

K980411

AUG 20 1998

**510(k) Summary  
for  
Analogic Corporation  
NPB3900 Series Patient Monitors**

**DATE THIS SUMMARY WAS PREPARED: JANUARY 30, 1998**

**SUBMITTER'S NAME AND ADDRESS:**

Analogic Corporation  
8 Centennial Drive  
Peabody, MA 01960

**CONTACT PERSON:**

Steven Clarke, Regulatory Specialist  
Telephone: (978) 977-3000 Extension 3316  
Facsimile: (978) 977-6808

**DEVICE NAME:**

Proprietary Name: NPB3900 Series Patient Monitors  
Common Name: Multi-Function Patient Monitor  
Classification Name: Physiological Patient Monitoring System and Accessories

**PREDICATE DEVICES**

The legally marketed devices to which equivalence is being claimed are:

- NPB-4000 patient monitor, manufactured by Analogic Corporation (K962424).
- SureTemp Thermometer Model 679, manufactured by Welch Allyn, Inc. (K943695 and K964643)

## DEVICE DESCRIPTION:

The NPB3900 Series Patient Monitors is a compact, lightweight monitor for measuring, processing, storing, and displaying information derived from four physiological measurements:

- **Electrocardiogram (ECG).** A three lead ECG is acquired and a waveform can be displayed real-time on the LCD screen or permanently recorded on the optional strip chart recorder. The design of the ECG function is derived directly from the predicate device, the NPB-4000.
- **Pulse Oximetry (SpO<sub>2</sub>).** Functional Oxygen Saturation is calculated from the ratio of light transmissivity through the capillary bed at two wavelengths. The SpO<sub>2</sub> subsystem uses the same printed wiring board, including microprocessor and imbedded firmware that is used in the predicate device, the NPB-4000.
- **The temperature is measured using thermistor probes and a “predictive” algorithm to enable temperature measurements to be completed more quickly.** The temperature subsystem uses technology licensed from the manufacturer of the Welch Allyn SureTemp® Portable Thermometer, which was cleared for marketing under premarket notification K943695 and K964643.
- **Blood pressure is measured noninvasively (NIBP) by the oscillometric method.** The design of the NIBP subsystem is an enhanced version of the NIBP subsystem used in the predicate device, the NPB-4000.
- **An optional thermal printer records waveforms, digital vital signs, and tabular trends on a 50-mm wide strip chart.**

The NPB3900 series monitors are powered by internal sealed lead-acid batteries. A fully charged battery will power the monitor for four hours.

**INTENDED USE:**

The NPB3900 Series Patient Monitors are multi-parameter patient monitors that is used to monitor ECG waveforms, heart rate, noninvasive blood pressure, (systolic, diastolic, and mean arterial pressure), functional arterial oxygen saturation, and temperature for adult and pediatric patients in all hospital areas and hospital type facilities and for patient transport in the hospital and in ambulances.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:**

The design of the NPB3900 Patient Monitors is derived from the design of the NPB-4000 Patient Monitor. The NPB3900 series consists of four models; the NPB3910 which monitors NIBP and SPO<sub>2</sub>; the NPB3920 which monitors NIBP, SPO<sub>2</sub>; and temperature, the NPB3930 which monitors NIBP, SPO<sub>2</sub>; and ECG; and the NPB3940 which monitors NIBP, SPO<sub>2</sub>; temperature, and ECG.

The NPB3900 series monitors are smaller and lighter than their predicate, and they feature a predictive temperature algorithm, licensed from Welch Allyn, Inc.

The NPB3900 series does not include the respiration monitoring function which is present in the NPB-4000.

**NONCLINICAL TEST USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE:**

The design of the NPB3900 Series Patient Monitors has been thoroughly validated at the unit and system level and meets all elements of its Requirements Specification. This included the following nonclinical tests:

- Electromagnetic Emissions Tests to determine if it was in compliance with the EN 55011, Group 1, Class B emissions limits.
- Electrostatic Discharge Susceptibility was tested according to IEC 801-2.
- Radio Frequency Interference Susceptibility was tested according to IEC 801-3.
- Electric Fast Transient Susceptibility was tested according to IEC 801-4.
- Fast Surge Susceptibility was tested according to IEC 801-5.

- Line Drop-Out and Variation Susceptibility was tested according to the FDA Reviewer Guidance for Premarket Notification Submissions, November 1993 (Anesthesiology and Respiratory Devices Branch).
- ECG Performance Testing According to ANSI/AAMI EC-13
- Battery Cycle Testing
- Operational Temperature Test
- Altitude Tests
- Alarm Volume Tests
- Cleanability Tests
- Mechanical Shock and Vibration Tests
- Shipping Container Transportation Test
- Measure of External Temperature Rise

All tests passed the stated criteria.

### **CLINICAL TESTING**

The following clinical testing was conducted:

- Accuracy of the SpO<sub>2</sub> measurement was verified in a study on human volunteers.
- Clinical testing to validate the accuracy of the NIBP function was conducted according to the ANSI/AAMI standard SP-10.
- A study was conducted to exercise all the device features in a typical clinical setting, to demonstrate that users perceive the NPB3900 as equivalent to other devices with the same intended use.

### **CONCLUSIONS FROM NONCLINICAL AND CLINICAL TESTING**

The testing of the NPB3900 Series Patient Monitors demonstrates that the performance is substantially equivalent to the predicate devices cited above.



AUG 20 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Steven A. Clarke  
Regulatory Affairs Specialist  
Analogic Corporation  
8 Centennial Drive  
Peabody, MA 01960

Re: K980411  
NPB3900 Series Patient Monitor  
Regulatory Class: II (two)  
Product Code: MXH  
Dated: June 29, 1998  
Received: July 2, 1998

Dear Mr. Clarke:

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 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). 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' (21CFR 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/dsma/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): K980411

Device Name: NPB3900 Series Patient Monitors

Indications For Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)  
Prescription Use  OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109) 8-20-98  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K980411