K021090

MAY 0 8 2002

tyco Healthcare

Nellcor

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510(k) Summary

Submitted by:	Nellcor Puritan Bennett, Incorporated (a business unit of Mallinckrodt Inc., a division of Tyco Healthcare Group, LP) 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	Gina To Senior Regulatory Affairs Project Manager (925) 463-4427 (925) 463-4020 – FAX
Date Summary Prepared:	April 3, 2002
Trade Name:	OxiMAX N-550 Pulse Oximeter
Common/Usual Name:	Pulse Oximeter
Classification Name:	Oximeter (74DQA) per 21 CFR §870.2700
Legally Marketed (Unmodified) Device:	Nellcor Puritan Bennett, Inc., OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter and OxiMAX Sensors (510(k) #K012891)

Device Description

The N-550 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 OxiMAX oxygen transducers (sensors). The N-550 Pulse Oximeter displays digital values of SpO2 and Pulse Rate, and individual LED's are used for status indicators. Pulse Amplitude is displayed by means of a "blip bar" presentation.

Intended Use

The N-550 Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The N-550 Pulse Oximeter 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. This device is for prescription use only.

Summary of Technological Characteristics of the Device Compared to the Legally Marketed (Unmodified) Device

The N-550 Pulse Oximeter has the same technological characteristics as the above referenced predicate device, the N-595 Pulse Oximeter. The only modifications relate to an ergonomic change from LCD to LED display and a change in oximeter module.

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.

Conclusions

The technological characteristics of the N-550 Pulse Oximeter and the results of non-clinical and clinical tests do not raise new questions of safety or effectiveness when compared to the legally marketed (unmodified) device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2002

Nellcor Puritan Bennett, Incorporated
c/o Ms. Gina To
4280 Hacienda Drive
Pleasanton, CA 94588

Re: K021090
OxiMAX N-550 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: April 24, 2002
Received: April 25, 2002

Dear Ms. To:

This letter corrects our substantially equivalent letter of May 8, 2002 regarding the indications for use of your device. Our letter incorrectly limited your device to use in military environments.

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 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 (PMA), it may be subject to 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 continue 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 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K021090

Device Name: OxiMAX N-550 Pulse Oximeter

Indications For Use:

The N-550 Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The N-550 Pulse Oximeter 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. This device is 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)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021090