510(k) Summary
For
Analogic Corporation
C3 Patient Monitor

DATE THIS SUMMARY WAS PREPARED:

March 3, 2003

SUBMITTER'S NAME AND ADDRESS:

Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

CONTACT PERSON:

Marvin Rosenbaum, Regulatory Affairs Manager
Telephone (978) 977-3000 extension 3049
Facsimile (978) 977-6808

DEVICE NAME:

Proprietary or Trade Name:	C3 Patient Monitor
Common Name:	Multi-Function Patient Monitor
Classification Name:	Physiological Patient Monitoring System and Accessories

PREDICATE DEVICE:

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

The NPB-4000 Patient Monitor that was cleared under Premarket Notification K962424.

DEVICE DESCRIPTION:

The C3 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-4000.

- Pulse Oximetry (SpO2). Functional Oxygen Saturation is calculated from the ratio of light transmissivity through the capillary bed at two wavelengths. The SpO2 subsystem uses a similar printed wiring board, software and firmware that is used in the predicate device, the NPB-4000.

- The temperature is measured using thermistor probes for continuous temperature measurements.

- 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-4000.

- End-tidal CO_2. This method pulls a constant sample flow of exhaled breath from the patient, and analyzes it with a remote CO_2 sensor built into the measurement system.

- An optional thermal printer records waveforms, digital vital signs, and tabular trends on a 50-mm wide strip chart.

The C3 monitor is powered by internal sealed lead-acid batteries. A fully charged battery will power the monitor for four hours.

INTENDED USE:

The purpose and function of the C3 patient monitor is to monitor continuous ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (SpO2), respiration rate, temperature and carbon dioxide (CO2) for single patient use on adult and pediatric patients in hospital areas and hospital-type facilities, such as clinics. Clinical users may use the monitor during hospital transport.

COMPARISION OF TECHNOLIGICAL CHARACTERISTICS:

The design of the C3 Patient Monitor is derived from the design of the NPB-4000 Patient Monitor
The C3 monitor is smaller and lighter than the predicate.

NONCLINICAL TEST USED IN DETERMINATION OF SUBSTANIAL EQUIVALENCE:

The design of the C3 Patient Monitor has been thoroughly validated at the unit and system level and meets all element of its Requirements Specification. This included the following non-clinical tests:

- IEC 60601-1, an FDA recognized consensus standard for safety of medical electrical equipment.
- Electromagnetic Emissions Tests to determine if it was in compliance with the EN 55011, Group 1, and Class B emissions limits.
- IEC 60601-1-2, an FDA recognized consensus standard for electromagnetic compatibility.
- Line Dropout and Variation Susceptibility were tested according to the FDA Reviewer Guidance for PreMarket Notification Submissions, November 1993 (Anesthesiology and Respiratory Devices Branch).
- 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

- ECG Performance Testing According to AAMI/ANSI EC-13
- EtCO2 Function Test According to EN 864/1996
- SpO2 Tested According to EN865, Pulse Oximeters - Particular requirements: 1997.
- NIBP Functional Testing to AAMI/ANSI SP10, Electronic or Automated Sphygmomanometers, 2nd Ed.: 1992.

All tests passed the stated criteria.

CONCLUSIONS FROM NONCLINCAL TESTING

The testing of the C3 Patient Monitor demonstrates that the performance is substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Analogic Corporation
c/o Mr. Marvin Rosenbaum
Regulatory Affairs Manager
360 Audubon Road
Wakefield, MA 01880

Re: K030931
Trade Name: C3 Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: April 30, 2003
Received: May 1, 2003

Dear Mr. Rosenbaum:

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 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

K030931

510(k) Number (K030931):

Device Name: C3 Patient Monitor

Indications For Use:

The purpose and function of the C3 patient monitor is to monitor continuous ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (SpO2), respiration rate, temperature and carbon dioxide (CO2) for single patient use on adult and pediatric patients in hospital areas and hospital-type facilities, such as clinics. Clinical users may use the monitor during hospital transport.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030931