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16. 510(k) SUMMARY

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(a) Date Summary Prepared:

26 August 1996

(b) Company Information:

Establishment:

Nellcor Puritan Bennett Inc.
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(c) Name of Device:

Proprietary:

NELLCOR SYMPHONY™ N-3000 Patient Monitor

Common/Usual:

Respiration Rate Monitor combined with ECG and Pulse Oximeter

Classification:

Breathing (Ventilatory) Frequency Monitor (§868.2375/73BZQ), combined with Electrocardiograph (§ 70.2340/ 79FYW) and with Oximeter (§ 870.2700 / 74DQA)

Proprietary:

NELLCOR SYMPHONY™ N-3200 Display/Printer

Common/Usual:

Display and printer accessory

Classification:

Electrocardiograph (visual display feature) (§870.2340 / 74FYW) and Paper Chart Recorder (§ 870.2810 / 74DSF)

One or both devices may also be connected to:

Proprietary:	NELLCOR SYMPHONY™ N-3100 Blood Pressure Monitor
Common/Usual:	Noninvasive Blood Pressure Monitor
Classification:	Noninvasive Blood Pressure Measurement System (§870.1130 / 74DXN)

(d) Equivalent Devices:

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by comparison of product features, as described in the labeling and promotional literature for the predicate devices, as well as testing to accepted industry standards.

- (1) *PASSPORT* Monitor, Datascope Corp. , K911598.
- (2) *PROPAQ* 104 Ultra-Portable Patient Monitor with SpO2, Protocol Systems Inc., K902730.
- (3) *ASSURANCE* 2000 Monitor, EdenTec Corp., K905575
- (4) *NELLCOR SYMPHONY™* N-3000E Patient Monitor and N-3200 Display/Printer, Nellcor Puritan Bennett Incorporated, K955642.
- (5) *NELLCOR SYMPHONY™* N-3100 Blood Pressure Monitor, standalone and in combination with the *NELLCOR SYMPHONY™* N-3000 Patient Monitor, Nellcor Puritan Bennett, Incorporated, K955642.and K945947.

(e) Device Description:

The device which is the subject of this submission comprises a patient monitor, namely, a Respiration Rate Monitor combined with a Pulse Oximeter and ECG, model N-3000. The submitted device can also be connected to a noninvasive Blood Pressure Monitor, model N-3100 and to an accessory display/printer, model N-3200. Previous 510(k) submissions K945947 and K955642 cleared the N-3100 Blood Pressure Monitor and the related N-3000 Patient Monitor with ECG and SpO2 modalities and N-3200 display/printer for market release in 1995 and 1996, respectively.

The present submission covers software and hardware modifications to the predicate N-3000 patient monitor in order to incorporate a Respiration Rate measurement function and enable the display and printout of Respiration Rate information on the optional N-3200 Display/Printer. No hardware or software changes are required to the N-3100 blood pressure monitor or the N-3200 Display/Printer to accomplish the above.

This submission also covers software changes incorporated in the N-3000, N-3100 and N-3200 to enable data communication between these individual monitors and with the N-3200 display/printer when operating in the connected configuration.

The N-3000 can operate as a standalone monitor or it can be connected to (stacked with) other *NELLCOR SYMPHONY* instruments, such as the N-3100 Blood Pressure Monitor. The N-3200 Display/Printer accessory is functional only when connected to either the N-3000, N-3100 or both monitors stacked together.

The SpO₂, ECG and noninvasive blood pressure functions and algorithms remain unchanged from those described in K955642 and K945947 respectively. The new Respiration Rate feature utilizes the ECG lead set and patient surface ECG electrodes, together with additional electronics processing on the ECG PC board located within the N-3000 housing. Respiration Rate in breaths/minute is displayed numerically on the N-3000 front panel display, when selected by the user. As a standalone device, the N-3000 incorporates alarms for high and low Respiration Rate, SpO₂, pulse rate and heart rate.

The N-3200 Display/Printer accessory comprises an electroluminescent, EL or, alternatively, a liquid crystal, LCD graphic display, a User Interface (UIF) PCB, a display driver PCB and a sealed, lead-acid battery. The N-3200 also incorporates a thermal strip printer.

The N-3200 displays and prints Respiration Rate, SpO₂, ECG or NIBP waveforms, graphical and trend data when connected to an N-3000 or to an N-3100 or to both monitors.

(f) Intended Use:

The purpose and function of the N-3000 Patient Monitor is to:

- noninvasively and continuously monitor functional arterial oxygen saturation and pulse rate (using an accessory SpO₂ sensor);
- noninvasively and continuously monitor ECG and heart rate (using accessory ECG leads).
- noninvasively and continuously measure Respiration Rate.

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When connected to the N-3200 Display/Printer, the purpose and function of the combined device is expanded to:

- display and print out associated ECG and Plethysmographic waveforms, SpO₂, pulse rate, heart rate and respiration rate.

When further connected to the N-3100 Blood Pressure Monitor, the intended use of the interconnected N-3000/N-3100/N-3200 is also to:

- noninvasively and automatically measure systolic, diastolic and mean arterial blood pressure and to derive pulse rate from these measurements (using accessory blood pressure cuffs); and display and print out systolic, diastolic and mean arterial blood pressure (on the N-3200 display/printer).

The N-3000 Patient Monitor is intended for use in hospital and hospital-type environments as a "standalone" product and when connected to the N-3200 display/printer and/or the N-3100 blood pressure monitor. It is also intended for use during hospital transport when connected to and operating off of the N-3000 and/or N-3200 internal battery, to monitor neonatal, pediatric, or adult patients. The N-3000, N-3200 and N-3100 are for prescription use only.

The N-3000, the N-3000 connected to the N-3200, the N-3000 connected to the N-3100 and the N-3000 connected to both the N-3200 and N-3100 have the following similar intended uses to the predicate devices, in terms of function/purpose, environment of use and patient population:

Datascope *PASSPORT* - respiration rate, pulse oximetry, ECG, NIBP, display/printing functions; hospital and hospital-type environments; adult/pediatric/neonatal patients.

Protocol Systems *PROPAQ 104* - respiration rate, pulse oximetry, ECG, NIBP, display/printing functions; hospital, hospital-type, transport/mobile environments; adult/pediatric patients.

EdenTec *ASSURANCE 2000* - respiration rate, ECG, heart rate functions, hospital environment, adult/pediatric/neonatal patients.

NELLCOR SYMPHONY™ N-3000E Patient Monitor - pulse oximetry, ECG functions; hospital, hospital-type environments; adult/pediatric/ neonate patients.

NELLCOR SYMPHONY™ N-3100 Blood Pressure Monitor, standalone and in combination with the *NELLCOR SYMPHONY™ N-3000* Pulse Oximeter; pulse oximetry, NIBP functions; hospital, hospital-type and transport/mobile environments; adult/pediatric/neonate patients.

The N-3000, differs from the *PASSPORT* and *PROPAQ* 104 in having fewer measurement/monitoring parameters available. but more than the *ASSURANCE*. It also differs from the *PROPAQ* in that it includes neonates in the intended patient population. Considering Environment of Use, the *PASSPORT* and *PROPAQ* include mobile use.

The N-3000 has the same patient population as the predicate N-3000E patient monitor and predicate N-3100 blood pressure monitor, including adult, pediatric and neonate patients. It differs only in that it features Respiration Rate as an additional measurement parameter

(g) Technological Characteristics

A respiratory-related signal is generated by a low-level, high frequency current, applied to the patient via conventional ECG leads to measure the patient's trans thoracic impedance, TTI. Variations in the collected TTI signal are analyzed to determine Respiration Rate.

The technological characteristics of the pulse oximetry and ECG modalities of the N-3000 Patient Monitor are **identical** to those in the predicate N-3000E Patient Monitor. The same algorithms are used in both products. Testing has been conducted to confirm that modification of the N-3000E Patient Monitor to add a respiration rate function and access to the N-3200 display/printer has not affected the safety or effectiveness of the oximetry or ECG functions of the N-3000.

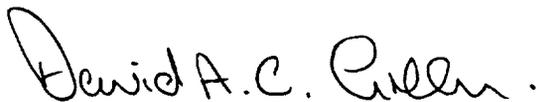
Safety and effectiveness of the N-3000, alone and in combination with the N-3200 display/printer and/or the N-3100 blood pressure monitor, have been confirmed by complying with the requirements of the *Reviewer Guidance for Premarket Notification Submissions*, November 1993, through design, testing and labeling.

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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.



David A. C. Green
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for Nellcor Puritan Bennett Inc.

26 August 1996