K041376
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510(k) Summary
For
Analogic Corporation
C1 Series Patient Monitor

DATE THIS SUMMARY WAS PREPARED:

May 21, 2004

SUBMITTER'S NAME AND ADDRESS:

Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

CONTACT PERSON:

Donald J Sherratt, Regulatory Affairs Manager
Telephone (978) 977-3000 extension 3049
Facsimile (978) 977-6808

DEVICE NAME:

Proprietary or Trade Name:	C1 Series Patient Monitor
Common Name:	Multi-Function Patient Monitor
Classification Name:	Physiological Patient Monitoring System and Accessories

PREDICATE DEVICE:

The legally marketed device to which equivalence is being claimed is:
The NPB 3900 (A1) Patient Monitor that was cleared under Premarket Notification K980411

DEVICE DESCRIPTION:

The C1 Series Patient Monitor is a compact, lightweight monitor for measuring, processing, storing, and displaying information derived from five 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 optical strip chart recorder. The design of the ECG function is derived directly from the predicate device, the NPB 3900 (A1).
- Pulse Oximetry (SpO_2). Functional Oxygen Saturation is calculated from the ratio of light transmissivity through the capillary bed at two wavelengths. The SpO_2 subsystem uses the same printed wiring board layout as well as the same microprocessor and imbedded firmware that is used in the predicate device, the NPB 3900 (A1).
- 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 manufactures of the Welch Allyn SureTemp® Portable Thermometer, which was cleared for marketing under premarket notification K943695 and K964643.
- Blood pressure is measured non-invasively (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 3900 (A1) and cleared for use in the C3 Patient Monitor cleared under K030931.
- An external optional thermal printer records waveforms, digital vital signs, and tabular trends on a 50-mm wide strip chart.
- The C1 Series Patient Monitor is powered by internal sealed lead-acid batteries. A fully charged battery will power the monitor for 2.5 hours.

INTENDED USE:

The purpose and function of the C1 Series Patient Monitor is to monitor ECG, heart rate, non-invasive blood pressure (NBP), functional arterial oxygen saturation (SpO2) and temperature for single patient use on adult and pediatric patients in hospital areas and hospital-type facilities, such as clinics.

COMPARISION OF TECHNOLIGICAL CHARACTERISTICS:

The design of the C1 Series Patient Monitor is derived from the design of the NPB 3900 (A1) Patient Monitor. Clinically the two devices are nearly identical.

The C1 Series Patient Monitor uses the same base technology as the predicate and incorporates a step-bleed algorithm for NIBP licensed from SunTech that has been cleared by FDA for use in the Analogic C3 patient monitor (K030931). Software changes were made to allow the use of a color display and update the alarms to bring them in line with current technology and international standards.

The materials of construction, physical size, weight and footprint are the same as predicate.

NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANIAL EQUIVALENCE:

The design of the C1 Patient Monitor has been thoroughly validated at the unit and system level and meets all element of its Requirements Specification. The C1 patient monitor will comply with the following recognized standards:

- Electromagnetic Compatibility Tests to determine if it was in compliance with IEC 60601-1-2: 2001 - Group 1, and Class B emissions limits.
  - CISPR 11 – Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement.
  - IEC 61000-3-2 – Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current <= 16A per phase)
  - IEC 61000-3-3 – Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16A per phase and not subject to conditional connection
  - IEC 61000-4-2 – Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test
  - IEC 61000-4-3 – Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio frequency, electromagnetic field immunity test
  - IEC 61000-4-4 – Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Section 4: Electrical fast transient/burst immunity test. Basic EMC Publication
  - IEC 61000-4-5 – Electromagnetic compatibility (EMC) Part 4-5: Testing and measurement techniques – Surge immunity test
  - IEC 61000-4-6 – Electromagnetic compatibility (EMC) Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields
  - IEC 61000-4-8 – Electromagnetic compatibility (EMC) Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test
  - IEC 61000-4-11 – Electromagnetic compatibility (EMC) Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests

- Safety and Performance Tests
  - IEC 60601-1:1988 +A1:1991 +A2:1995, Medical Electrical Equipment-Part 1: General Requirements for Safety
  - ECG Performance Testing According to ANSI/AAMI EC-13 Cardiac Monitors, Heart Rate Meters, and Alarms
  - ANSI/AAMI SP10 – Manual, Electronic, or Automated Sphygmomanometers
  - IEC 60601-2-30 – Medical electrical equipment – Part 2-30: particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment.
  - IEC 60601-2-27 – Medical electrical equipment-- Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
  - IEC 60601-2-49 – – Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
  - IEC 60601-1-8 – Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

CONCLUSIONS FROM NONCLINCAL TESTING

The testing of the C1 Patient Monitor demonstrates that the performance is substantially equivalent to the predicate device cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2004

Mr. Donald J. Sherratt
Regulatory Affairs Manager
Analogic Corporation
8 Centennial Drive
Centennial Industrial Park
Peabody, MA 01960

Re: K041376
Trade Name: C1 Series Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia alarms)
Regulatory Class: II (two)
Product Code: MWI
Dated: May 21, 2004
Received: May 24, 2004

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ANALOGIC®

Indications for Use Form

510(k) Number (if known): K041376

Device Name: C1 Series Patient Monitor

Indications For Use:

The C1 Series Patient Monitor series are multi-parameter patient monitors that are used to monitor ECG waveforms, heart rate, noninvasive blood pressure (systolic, dialstolic), functional arterial oxygen saturation and temperature for adult and pediatric patients in all hospital areas and health care facilities.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041376

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)