DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 23, 2014

Advanced Instrumentations, Inc.
Jorge Millan
601 West 20th Street
Hialeah, FL 33010 US

Re: K132077

Trade/Device Name:	PM-2000M Patient monitor
Regulation Number:	21 CFR 870.1025
Regulation Name:	Patient Physiological Monitor (With Arrhythmia Detection or Alarms)
Regulatory Class:	Class II
Product Code:	MHX, DRT, DXN, DSK, FLL, DQA, CCK, CBQ, CBS, CBR, CCL, DSA, DRT, DSI, MLD
Dated:	March 26, 2014
Received:	March 28, 2014

Dear Jorge Millan,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

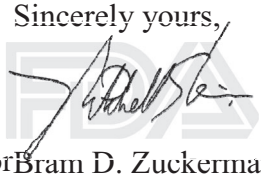
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

510(k) Number (if known): K132077

Device Name:

PM-2000M Patient Monitor

Indications for Use:

This monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters including ECG, respiration (RESP), temperature (TEMP), functional arterial oxygen saturation (Sp02), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), expired C02, cardiac output (C.O.) and anesthetic gas (AG)of adults, pediatrics and neonates in hospital environments. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

This monitor is suitable for use in hospital environments including but not limited to OR, PACU, ICU and neonate intensive care room.

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)

Date: 2014.04.23
08:55:00 -04'00'

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: __K132077_____

Submitter

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Official correspondent :

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Date Prepared:

March 26, 2014

Device name and classification:

- **Device Name:** PM-2000M Patient Monitor
- **Common Name:** Patient Monitor Arrhythmia detector and alarm

- **Classification**

Description	Classification	Product Code
21 CFR 870.1025 monitor, physiological, patient (with arrhythmia detection or alarms)	II	MHX
21 CR 870.2300 Cardiac monitor (including cardiotachoment and rate alarm)	II	DRT
21 CFR 870.1130 Non-Invasive blood pressure measurement	II	DXN
21 CFR 870.1110 Blood pressure computer	II	DSK
21 CFR 880.2910 Clinical Electronic Thermometers-Temperature Monitor with Probe	II	FLL
21 CFR 870.2700 Oximeter, Pulse	II	DQA
21 CFR 868.1400 Carbon Dioxide Gas Analyzer	II	CCK
21 CFR 868.1500 Enflurane gas analyzer	II	CBQ
21 CFR 868.1620 Halothane gas analyzer	II	CBS
21 CFR 868.1700 Nitrous Oxide gas analyzer	II	CBR
21 CFR 868.1720 Oxygen gas analyzer	II	CCL
21 CFR 870.2900 cable, transducer and electrode, patient, (including connector)	II	DSA
21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm)	II	DRT
21 CFR 870.1025 Detector and Alarm, Arrhythmia	II	DSI
21 CFR 870.1025 Monitor, ST Segment with Alarm	II	MLD

- **Regulatory Class:** Class II

Predicate Device:

V8 Patient Monitor, K120173 Manufacturer: EDAN Instruments

Device Description:

The PM-2000M Patient Monitor can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormities happen.

The PM-2000M realizes the monitoring of physiological parameters by configuration with different parameter modules which include Sp02 (pulse oxygen saturation, pulse rate and Sp02 plethysmogram) with EDAN Sp02 module or Nellcor SP02 module, NIBP (systolic pressure, diastolic pressure, mean pressure and pulse rate), TEMP, ECG, RESP, C02, IBP, C.O. and AG.

The above is the maximum configuration for elite VB, the user may select different monitoring parameters in according with the requirement.

The PM-2000M is configured with a 17-inch touch screen and build-in Lithium-ion battery, Besides, and supports software upgrade online and networking

Comparison to the predicate device:

The subject device has same technology characteristics, materials, design, manufacturing processes, operating principle, performance specifications and has the same indications for use as the predicate device.

Intended Use:

This monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters including ECG, respiration (RESP), temperature (TEMP), functional arterial oxygen saturation (Sp02), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), expired C02, cardiac output (C.O.) and anesthetic gas (AG)of adults, pediatrics and neonates in hospital environments. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

This monitor is suitable for use in hospital environments including but not limited to OR, PACU, ICU and neonate intensive care room.

Contraindications

It is not intended for use in patient's home or residence, or when it has not been ordered by a physician.

Effectiveness and Safety Contraindications:

Test Summary

The following quality assurance measures were applied to the development of the Patient Monitor

Software testing
Hardware testing
Safety testing

Environment testing
Risk analysis
Final validation

Substantially Equivalent Determination:

This premarket notification submission demonstrates that PM-2000M Patient Monitor is substantially equivalent to the predicate device.