

K955642

ATTACHMENT 7

JUL 2 1998

510(k) SUMMARY, REVISED

(f) Intended Use:

The purpose and function of the N-3000E 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).

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 and heart rate.

When further connected to the N-3100 Blood Pressure Monitor, the intended use of the interconnected N-3000E/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)

When the N-3100 is connected to the N-3200 Display/Printer, the purpose and function of the combined device (compared to K945947) is expanded to:

- display and print out associated pulse rate and systolic, diastolic and mean arterial blood pressure.

The N-3000E Patient Monitor is intended for use in hospital, hospital-type and hospital transport 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 to monitor neonatal, pediatric, or adult patients. The N-3000E, N-3200 and N-3100 are for prescription use only.

The N-3000E, the N-3000E connected to the N-3200, the N-3000E connected to the N-3100 and the N-3000E 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* - pulse oximetry, ECG, NIBP, display/printing functions; hospital and hospital-type environments; adult/pediatric patients

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

NELLCOR SYMPHONY™ N-3000 Pulse Oximeter - pulse oximetry function; hospital, hospital-type; 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 environments; adult/pediatric/neonate patients.

The N-3000E, N-3200 and N-3100 differ from the Datascope *PASSPORT* and Protocol Systems *PROPAQ* 104 in having fewer measurement/monitoring parameters available. They also differ in that they include neonates in their intended patient population but do not include home or mobile environments.

The N-3000E/N-3200/N-3100 devices have the same patient population as the predicate N-3000 pulse oximeter and predicate N-3100 blood pressure monitor, including adult, pediatric and neonate patients. They differ only in that they feature ECG as an additional measurement parameter and include a display/printer function, but do not include home or mobile environments.

(g) **Technological Characteristics**

Intrinsic electrocardiac signals are collected by conventional patient surface electrodes and conducted via a 3-lead ECG lead set and cable to the N-3000E's ECG processing module. These signals then undergo amplification and noise filtering. A software algorithm operates on the processed ECG signal to identify sequential QRS complexes and, hence, determine heart rate for numerical presentation on the N-3000E's front panel display. The processed ECG signal may also be supplied to the N-3200 Display/Printer for graphical presentation and printout. The ECG module is designed to comply with the AAMI/ANSI EC-13 standard, with the exception of clause 3.2.6.1. Test results confirming compliance with this standard have been included in the 510(k) submission.

The technological characteristics of the pulse oximetry function of the N-3000E are identical to those in the predicate N-3000 pulse oximeter. The same algorithm is used in both products. Testing has been conducted to confirm that modification of the N-3000 pulse oximeter to add an ECG function and access to the N-3200 display/printer have not affected the safety or effectiveness of the oximetry function of the N-3000E.

Safety and effectiveness of the N-3000E, 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.