K033973

tyco Healthcare

Nellcor

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DEC 1 3 2004

# 510(k) Summary

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| **Submitted by:** | Nellcor Puritan Bennett, Inc.<br>4280 Hacienda Drive<br>Pleasanton, CA 94588 |
| **Company Contact:** | Luanne Ng<br>Regulatory Affairs Manager<br>(925) 463-4372<br>(925) 463-4020 – FAX |
| **Date Summary Prepared:** | December 18, 2003 |
| **Trade Name:** | 1. Reprocessed Oxisensor II Sensor<br>2. Reprocessed OxiMax Sensor |
| **Common/Usual Name:** | Oximetry Sensor |
| **Classification Name:** | Oximeter, NLF per 21 CFR §870.2700 |
| **Substantially Equivalent Devices:** | Sensors cleared with:<br>Nellcor N-395 Pulse Oximeter, K993637 and<br>OxiMax Pulse Oximetry System with N-595 Pulse Oximeter, K012891 |

## DEVICE DESCRIPTION

The Reprocessed Nellcor Oxisensor and OxiMax Sensors are designed for use with Nellcor and Nellcor-licensed pulse oximetry monitors that provide continuous noninvasive measurement of pulse rate and arterial oxygen saturation. The sensor contains three optical components: two light emitting diodes (LEDs) that serve as light sources and one photodiode that acts as a light detector. Both the LEDs and the photodiode are contained within a laminated envelope with an adhesive bandage for attachment to a patient. Attached to a laminated envelope is a sensor cable which terminates in a connector element that connects to the oximeter.

The sole difference between the OxiMax sensors and the Oxisensor II sensors is the 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.

## INDICATIONS FOR USE

The Reprocessed Oxisensor II and OxiMax Sensors are intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. They are intended 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, intra-hospital transport, and home environments.

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

The technological characteristics of the subject devices and the predicate devices are identical. The predicate devices and the Reprocessed Oxisensor II and the OxiMax Sensors contain a photodetector that senses the signal strength of two wavelengths of light, which vary with the amount of light transmitted through the tissue. The Reprocessed Oxisensor II and OxiMax Sensors meet the same performance requirements as the predicate devices.

## CONCLUSIONS

The technological characteristics of the Reprocessed Oxisensor II and OxiMax Sensors and the results of bench tests and laboratory tests do not raise new questions of safety or effectiveness when compared to the legally marketed predicate devices. The technological characteristics of the Reprocessed Oxisensor IIs and the OxiMax Sensors are identical in all aspects to those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2006

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

Re: K033973
Trade/Device Name: Reprocessed Oxisensor II and OxiMax Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: October 8, 2004
Received: October 12, 2004

Dear Ms. Ng:

This letter corrects our substantially equivalent letter of December 13, 2004.

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 (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.

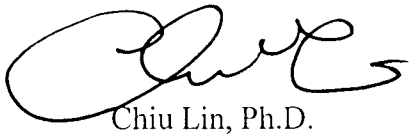
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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), 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/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
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Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

List of Models: Nellcor Reprocessed Oxisensor II and OxiMax Sensors

| **Nellcor Oxisensor II** |
|---|
| D-20 |
| D-25L |
| D-25 |
| N-25 |
| I-20 |
| **Nellcor OxiMax** |
| MAX-A |
| MAX-AL |
| MAX-I |
| MAX-P |
| MAX-N |