1/2 K101052

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

AUG 11 2010

Regulatory Correspondent:

AJW Technology Consultants Inc
962 Allegro Lane
Apollo Beach, FL 33572
John O'Brien
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813-645-2855
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Submitter of 510(k):

Infinium Medical
12151 62nd Street North #5
Largo, FL 33773
Suleyman Bilgutay
sales@infiniummedical.com

Date of Summary: **February 24, 2010**

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

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

Product Code: **MWI**

Intended Use:
The purpose and function of the OMNI III 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 III monitor is a comprehensive monitoring system with eight traces compiling, processing, analyzing and displaying data from up to six 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.

Predicate Device:	**K021154 – Goldway UT4000F Patient Monitor**
Substantial Equivalence:	The proposed device is substantial equivalent to the Goldway UT4000F, which has been cleared under K021154. The proposed device has the same intended use and similar technological characteristics as compared to the predicate device.

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

Infinum Medical, Inc.
c/o John O'Brien
AJW Technology Consultants, Inc.
962 Allegro Ln.
Apollo Beach, Florida 33572

AUG 11 2010

Re: K101052
Trade/Device Name: Omni III Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm
Regulatory Class: Class II (two)
Product Code: MWI
Dated: July 6, 2010
Received: July 8, 2010

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

1/1 K101052

Indications for Use

AUG 1 1 2010

510(k) Number (if known): K101052

Device Name: OMNI III Patient Monitor

The purpose and function of the OMNI III 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.

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

510(k) Number K101052