NOV 14 1997

Section 16. 510(k) Summary

Section 16.a Date Summary Prepared

22 August 1997

Section 16.b Company Information

Establishment:

Nellcor Puritan Bennett Inc.
4280 Hacienda Drive
Pleasanton, CA 94588

Official Correspondent:

Roger D. Brown
Regulatory Affairs Specialist
Nellcor Puritan Bennett Inc.
11150 Thompson Avenue
Lenexa, KS 66219
(913) 495-7146 (direct phone)
(913) 495-7285 (fax)

Section 16.c Name of Device

Proprietary: NPB-295 Pulse Oximeter

Common/Usual: Pulse Oximeter

Classification: Oximeter (§870.2700/74DQA)

Section 16.d Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for predicate devices and the NPB-295, as well as testing to accepted industry standards. In addition, in-vitro and non-invasive controlled hypoxia studies were conducted to establish the NPB-295's accuracy and to ensure that the sensors meet their currently published accuracy specifications with the NPB-295. The predicate devices are as follows:

1. N-3000 Pulse Oximeter, Nellcor Puritan Bennett Inc., K942347 and K952316

Section 16.e Device Description

The NPB-295 Pulse Oximeter is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by use of one of a range of compatible Nellcor Puritan Bennett oxygen transducers (sensors). The NPB-295 displays digital values of SpO_2 and pulse rate, and pulse amplitude by means of a "blip bar" presentation. The NPB-295 can be powered by an internal power supply operating on AC from a standard electrical utility receptacle (manually switchable from 115V to 230V) or alternatively by an integral sealed 6V rechargeable lead-acid battery. The NPB-295 is intended for prescription use with adult, pediatric and neonatal patients in hospital, hospital-type, intra-hospital transport and home environments.

Audible and visual alarms for high/low saturation, pulse rate and pulse search are provided. The NPB-295 also includes adjustable alarm silence duration and other configurable power on settings. The NPB-295 provides an audible low battery warning to alert the user of impending loss of power and consequent loss of monitoring capability. The NPB-295 Pulse Oximeter has visual indicators for pulse search, motion, power mode (i.e. battery or AC) and alarm silence in addition to alarm features.

In addition to the above mentioned device features, the instrument has been designed to satisfy the needs of both the user and the patient. A convenient carrying handle is incorporated into the case. There is also a serial port (EIA-232 and RS-422 interface) that provides ASCII output of real-time data every two seconds. This data can be printed on serial printers. There is also an interface for nurse call systems through the rear connector. The device is also Flash ROM upgradable.

Section 16.f Intended Use

The intended use of the NPB-295 Pulse Oximeter is for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric and neonate patients. The environments of use are hospital, hospital-type facilities, intra-hospital transport and the home. The intended use, patient population and environment of use are the same or similar to the predicate device, the N-3000 Pulse Oximeter.

Section 16.g Technological Characteristics

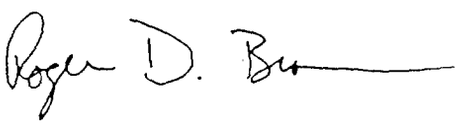
The NPB-295 Pulse Oximeter measures functional oxygen saturation by calculating the light absorption of tissue, bone, and blood in the sampling light beam path during the pulsatile cycle. Red and infrared LED's are utilized as light sources. A photodiode acting as a photodetector senses the signal strength of the two wavelengths of light, which vary inversely with the amount of light transmitted through the tissue. The NPB-295 receives this electrical information from the sensor and processes the information by use of an oximetry algorithm to provide a real time value of SpO_2, Pulse Rate and Pulse Amplitude.

The oximetry algorithm is contained in the NPB-295 "engine". The "engine" (part of the instrument that processes the analog signals from the sensors) consists of electrical circuitry and processors that calculate the SpO_2, pulse rate, and pulse amplitude. The NPB-295 uses the same SpO_2 and Pulse Rate software algorithm to process the information from the sensor as the predicate device, **N-3000**, cleared under **K942347** and **K952316**.

Section 16.h Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

Nellcor Puritan Bennett Inc. believes that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.



Roger D. Brown
Regulatory Affairs Specialist
for Nellcor Puritan Bennett Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 1997

Mr. Roger D. Brown
Nellcor Puritan Bennett Inc.
11150 Thompson Avenue
Lenexa, Kansas 66219-2301

Re: K973147
NPB-295 Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: August 19, 1997
Received: August 22, 1997

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973147

Device Name: NPB-295 Pulse Oximeter

Indications For Use:

The intended use of the NPB-295 Pulse Oximeter is the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. For use with neonatal, pediatric and adult patients, in hospital, hospital-type, intra-hospital transport and home environments. 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)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973147