SEP 2 4 2002

K022819

tyco Healthcare

Nellcor

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510(k) Summary

Submitted by:	Nellcor Puritan Bennett, Incorporated 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:	August 22, 2002
Trade Name:	Nellcor N-200 Pulse Oximeter
Common/Usual Name:	Pulse Oximeter
Classification Name:	Oximeter (74DQA) per 21 CFR §870.2700
Legally Marketed (Unmodified) Device:	Nellcor N-200 Pulse Oximeter, 510(k) #K863784

Device Description

The Nellcor N-200 Pulse Oximeter provides continuous non-invasive measurement and display of pulse rate and oxygen saturation values with visual and audible alarms, and features C-Lock, Nellcor's patented ECG Synchronization technology which reduces motion artifact. The N-200 Pulse Oximeter functions with all Nellcor reusable and disposable oximeter sensors.

This Special 510(k) covers the labeling modification of Nellcor N-200 Pulse Oximeter that was cleared under 510(k) #K863784. The modification involves revising the N-200 labeling to add performance specifications for motion and low perfusion when the N-200 is used with C-Lock ECG synchronization. Results from clinical evaluation are provided to support the labeling change. No device modifications have been made to the N-200. The labeling change does not affect the intended use or alter the fundamental scientific technology of the device.

Intended Use

The Nellcor N-200 pulse oximeter is intended for non-invasive, continuous, beat-by-beat monitoring of oxygen saturation of functional arterial hemoglobin, pulse rate, and pulse amplitude. This device is for prescription use only.

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

No design modifications have been made to the N-200 Pulse Oximeter. Only labeling has been revised.

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-200 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

SEP 2 4 2002

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

Re: K022819
Trade/Device Name: N-200 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 22, 2002
Received: August 26, 2002

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 and additionally 21 CFR 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Timothy A. Ulatowski
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): K022819

Device Name: N-200 Pulse Oximeter

Indications For Use:

The Nellcor N-200 pulse oximeter is intended for non-invasive, continuous, beat-by-beat monitoring of oxygen saturation of functional arterial hemoglobin, pulse rate, and pulse amplitude. 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)

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

510(k) Number: K022819