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____