February 5, 2024

Edan Instruments, Inc.
Tracy Yue
Regulatory Engineer
15 Jinhui Road, Jinsha Community, Kengzi Sub-district,
Pingshan District
Shenzhen, 518122
China

Re: K232694
Trade/Device Name: Central Monitoring System (MFM-CMS)
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: January 5, 2024
Received: January 5, 2024

Dear Tracy Yue:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices

Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

k232694

Device Name

Central Monitoring System (MFM-CMS)

Indications for Use *(Describe)*

MFM-CMS central monitoring system (hereinafter referred to as MFM-CMS) supports centralized management of patients' clinical data provided by EDAN medical devices. Clinicians can obtain patient clinical data via MFM-CMS. The indications for use of the MFM-CMS central monitoring system include:

- Viewing patient real-time clinical data and alarms.
- Storing and reviewing patient clinical data and alarms.
- Printing real-time and history patient data.
- Configuring local settings as well as synchronizing settings to a remote device through network.
- Accessing patient clinical data between several departments.

MFM-CMS is intended to be used only in clinical or hospital environment by well-trained healthcare professionals.

MFM-CMS is indicated for use when monitoring adult and/or pediatric and/or neonate patients as indicated by labeling of the medical device providing the data.

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.

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510(k) Summary
Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Edan Instruments, Inc.
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Tel: +86(0755) 84513592
Fax: +86(0755) 26882223

2. Contact person:

Tracy Yue

Preparing date:

Sep. 4, 2023

3. Device name and classification:

Trade name: Central Monitoring System, model: MFM-CMS
Classification Name/ Product code:
21 CFR 870.1025 Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)
MHX
Regulatory Class: Class II

4. Predicate Device(s):

1) Shenzhen Mindray Bio-Medical Electronics Co., LTD, BeneVision Central Monitoring System, cleared under K220058 (Primary)
2) Edan Instruments, MFM-CMS Central Monitoring System, cleared under K120727 (Reference)

5. Reason for Submission

By submission of the Traditional 510(k), Edan Instruments is requesting clearance for an updated version of the MFM-CMS Central Monitoring System (K120727).

6. Device Description:

MFM-CMS is a central monitoring system product, which can connect and manage information from EDAN medical devices. MFM-CMS offers central management for monitoring information from the medical devices. All these collected information can be displayed, printed, alarmed and recorded.

Modifications:
The following are the main changes to the software which is the subject of this 510(k) submission compared with the previous cleared K120727 version:

1. Add distributed function.
2. Add license authorization.
3. Support department management, device management and user management.
4. Support time synchronization function.
5. Support data automatic dump function.
6. Replace the software development platform.
7. Supports simultaneous login of multiple clients.
8. Support domain account to log in to the CMS client.

8. Indication for Use

MFM-CMS central monitoring system (hereinafter referred to as MFM-CMS) supports centralized management of patients' clinical data provided by EDAN medical devices. Clinicians can obtain patient clinical data via MFM-CMS. The indications for use of the MFM-CMS central monitoring system include:

- Viewing patient real-time clinical data and alarms.
- Storing and reviewing patient clinical data and alarms.
- Printing real-time and history patient data.
- Configuring local settings as well as synchronizing settings to a remote device through network.
- Accessing patient clinical data between several departments.

MFM-CMS is intended to be used only in clinical or hospital environment by well-trained healthcare professionals.

MFM-CMS is indicated for use when monitoring adult and/or pediatric and/or neonate patients as indicated by labeling of the medical device providing the data.

9. Predicate Device Comparison

The subject device is technologically equivalent to predicate devices. Any differences are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness. The table below compares the intended use and technological characteristics of the subject and primary predicate device：

Item	<Subject Device> **MFM-CMS Central Monitoring System**	<Primary Predicate Device> **BeneVision Central Monitoring System（K220058）**	**Comparison Result**
Intended Use			
Intended use	MFM-CMS central monitoring system (hereinafter referred to as MFM-CMS) supports centralized management of patients'	The indications for use of the BeneVision Central Monitoring System include: ■ Real time viewing of patient clinical data and	Different

Item	<Subject Device> **MFM-CMS Central Monitoring System**	<Primary Predicate Device> **BeneVision Central Monitoring System（K220058）**	**Comparison Result**
	clinical data provided by EDAN medical devices. Clinicians can obtain patient clinical data via MFM-CMS. The indications for use of the MFM-CMS central monitoring system include: ■ Viewing patient real-time clinical data and alarms. ■ Storing and reviewing patient clinical data and alarms. ■ Printing real-time and history patient data. ■ Configuring local settings as well as synchronizing settings to a remote device through network. ■ Accessing patient clinical data between several departments. MFM-CMS is intended to be used only in clinical or hospital environment by well-trained healthcare professionals. MFM-CMS is indicated for use when monitoring adult and/or pediatric and/or neonate patients as indicated by labeling of the medical device providing the data.	alarms ■ Storage and historical review of patient clinical data and alarms ■ Printing of real time and historical patient data ■ Configuration of local settings as well as synchronizing settings across the network to a remote device ■ Transfer of patient clinical data and settings between several Central Stations ■ Provides a Resting 12 Lead interpretation of previously stored data The BeneVision Central Monitoring System is a networked patient monitoring system intended for use in a fixed location, installed in professional healthcare facilities to provide clinicians remote patient monitoring. The network connections between the various devices can be any combination of Ethernet (Wired), Wireless WIFI (WLAN), and Wireless WMTS. The BeneVision Central Monitoring System supports one or more Mindray compatible physiological monitors and will display, store, print, and transfer information received from the compatible monitors; The BeneVision Central Monitoring System supports bi-directional configuration of the compatible monitors. The telemetry monitoring systems are designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The BeneVision Central Monitoring System supports Telemetry Systems: TMS-6016, Telepack-608, TMS60, TM80, and TM70. ■ The TMS-6016 transmitter is intended for use on Adult and Pediatric patients to monitor	

Item	<Subject Device> **MFM-CMS Central Monitoring System**	<Primary Predicate Device> **BeneVision Central Monitoring System（K220058）**	**Comparison Result**
		ECG and SpO2 physiological data. ■ The Panorama Telepack-608 transmitter is intended for use on Adult patients to monitor ECG and SpO2 physiological data. ■ The TMS60 transmitter is intended for use on Adult and Pediatric patients over three years old to monitor ECG, SpO2, NIBP and Resp physiological data. The physiological data can be reviewed locally on the display of the transmitter. The Central Station will support ECG, Heart Rate, SpO2, NIBP, Resp, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TMS60. ■ The TM80/TM70 telemetry monitor is intended for use on Adult and Pediatric patients over three years old to monitor ECG, SpO2, NIBP and Resp physiological data. The physiological data can be analyzed, alarmed, stored, reviewed locally on the display of the monitor, and the Central Station can configure and display the physiological parameters from the TM80/TM70. The BeneVision Central Monitoring System is intended for use in professional healthcare facilities under the direct supervision of a licensed healthcare practitioner.	
Technical			
Operation System	Support Windows 10 Pro 32/64 bit, Windows 11 Pro 64 bit, Server 2012, Server 2016	Support Microsoft Windows 8/10, Server 2012/Server 2016/ Server 2019	Different
Performance			
Bi-directional Configuration	Support	Support	Same
Data Review	Short trends for all parameters; trend graph and trend table for all parameters; full disclosure waveforms and ECG compressed waveforms; physiological alarm events,	Trend data, events review, dynamic short trend, C.O. measurements, ST segments, full-disclosure waveforms and compressed waveforms, NIBP measurements, 12-lead	Different

Item	<Subject Device> **MFM-CMS Central Monitoring System**	<Primary Predicate Device> **BeneVision Central Monitoring System（K220058）**	**Comparison Result**
	nurse call events, and patient call events; 12-lead analysis results; NIBP measurement data; C.O. measurement results; score trend review.	analysis results, 12 analysis waveforms for each analysis result	
Calculations	MFM-CMS provides functions including drug calculation and titration table, hemodynamic calculation, oxygenation calculation, renal function calculation and ventilation calculation.	BeneVision provides functions including drug calculation and titration table, hemodynamic calculation, oxygenation calculation, renal function calculation and ventilation calculation.	Same
Telemetry	Support	Support	Same
Print	Patient information, Real-time monitoring data, Alarm list or waveform, Waveform review, Trend table/graph, NIBP review, 12-lead analysis result, C.O. review, Score trend, ECG, NIBP, Nursing report, Calculation result	Patient information, Real-time waveform, Real-time alarm, Alarm Settings, Multi-lead ECG Report, CSA Report, Waveform review, Arrhythmia Statistic Result, Trend Review, C.O. measurement, events, 12-lead Review, ST review, QT View Report, Drug calculations, Hemodynamics calculations, Oxygenation calculations, Ventilation calculations, Renal calculations, ICG hemodynamic parameter, CCO hemodynamic parameter, SvO2/ScvO2 oxygenation parameters	Different
Network Connect	Support wired and wireless network.	Support wired and wireless network.	Same
Patient Monitor Numbers –Number Supported	1. Support 64 monitors running as application 2. Running as Monitoring Station up to 128 monitors with no patient display, the display is provided by Viewer Stations	1. Support 64 monitors running as application 2. Running as service Up to 128 monitors with no patient display, the display is provided by Work Stations	Similar

10. Performance Data:

Non-clinical test:

Biocompatibility Testing

Not applicable.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Bench Testing:

Edan has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets relevant consensus standards.

- IEC 60601-1-8:2006 + Am1:2012 Medical electrical equipment - part 1-8: general requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Clinical testing:

Not applicable. Clinical testing is not required to establish substantial equivalence to the predicate device.

11. Conclusion

The bench testing data and software verification and validation demonstrate that MFM-CMS Central Monitoring System is substantially equivalent to the predicate devices.