K091787

510(k) Summary

June 8, 2009

OCT - 9 2009

Name and Address of Applicant

Ivy Biomedical Systems, Inc.
11 Business Park Drive
Branford, CT, 06405

Phone: (203) 481-4183
Fax : (203) 481-8734

Primary Contact

Jennifer Laine
Electrical Engineer
(203) 481-4183 x185

Proprietary Name of Device

Model 6000 Two Parameter Bedside Monitor

Common Names of the Device

SpO_2 and $EtCO_2$ Monitor

Device Classification

The device is classified as a Class II device by the both the Cardiovascular and Anesthesiology Panels under 21 CFR Part 870.2700 "Oximeter" per DQA and 21 CFR Part 868.1400 "Carbon Dioxide Gas Analyzer" per CCK respectively.

Establishment Registration Number of Manufacturer

1221108

Legally Marketed Predicate

Oridion Capnography, Inc. Capnostream20 Two Parameter Bedside Monitor, cleared under 510(k), K060065

Summary of Technological Characteristics of Device Compared to Predicate

The device has similar indications for use and intended use as the predicate device. Both systems monitor $EtCO_2$ or the relative level of carbon dioxide in exhaled breath, respiratory rate, oxygen saturation in arterial hemoglobin (SpO_2), and pulse rate. In both devices, the measurements are collected noninvasively and displayed on a VGA color TFT LCD display. The trend of each measured indication may be stored and represented at multiple resolutions. They are both non-ambulatory devices and applicable to patients of all ages. Unlike the predicate, the Model 6000 device is not intended to be used in home environments.

Both devices deliver alarms meeting the voluntary harmonized standard IEC 60601-1-8.

The energy source for both the device and predicate is equivalent. They receive power and ground either through AC Mains or a battery pack. Neither device makes physical contact with the patient; the patient-side electronics of both are electrically isolated from Mains power.

Description

The device is a two parameter patient monitor. Both $EtCO_2$ and SpO_2 parameters are derived from commercially available modules that are incorporated internally. The device displays the waveforms and numerical values associated with each parameter on a color LCD display, and transmits the information to a network based computing device over the 802.11a – g IEEE wireless protocol. The device is intended for use on adult, geriatric, pediatric, and neonatal patients only under the direction of a physician or qualified clinician.

Intended Use

The Model 6000 is intended to provide continuous noninvasive monitoring of SpO_2 and $EtCO_2$ indications. The parameters are derived from both the measurements of arterial oxygen hemoglobin saturation and pulse rates as well as relative expired and inspired CO_2 levels. The recorded data may be displayed locally and also transmitted wirelessly to any device supporting the 802.11 communication protocol. This device is intended for use on adult, geriatric, pediatric, and neonatal patients in bedside or mobile applications within health care institutions and/or health care environments.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Performance and Safety Testing

The device complies voluntarily with the following industrial standards:

UL 60601-1, 2nd Edition
IEC 60601-1-2:2001
IEC 60601-1-4:2004
IEC 60601-1-6, 2nd Edition
IEC 60601-1-8, 2nd Edition
IEC 60601-2-49:2001
ISO 13485:2003
CAN/CSA 22.2 No 601.1 M90
CAN/CSA-ISO13485:2003
21 CFR Part 870
MDD: 93/42/EEC Annex II, IIa (per manufacturer)
CISPR11 Group 1, Class B

These standards guarantee that the device was designed by a company possessing a full quality system and meets the safety and performance criteria required for an Electrical Medical Device in markets within the European Union. The device was verified and validated according to the product specifications. The test criteria consist of standardized levels and internal product requirements. Tests performed on the device include environmental and mechanical stress testing, electromagnetic immunity and emissions testing, and medical device safety testing. Software on the device was verified and validated according to the functionality of the operations of the device. The test results confirm that the device is in accordance with its specifications.

Classification Criteria

- The device provides Class II protection against electric shock.
- The device does not contact the patient directly but plugs into a pulse oximetry sensor and/or $EtCO_2$ cable with nasal cannula which do contact the skin of the patient. These accessories are legally marketed and sold in the United States.
- The degree of protection against the ingress of water is IPX1.
- The device is not sterile.
- The use of the device is not suitable in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- During normal operating conditions, the device is in a continuous mode of operation.
- The device is externally supplied by AC Mains power, but may also be powered by an internal Li-polymer battery pack.
- The device is portable. It may be moved between uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Ms. Jennifer Laine
Electrical Engineer
Ivy Biomedical Systems, Incorporated
11 Business Park Drive
Branford, Connecticut 06405

OCT - 9 2009

Re: K091787
Trade/Device Name: Model 6000 Two Parameter Bedside Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, CCK
Dated: October 6, 2009
Received: October 7, 2009

Dear Ms. Laine:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091787

Device Name: Model 6000 Two Parameter Bedside Monitor

Indications for Use:

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This device is intended for use on adult, geriatric, pediatric, and neonatal patients in bedside or mobile applications within health care institutions and/or health care environments only under the direction of a physician or qualified clinician.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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