K103737

JUN - 2 2011

Special 510(k) SUMMARY
(as required by 807.92(c))

Regulatory Correspondent:

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Submitter of 510(k):

Infinium Medical
12151 62nd Street North #5
Largo, FL 33773
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Date of Summary: **December 10, 2010**

Trade/Proprietary Name: **Omni II Patient Monitor**

Classification Name: **Monitor, physiological, patient (without arrhythmia detection or alarms.**

Product Code: **MWI**

Reason for Submission:
The reason for this submission is to provide information that will verify the safety and effectiveness of the Omni II patient monitor in order to be cleared for sale in the United States. The main differences between the Omni II and the Omni Express are:

- The Omni II is larger which enables it to have a display that is 12.1 inches compared to the predicates 7 inch display.
- The Omni II uses a rechargeable lead acid battery and the predicate uses a rechargeable lithium ion battery.

Intended Use:
The purpose and function of the Omni II patient monitor is to monitor basic physiological parameters including, ECG, heart rate, NIBP (systolic, diastolic, and mean arterial pressures), SpO_2, respiration, and temperature for adult, neonate and pediatric patients. It may be used as a bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities.

Device Description:
The OMNI II monitor is a comprehensive monitoring system with four, six or eight traces compiling, processing, analyzing and displaying data from up to eight different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.

The OMNI II monitor can be powered by an internal battery pack that provides 1 hour of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

Predicate Device:	K103268 – OMNI Express Patient Monitor
Substantial Equivalence:	The proposed device is substantially equivalent to the Infinium OMNI Express Patient monitor which has been cleared under K103268. The proposed device has the same intended use and similar technological characteristics as compared to the predicate device.
Performance Testing:	The Omni II Patient monitor underwent several electrical safety tests to verify safety and effectiveness as well as Software Validation. • ANSI/AAMI EC13:2002 – Cardiac Monitors, Heart rate meters and alarms • IEC 60601-1-2:2007 - Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests • ISO 9919:2005 Medical electrical equipment - particular requirements for the basic safety and essential performance of pulse oximeters. • IEC 60601-2-27: (2005-08), Medical electrical equipment -- Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment. • AAMI/ANSI SP10:2002 Manual, electronic or automated sphygmomanometers. (Cardiovascular) Based on the conclusions of each of these tests it is determined that the Omni II patient monitor is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 2 2011

Infinium Medical
c/o Mr. John O' Brien
Regulatory Specialist
AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Re: K103737

Trade/Device Name: OMNI II Patient Monitor
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: MWI
Dated: April 27, 2011
Received: May 2, 2011

Dear Mr. O'Brien:

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Section 4- Indications for Use

510(k) Number (if known): K103737

Device Name: OMNI II Patient Monitor

The purpose and function of the OMNI II Patient monitor is to monitor ECG, heart rate, NIBP (systolic, diastolic, and mean arterial pressures), SpO_2, respiration, and temperature, for adult, neonate and pediatric patients. It may be used as a bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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