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ANALOGIC®

510(k) Summary
For
Analogic Corporation

LIFEGARD II Family

1. Date this Summary was Prepared:

April 8, 2005

2. Submitter's Name and Address:

Submitter's Name:	Analogic Corporation
Address:	8 Centennial Drive
City, State, and Zip:	Peabody, MA 01960
Registration Number:	1219601

3. Contact Person:

Name:	Janet R. Kwiatkowski
Title:	Regulatory Affairs
Telephone:	(978) 326-4186
Facsimile:	(978) 977-6808
E-mail:	Jkwiatkowski@analogic.com

4. Device Name:

Proprietary or Trade Name:	LIFEGARD II Family
Common Name:	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Classification Name:	Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)
Classification Panel:	Cardiovascular Devices
Product Codes:	MHX, DSI, DSJ, DXN, MLC, DQA, DSB, DSA, FLL
Code of Federal Regulations:	870.1025, 870.1100, 870.1130, 870.2340, 870.2700, 870.2770, 870.2900, 880.2910

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Regulatory Classification of LIFEGARD II Family

Device Panel	CFR Section	Product Code	Device Class	Description
Cardiovascular Devices	870.1025	MHX	II	Monitor, physiological, patient(with arrhythmia detection or alarms)
	870.1025	DSI	II	Detector and alarm, arrhythmia
	870.2770	DSB	II	Plethysmograph, impedance
	870.1100	DSJ	II	Alarm, blood-pressure
	870.1130	DXN	II	System, measurement, blood-pressure, non-invasive
	870.2340	MLC	II	Monitor, ST segment
	870.2700	DQA	II	Oximeter
	870.2900	DSA	II	Cable, transducer and electrode, patient, (including connector)
General Hospital and Personal Use	880.2910	FLL	II	Thermometer, electronic, clinical

5. Predicate Devices:

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

The C3 Patient Monitors cleared under Premarket Notification K030931 and K041434.

- The Impedance Cardiography (ICG) parameter incorporated in the LIFEGARD II Family is identical in all aspects to the parent C3 Family.
- The electrocardiograph (ECG) parameter incorporated in the LIFEGARD II Family is identical to the parent C3 Family.
- The end-tidal carbon dioxide ($EtCO_2$) method of measurement is identical to the parent C3 Family.
- The temperature probes are pre-amendment devices. The method of temperature measurement is identical to the parent C3 Family.
- The non-invasive blood pressure (NIBP) measurement method is identical to parent C3 Family.

The M3046A (M2/M3/M4) Compact Portable Patient Monitor device cleared under K023871. This predicate device was chosen specifically for the arrhythmia with ST segment indication.

The continuous non-invasive blood pressure Multi-parameter patient monitoring system cleared under K011152. The LIFEGARD II contains the identical technology of the predicate device.

The Pulse Oximeter, Sensors and Cables with accessories and Physiological Signal Amplifier cleared under K012891and K040113, respectively. The technology as cleared in K012891 and K040113 is identical to the technology incorporated in the LIFEGARD II Family of devices.

6. Description of LIFEGARD II Family

The LIFEGARD II Family is a compact, lightweight device for measuring, processing, printing, and displaying information derived from nine physiological measurements:

- Electrocardiogram (ECG). A three lead or five lead ECG is acquired and a waveform can be displayed real-time on the LCD screen or permanently recorded on the optional printer. The design of the ECG function is derived directly from the predicate devices, the parent C3 Family of patient monitors.
- Respiration. Waveform and numeric respiration rate value from ECG. Airway respiration rate from $EtCO_2$ if available. The design of the respiration parameter is derived directly from the predicate devices, the parent C3 Family of patient monitors.
- Arrhythmia with ST segment analysis software performs five distinct operations: beat detection, lead selection, beat classification, ventricular tachyarrhythmia detection, and ST segment measurement. The design of arrhythmia with ST segment function provides VF and ST segment deviation functionality similar to the predicate device, M3046A (M2/M3/M4) Compact Portable Patient Monitor
- 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 software and firmware that is used in the OxiMAX Pulse Oximetry System and Sandman SD20 Amplifier patient monitor and system.
- The temperature is measured using thermistor probes for continuous temperature measurements. These are pre-amendment devices.
- Blood pressure is measured non-invasively (NIBP) by the oscillometric method. This is the same as in the predicate devices, parent C3 Family of patient monitors.

- Continuous non-invasive blood pressure (CNIBP) is a non-invasive blood pressure monitor which uses a pressure sensor placed on the wrist over the radial artery. This is the same technology as in the predicate device, Vasotrac APM205A.
- End-tidal CO_2 ($EtCO_2$) 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. This is the same as in the predicate devices, parent C3 Family of patient monitors.
- Impedance Cardiograph (ICG). This mode uses Thoracic Electrical Bioimpedance (TEB). This is identical in all aspects to the predicate device, the C3 ICG.
- An internal thermal printer records waveforms, hemodynamic parameters and tabular trends on a 50-mm wide strip chart.
- External USB printing identical to the parent C3 Family.

The LIFEGARD II Family is powered by internal sealed lead-acid batteries or from the mains supply via a battery eliminator. A fully charged battery will power the monitor for three hours.

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7. Intended Use:

The device is for use on individual adult and pediatric patients in hospital areas and hospital-type facilities, such as clinics. Clinical users may use the monitor during hospital transport. These indications were previously cleared under K030931 and K041434.

The purpose and function of the LIFEGARD II Family is to monitor:

- ECG
- Heart rate
- Non-invasive blood pressure (NIBP)
- Functional arterial oxygen saturation (SpO_2)
- Respiration rate
- Temperature and
- End-tidal carbon dioxide ($EtCO_2$)
- Impedance Cardiography (ICG)
- Arrhythmia with ST segment detection
- Continuous non-invasive blood pressure (CNIBP)

The Impedance Cardiography (ICG) is intended for use on individual adult patients that meet the limits specified below:

- Height: 4 ft – 7 ft – 6 in (122 – 229 cm)
- Weight: 67 – 350 lbs (30 – 159 Kg)

The CNIBP is a non-invasive blood pressure monitor which uses a pressure sensor placed on the wrist over the radial artery. This device is intended to be used on patients by trained medical personnel to continuously monitor systolic, diastolic and mean blood pressure and pulse rate. This pressure information is intended to guide clinicians in the therapeutic management of their patients by providing accurate and frequent updated blood pressure information in a safe, non-invasive, easily obtained and comfortable manner.

8. Comparison of Technological Characteristics:

The technological characteristics of the LIFEGARD II Family are the same as the legally marketed predicate devices.

9. Non-clinical Tests to Be Used In Determination of Substantial Equivalence:

Prior to marketing the LIFEGARD II Family, verification testing activities will be conducted to establish the compliance, performance and reliability characteristics of the LIFEGARD II Family. This is to include the following non-clinical tests:

IEC 60601-1 (including Amendments 1 & 2), Medical Electrical Equipment - General Requirements for Safety

IEC 60601-1-2: 2001 Medical electrical equipment - Electromagnetic compatibility emission limits meet Group 1 Class B

IEC 60601-2-27 Medical electrical equipment – Particular requirements for the safety of electrocardiographic monitoring equipment

IEC 60601-2-30 Medical electrical equipment – Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

IEC 60601-2-49 Medical electrical equipment – Particular requirements for the safety of multifunction patient monitoring equipment

ANSI/AAMI EC 13 Cardiac monitors, heart rate meters, and alarms

ANSI/AAMI EC 57 Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms

ANSI/AAMI SP10 Manual, Electronic, or Automated Sphygmomanometers

EN 864 Capnometers for use with humans

EN 865 Pulse Oximeters

Mechanical shock and vibration tests will be performed in accordance with IEC 60068 series of standards to ensure transport does not damage the device

Shipping container transportation tests will be performed in accordance with IEC 60068-2-27 to ensure packaging of equipment is not adversely affected during shipping

Altitude tests will be performed to ensure that operation at higher altitudes does not adversely affect electrical safety or performance

Tests will be performed to verify enclosure material robustness and resistance to cleaning materials commonly used in hospitals

10. Conclusions from Non-clinical Testing:

The test schedule of the LIFEGARD II Family combined with the AAMI EC 57 tests already performed including the current test data from Nellcor showing equivalent performance of the SpO_2 module incorporated into the LIFEGARD II Family demonstrates that the performance of the LIFEGARD II Family patient monitors is substantially equivalent to the parent C3 Family of patient monitors and the non-Analogic predicate devices cited in Section 5 of this summary. The device will present no new concerns regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2005

Ms. Janet R. Kwiatkowski
Regulatory Affairs Specialist
Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

Re: K050919
Trade Name: LIFEGARD II Family
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: DSI
Dated: April 8, 2005
Received: April 12, 2005

Dear Ms. Kwiatkowski:

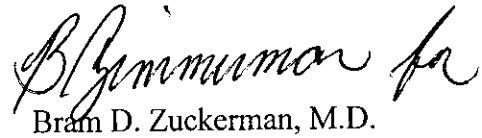
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0295. 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/industry/support/index.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®

Device Name: LIFEGARD II Family

Indications for Use Statement

The device is for use on individual adult and pediatric patients in hospital areas and hospital-type facilities, such as clinics. Clinical users may use the monitor during hospital transport. These indications were previously cleared under K030931 and K041434.

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Prescription Use	X	AND/OR	Over-The-Counter Use	
(Per 21 CFR 801 Subpart D)			(Per 21 CFR 801 Subpart C)	

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Hammond

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050919