

K963707

16. 510(k) SUMMARY

September X, 1996

DEC 13 1996

1. COMPANY INFORMATION

Establishment: Nellcor Puritan Bennett Incorporated
4280 Hacienda Drive
Pleasanton, CA 94588
(510) 463-4348

Official Correspondent: Donna Page
Manager, Regulatory Affairs

2. DEVICE NAME

Proprietary: NPB-40 Handheld Pulse Oximeter

Common/Usual: Pulse Oximeter

Classification: Oximeter, 74DQA

3. EQUIVALENT DEVICE

The NPB-40 Handheld Pulse Oximeter is technically equivalent to the N-20 Handheld Pulse Oximeter. The NPB-40's indications for use are also equivalent to the intended use of the N-20 Handheld Pulse Oximeter. The N-20 Handheld Pulse Oximeter was originally cleared under 510(k) #K915699 on May 27, 1993.

4. DEVICE DESCRIPTION

The NPB-40 Handheld Pulse Oximeter is a light-weight, portable, hand-held noninvasive pulse oximeter that operates on four size "AA" alkaline batteries and utilizes conventional oximetry technology to measure arterial oxygen saturation and pulse rate. The device consists of a copper-acrylic-shielded plastic box which houses two PCB boards and a power supply. On the boards are the digital and analog hardware with embedded software and power supply regulation. On the front of the device is an LCD display panel for the various readouts provided. The readouts consist of a numeric display showing oxygen saturation (SpO2) and pulse rate along with a lighted bar showing pulse amplitude. The display panel has visual icons to indicate low battery, pulse search, sensor disconnect, store data and print data. The device has audible indicators of varying tones and duration for the following conditions: pass self-test, sensor disconnect, no pulse detected initially, pulse detected then lost, low battery, impending dead battery. The device produces a constant pitch "beep" sound for each pulse. The NPB-40 is not equipped with alarms and is labeled for "attended" monitoring only. The NPB-40 has the ability to

print stored event data when used with a Hewlett Packard printer, model HP82240B. Available accessories include a protective rain boot, a rain jacket, EC-4 sensor extension cable, and a carrying case. The NPB-40 is compatible with all Nellcor Puritan Bennett reusable and patient-dedicated oxygen transducers (sensors).

The NPB-40's pulse oximetry technology is based on the principles of spectrophotometry and plethysmography.

5. INTENDED USE

The NPB-40 Handheld Pulse Oximeter is intended for non-invasive spot-check measurement of functional arterial oxygen saturation (SpO₂) and pulse rate of adults, pediatric, and neonatal patients in hospital, emergency, transport, and mobile environments, as well as in the home. The NPB-40 is for attended monitoring only and is intended to be used under the direct observation of a qualified health care provider. The indications for use of the NPB-40 are equivalent to those for the legally marketed predicate device, the N-20 Handheld Pulse Oximeter, therefore, there is no impact on safety and effectiveness.

6. TECHNOLOGICAL CHARACTERISTICS

The NPB-40 Handheld Pulse Oximeter has technological characteristics equivalent to those of the N-20 Handheld Pulse Oximeter. A comparison of the devices' design, features, principles and methods of operation and labeling support technical equivalency. In addition, testing has been done on the NPB-40 to confirm that oximetry performance is equivalent to that of the predicate N-20. The same oximetry algorithm is used in both products.

Comparative Performance Evaluations - The safety and effectiveness of the NPB-40 Handheld Pulse Oximeter has been demonstrated by design and testing. Environmental and EMC testing has been conducted as recommended by applicable sections of the Anesthesiology and Respiratory Devices Branch *Draft Reviewer's Guidance for Premarket Notification Submissions*, November 1993. Software design and validation has been conducted in accordance with the *Reviewer's Guidance for Computer Controlled Medical Devices*. Testing results demonstrated that all applicable requirements have been met.

Nellcor Puritan Bennett evaluated the NPB-40 Handheld Pulse Oximeter in comparison to the currently marketed N-20 Handheld Pulse Oximeter in *in vitro* laboratory studies in order to demonstrate equivalent pulse rate accuracy between the two devices. Results of the *in vitro* tests demonstrated that the NPB-40 performed in accordance with its specification relative to pulse rate accuracy. NPB also conducted a Non-Invasive Controlled Hypoxia Study to validate oxygen saturation accuracy of the NPB-40 across the NPB sensor line. The goal of this study was to validate that the NPB-40 has oxygen saturation accuracy performance equivalent to the predicate N-20 pulse oximeter. Results of this study demonstrated that the NPB-40 and N-20 Handheld Pulse Oximeters have equivalent oxygen saturation accuracy. The Non-Invasive Controlled Hypoxia Study was conducted

under a non-significant risk IDE and informed consent was obtained from each patient.

Conclusions: It can be concluded from the above referenced nonclinical and clinical tests that the NPB-40 Handheld Pulse Oximeter is equivalent to the N-20 Handheld Pulse Oximeter.