DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Ms. Gina To
Senior Regulatory Affairs Project Manager
Nellcor Puritan Bennett Incorporated
4280 Hacienda Drive
Pleasanton, California 94588

Re: K030930
Trade/Device Name: OxiMax SoftCare Sensor Models SC-A, SC-PR, SC-NEO, SC-N
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 24, 2003
Received: March 25, 2003

Dear Ms. To:

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030930

Device Name: Nellcor® OxiMax™ SoftCare™ Sensors

Indications For Use:

The Nellcor OxiMax SoftCare adult oxygen sensor, model SC-A, is indicated for single patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for adults weighing more than 40 kg.

The Nellcor OxiMax SoftCare preterm infant oxygen sensor, model SC-PR, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for neonates weighing less than 1.5 kg.

The Nellcor OxiMax SoftCare neonatal oxygen sensor, model SC-NEO, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for neonates weighing 1.5 kg to 5 kg.

The Nellcor OxiMax SoftCare neonatal oxygen sensor, model SC-N, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for neonates weighing less than 3 kg.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030930

Prescription Use ✓ OR Over-The-Counter Use ____

Optional Format (1-2-96)

K030930

tyco Healthcare

Nellcor

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510(k) Summary

Submitted by:	Nellcor Puritan Bennett, Inc. 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:	March 24, 2003
Trade Name:	OxiMax™ SoftCare™ Sensors
Common/Usual Name:	Oxygen Sensor
Classification Name:	Oximeter (DQA) 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, K012891

DEVICE DESCRIPTION

The OxiMax SoftCare sensors are sterile, latex-free, single patient use, non-adhesive sensors. These sensors have a hook and loop closure system as a means of attachment. Since the sensor is adhesive-free, the risk of adhesive related skin trauma is eliminated.

These sensors 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. The OxiMax SoftCare sensors are compatible with OxiMAX monitors.

INTENDED USE

The OxiMax SoftCare Sensors are indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required.

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

The OxiMax SoftCare Sensors have the same technological characteristics as the OxiMax MAX-N. The differences relate to patient contact surface, attachment means, electro-optical specifications, and labeling. The dimensions of the MAX-N have been modified to result in four distinct SoftCare sensors, to provide different sized sensors and graphics for various patient weight ranges within the adult and neonatal populations.

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.

CONCLUSIONS

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