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AUG 1 1 2005

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K051352

510(k) Summary

Submitted by:	Nellcor Puritan Bennett 4280 Hacienda Drive Pleasanton, CA 94588 FAX: (925) 463-4020
Company Contact:	Sarah Harrington, Regulatory Affairs Manager (925) 463-4151 sarah.harrington@tycohealthcare.com
Date Prepared:	May 20, 2005
Trade Name:	OxiMax™ NPB-40 Pulse Oximeter
Common/Usual Name:	Pulse Oximeter
Classification Name:	Oximeter (DQA) 21 CFR 870.2700
Substantially Equivalent Devices:	Nellcor Puritan Bennett NPB-40 Handheld Pulse Oximeter, K963707. Nellcor Puritan Bennett N-550 Pulse Oximeter, K021090

Device Description

The OxiMax NPB-40 is a handheld, battery powered pulse oximeter used for monitoring of pulse rate and saturated oxygen in arterial blood. The OxiMax NPB 40 include the addition of audible alarms, addition of keys and display icons in the user interface board to access the alarm settings and the OxiMax in-sensor data features. The OxiMax NPB-40 also has menu features to allow the user to set the time, date and measurement alarm limits

Intended Use

The OxiMax™ NPB-40 handheld pulse oximeter is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric and neonatal patients in hospital, hospital type facilities, transport and mobile environments as well as in the home care environment.

Technological Characteristics

The OxiMax NPB-40 shares the same intended use and indications for use as the predicate devices. The NPB-40 is indicated for spot check use, while the N-550 is intended for continuous use. The NPB-40 four button configuration panel has been redesigned and replaced with a new seven button panel to accommodate the additional OxiMax functionality. The N-550 also incorporates the OxiMax technology. Both the OxiMax NPB-40 and the N-550 have visual and audible alarms with adjustable limits.

Performance Data

Performance data includes results from environmental testing, in-house clinical studies and laboratory testing. Environmental testing includes testing for electromagnetic compatibility, electrical safety and reliability.

Clinical and non-clinical laboratory testing was conducted to evaluate oxygen saturation and pulse rate accuracy of the OxiMax NPB-40 during non-motion and motion conditions as well as low perfusion levels.

The performance data demonstrates substantial equivalence between the OxiMax NPB-40 and the legally marketed predicates, the NPB-40 and the N-550 oximeters.

Conclusion

The technological characteristics and the results of the performance data demonstrate that the OxiMax NPB-40 Handheld Pulse Oximeter is as safe and effective and performs as well or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2005

Ms. Sarah Harrington
Regulatory Affairs Manager
Nellcor Puritan Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, California 94588-2719

Re: K051352
Trade/Device Name: OXIMAX NPB-40 Handheld Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 2, 2005
Received: August 3, 2005

Dear Ms. Harrington:

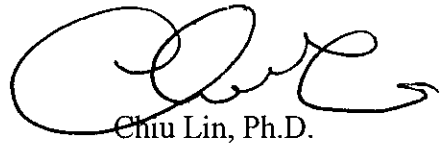
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

Statement of Indications for Use

510(k) Number (if known): K 051352

Device Name: OxiMax™ NPB-40 Pulse Oximeter

Indications For Use:

The OxiMax™ NPB-40 handheld pulse oximeter is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric and neonatal patients in hospital, hospital type facilities, transport and mobile environments as well as in the home care environment.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CRF 801 Subpart D) (21 CFR 807 Subpart C)

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

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K051352