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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 Bonds Senior Director Regulatory Affairs (925) 463-4371 Fax (925) 463-4020
Date Summary Prepared:	February 9, 2007
Trade Name:	DuraMax® Reusable Oximetry Sensor
Common/Usual Name:	Oxygen Sensor
Classification Name:	Oximeter (DQA) per 21 CFR §870.2700
Substantially Equivalent Devices:	Nellcor Puritan Bennett, Inc., OxiMax Pulse Oximetry System with N-595 Pulse Oximeter and OxiMax Sensors, K012891

DEVICE DESCRIPTION

The DuraMax is a reusable sensor, sized appropriately to fit the digit of a pediatric or adult patient weighing 40 kg or more.

The DuraMax sensor consists of an internal frame containing the optical components and flexible circuit encapsulated in a synthetic, latex-free rubber overmold.

The DuraMax sensor plug contains a memory chip carrying information about the sensor which the oximeter needs for correct operation, including Advanced Signal Evaluation, lot code and data set revision, and sensor model. The DuraMax sensor is compatible with Nellcor and other monitors incorporating either Nellcor R-Cal or OxiMAX (DigiCal) oximetry technology.

K070408

INTENDED USE

The DuraMax® reusable digit sensor is intended for use with patients weighing 40 kg or more when noninvasive arterial oxygen saturation and pulse rate monitoring are required.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The Nellcor DuraMax sensor has the same technological characteristics as the Nellcor DS-100A reusable sensor. The sensor uses the same optical components as the DS-100A. The differences relate to dimensions, one-piece external design, materials of construction, and labeling.

TESTS PERFORMED TO SUPPORT DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Human and bench tests were performed to support the determination of substantial equivalence. Human oxygenation evaluations were conducted to confirm conformance to accuracy and precision specifications.

The DuraMax sensor has been designed and tested for conformance with the applicable requirements of ISO 9919:2005, *"Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use"*. When properly connected to an oximeter that is also compliant with this standard, the resulting system will comply with the standard.

CONCLUSIONS

The technological characteristics of the DuraMax sensor and the results of testing do not raise new questions of safety or effectiveness when compared to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2007

Mr. James Bonds
Senior Director Regulatory Affairs
Nellcor Puritan Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, California 94588

Re: K070408
Trade/Device Name: Nellcor® DuraMax® Reusable Oximetry Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 30, 2007
Received: May 1, 2007

Dear Mr. Bonds

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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): _____

Device Name: *Nellcor® DuraMax®* Reusable Oximetry Sensor

Indications for Use:

The *Nellcor® DuraMax®* reusable oximetry sensor is indicated when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing 40 kg or more.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number: _____