December 8, 2017

Advanced Instrumentations, Inc.
Jorge Millan
Regulatory Affairs Manager
6800 NW 77th. Ct.
Miami, Florida 33166

Re: K172966
Trade/Device Name: CMS-2000 Central Monitoring System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: August 22, 2017
Received: September 26, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172966

Device Name

CMS-2000 Central Monitoring System

Indications for Use *(Describe)*

The CMS-2000 Central Monitoring System provides centralized monitoring and critical care management for patients monitored by bedside monitors. From the CMS-2000, clinicians can gain access to patient information for patients on the Network. The CMS-2000 displays waveforms, parameters and alarm status of bedside monitors for up to 32 patients on a single screen or up to 64 patients using two screens.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510K SUMMARY

CMS-2000 Central Monitoring System

SUBMITTER ADVANCED INSTRUMENTATIONS, INC
6800 NW 77th Ct, Miami, FL 33166
Phone: (305) 477-6331

US AGENT JORGE MILLAN, PHD
REGULATORY AFFAIRS CORRESPONDENT
Email: regulatory@advanced-inst.com
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DEVICE NAME AND CLASSIFICATION

TRADE NAME: CMS-2000 Central Monitoring System

CLASSIFICATION NAME: *870.1025* monitor, physiological, patient (with arrhythmia detection or alarms)

Product Code: MHX

REGULATORY CLASS: *Class II*
PANEL IDENTIFICATION *Cardiovascular*

DEVICE DESCRIPTION

The CMS-2000 Central Monitoring System is a software production, which runs on a PC platform running under the Microsoft Windows XP or Windows 7 operating system. Through specified protocol, one CMS-2000 can connect with multi-monitors from ADVANCED INSTRUMENTATIONS to collect patients' information and monitoring data such as physiological waveforms, physiological parameters and alarms. The CMS-2000 can also send bidirectional control instruction to bedside monitors to change patients' information, alarm limits and conduct NIBP measurements. The bedside Patient Physiological Monitors have been cleared by the FDA under K123048 separately. The monitoring information collected by the CMS-2000 can be saved and printed. At the same time, the old records can be searched conveniently and quickly.

Indications for Use: The CMS-2000 Central Monitoring System provides centralized monitoring and critical care management for patients monitored by bedside monitors. From the CMS-2000, clinicians can gain access to patient information for patients on the Network. The CMS-2000 displays waveforms, parameters and alarm status of bedside monitors for up to 32 patients on a single screen or up to 64 patients using two screens.

Predicate Devices: The CMS-2000 Central Monitoring System is equivalent to the EDAN Central Monitoring System, model MFM-CMS cleared under K120727.

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]

The CMS-2000 Central Monitoring System is comparable with and substantially equivalent to the EDAN Central Monitoring System, model MFM-CMS cleared under K120727. Compared with the MFM-CMS the Subject Device CMS-2000 has the same intended uses and functionality.

Technical Characteristics Comparison:

The basic and main technical features of the subject device CMS-2000 are the same as the predicated device MFM-CMS including Design, Operation Controls, Display Modes and performance results. Table 1 provides the comparison of features and functionality:

ITEM	PROPOSED DEVICE CMS-2000 K# TBD	PREDICATE DEVICE MFM-CMS K120727
PRODUCT CODE	MHX	MHX
REGULATION NO.	870.1025	870.1025
CLASS	II	II
INTENDED USE	The CMS-2000 Central Monitoring System provides centralized monitoring and critical care management for patients monitored by bedside monitors. From the CMS-2000, clinicians can gain access to patient information for patients on the Network. The CMS-2000 displays waveforms, parameters and alarm status of bedside monitors for up to 32 patients on a single screen or up to 64 patients using two screens.	The MFM-CMS Central Monitoring System provides centralized monitoring and critical care management for patients monitored by bedside monitors. From the MFM-CMS clinicians can gain access to patient information for patients on the Network. The MFM-CMS displays waveforms, parameters and alarm status of bedside monitors for up to 32 patients on a single screen or up to 64 patients using two screens.
WAVEFORMS	2 ECG Waveforms 1 RESP waveform 1 PLETH waveform	2 ECG Waveforms 1 RESP waveform 1 PLETH waveform

	8 IBP waveform 1 CO2 waveform 4 AG waveforms for CO2, O2, N2O and AA	8 IBP waveform 1 CO2 waveform 4 AG waveforms for CO2, O2, N2O and AA
PARAMETERS	ECG: HR, ST value, PVCs RESP: RR NIBP: SYS, DIA, MAP SPO2: SPO2, PR IBP: ART, PA, CVP, RAP, ICP, LAP, P1, P2 (only IBP supported by the monitor will be displayed) CO2: EtCO2, FiCO2, AwRR TEMP: T1, T2, TD AG: EtCO2, FiCO2, AwRR, EtO2, FiO2, EtN2O, FuN2O, HAL/ISO/ENF/SEV/DES: Et, Fi, MAC C.O: C.O., TB	ECG: HR, ST value, PVCs RESP: RR NIBP: SYS, DIA, MAP SPO2: SPO2, PR IBP: ART, PA, CVP, RAP, ICP, LAP, P1, P2 (only IBP supported by the monitor will be displayed) CO2: EtCO2, FiCO2, AwRR TEMP: T1, T2, TD AG: EtCO2, FiCO2, AwRR, EtO2, FiO2, EtN2O, FuN2O, HAL/ISO/ENF/SEV/DES: Et, Fi, MAC C.O: C.O., TB
DISPLAY	The Central Monitoring supports one or two displays. It can display up to 32 bedside monitors on one display and 64 bedside monitors on two displays simultaneously	The Central Monitoring supports one or two displays. It can display up to 32 bedside monitors on one display and 64 bedside monitors on two displays simultaneously
RECORD CAPACITY	240-hour trend data, 72 hour waveform, 720 alarm events, 1~2 hours short trend, 720 group NIBP measurement review for each bedside monitor	240-hour trend data, 72 hour waveform, 720 alarm events, 1~2 hours short trend, 720 group NIBP measurement review for each bedside monitor
CALCULATION	Drug calculation and titration table	Drug calculation and titration table
REVIEW	Print patient information, wave review, alarm review, trend review, NIBP review, and drug calculation result	Print patient information, wave review, alarm review, trend review, NIBP review, and drug calculation result
ALARMS	Audible and visible alarms	Audible and visible alarms

NETWORK/CONNECTIVITY	Web observation in the hospital local area network Bidirectional control HL7	Web observation in the hospital local area network Bidirectional control HL7

Clinical Test:
Clinical testing is not required.

Non-clinical Test:
The following quality assurance measures were applied to the development of the CMS-2000 System:

- Software testing
- Risk analysis
- Safety testing
- Performance test

Substantially Equivalent Determination
The subject device has similar technology characteristics and has the same intended use, same design principle and same functionality as the predicate device. There are no differences between the devices. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, Advanced Instrumentations concludes that the CMS-2000 Central Monitoring System is substantially equivalent to the predicate device.