DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 30, 2015

Edan Instruments Inc.
Doug Worth
Sr. Director US RA/QA
1200 Crossman Ave, Suite 200
Sunnyvale, California 94089

Re: K143695
Trade/Device Name: Central Monitoring System
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: Class II
Product Code: HGM
Dated: December 19, 2014
Received: January 5, 2015

Dear Doug Worth,

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Joyce M. Whang -S

for

Benjamin Fisher
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K143695

Device Name
Central Monitoring System

Indications for Use *(Describe)*
The Maternal Fetal Monitoring – Central Nurse System (hereinafter called "MFM-CNS") is a clinical data managing software application and is indicated for antepartum and intrapartum monitoring of pregnant women in a healthcare setting.
The MFM-CNS is intended to manage perinatal monitoring data acquired from bedside monitors or manual input for viewing at the central nursing station. The system also produces an electronic medical record.

The MFM-CNS has display fields for the following obstetric data:

- patient demographics
- provider notes
- fetal heart rate (FHR)
- uterine activity (via tocodynamometry or IUP)
- fetal movement
- maternal heart rate
- SpO2
- non-invasive blood pressure (NIBP)
- respiratory rate
- temperature
- pulse

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.

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510（K） Summary

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

1. Submitter:	Edan Instruments, Inc. 3/F - B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, Shekou, Nanshan Shenzhen, 518067 P.R. China Tel: +86(0755) 26858736 Fax: +1 (408) 418-4059
Contact person:	Queena Chen
Preparing date:	March 24, 2015
2. Device name and classification:	**Device Name:** Central Monitoring System **Model:** MFM-CNS **Classification Name:** 21 CFR 884.2740 Perinatal monitoring system and accessories Product code: HGM **Regulatory Class:** Class II **Review Panel:** Obstetrics/Gynecology
3.Premarket Notification Class III Certification and Summary	Not applicable, the subject device is Class II.
4. Predicate Device(s):	CIV-ob Obstetrical Monitoring Software Application /K103172/ CIVNET Communication Ltd. Philips OB TraceVue Obstetrical Information Management System/K081203/ Philips Medizin System
5. Device Description:	The Maternal Fetal Monitoring – Central Nurse System (hereinafter called "MFM-CNS") is a clinical data managing software application. Its function is to manage clinical data of fetal heart and maternal vital signs (CTG - Cardiotocography), which is automatically acquired from bedside monitors, for the purpose of collecting, processing and saving the patient and/or clinical data that is normally provided on record papers and/or separate bedside monitors. It provides electronic medical records and operates with

off-the-shelf software and hardware.

The MFM-CNS is intended to be used in hospital clinical areas such as monitor units, delivery room, etc. It is intended to be operated by or under guidance of qualified healthcare professionals, not intended for home healthcare environment. During monitoring, the user should check the results on the bedside monitor in person, even though they could observe the results on the MFM-CNS system interface. The user cannot only depend on the MFM-CNS system to obtain monitoring data, because whether the data provided by the system is accurate depends on the stability of the operating system, the performance of PC station and the network. Although the software has its independent alarm system, the alarm information provided by the system is just for reference.

6. Indications for Use:

The Maternal Fetal Monitoring – Central Nurse System (hereinafter called "MFM-CNS") is a clinical data managing software application and is indicated for antepartum and intrapartum monitoring of pregnant women in a healthcare setting.

The MFM-CNS is intended to manage perinatal monitoring data acquired from bedside monitors or manual input for viewing at the central nursing station. The system also produces an electronic medical record.

The MFM-CNS has display fields for the following obstetric data:

- patient demographics
- provider notes
- fetal heart rate (FHR)
- uterine activity (via tocodynamometry or IUP)
- fetal movement
- maternal heart rate
- SpO2
- non-invasive blood pressure (NIBP)
- respiratory rate
- temperature
- pulse

7. Predicate Device Comparison

Item	CIV-ob ™ (plus)	MFM-CNS 3.82	SE
Manufacturer/K#	CIVNET Communication Ltd./ K103172	EDAN Instruments/N/A	
Classification			
Classified as per FDA regulation	Class II	Class II	Same
Network and Hardware			
Hardware	Off-the-shelf computers and accessories	Off-the-shelf computers and accessories	Same
Network connecting to bedside monitor	Ethernet	Ethernet	Same
Software			
Display	Fetal heart rate, TOCO, maternal vital signs, patient demography data, and notes. Providing the means to display multiple beds simultaneously.	Fetal heart rate, TOCO, maternal vital signs, patient demography data, and notes. Providing the means to display multiple beds simultaneously.	Same
Print	Print (locally or remotely) CTG, patient records, and CIV-ob™ (plus) data base definition (e.g. item names).	Print (locally or remotely) CTG and patient records.	Different
Archive	CTG and maternal vital signs. Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk). Providing automatic archiving of the data.	CTG and maternal vital signs. Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk). Saving data automatically.	Same
Alarm	Visual alerts of fetal/maternal monitor such as out-of-limit heart rate or poor signal quality.	Visual alerts of fetal/maternal monitor such as out-of-limit heart rate or poor signal quality.	Same
Electronic patient record.	Easy interfacing with any IT patient record system for data acquisition, viewing and storage of	Easy interfacing with any IT patient record system for data acquisition, viewing and	Same

	electronic patient record.	storage of electronic patient record.	
Notes	Providing the user the ability to enter comments and specific data.	Providing the user the ability to enter comments and specific data.	Same
Remote Access	Review fetal/maternal monitor data remotely over the TCP/IP.	Review fetal/maternal monitor data remotely over the TCP/IP.	Same
Standards compliance			
Detail	IEC 62304 IEC 62366	IEC 62304 IEC 62366	Same
Intended Use			
Intended use	The CIVNET CIV- ob ™ (plus) is a clinical data managing software application and is indicated for antepartumn and intrapartumn monitoring of pregnant women in a healthcare setting The **CIVNET** CIV- ob ™ (plus) is indented to manage perinatal monitoring data acquired from bedside monitors or manual inputs for viewing at the central nursing station. The system also produces an electronic medical record. The **CIYNET** CIV ob ™ (plus) has display fields for the following obstetric data: patient demographics, provider notes, fetal heart rate	The Maternal Fetal Monitoring – Central Nurse System (hereinafter called "MFM-CNS") is a clinical data managing software application and is indicated for antepartum and intrapartum monitoring of pregnant women in a healthcare setting. The MFM-CNS is intended to manage perinatal monitoring data acquired from bedside monitors or manual input for viewing at the central nursing station. The system also produces an electronic medical record. The MFM-CNS has display fields for the following obstetric data:	Same

	(FHR), uterine activity (via tocodynamometry or IUP), etc.	patient demographics, provider notes, fetal heart rate (FHR), uterine activity (via tocodynamometry or IUP), etc.	

Item	The Philips OB TraceVue Obstetrical Information Management System	MFM-CNS	SE
Manufacturer/K#	Philips Medizin System/K081203	EDAN Instruments/None	
Classification			
Classified as per FDA regulation	Class II	Class II	Same
Software			
CTG	The Philips OB TraceVue Obstetrical Information Management System can analyze signal loss, contractions, basal heart rate, accelerations, decelerations, short term variation, long term variation and other parameters.	The MFM-CNS can analyze signal loss, contractions, basal heart rate, accelerations, decelerations, short term variation, long term variation and other parameters.	Same
NICHD	The Philips OB TraceVue Obstetrical Information Management System can analyze FHR baseline and its scope, FHR baseline variation and its scope, accelerated number, early deceleration, late deceleration, variable deceleration, prolonged deceleration, sine curve and other parameters.	The MFM-CNS can analyze FHR baseline and its scope, FHR baseline variation and its scope, accelerated number, early deceleration, late deceleration, variable deceleration, prolonged deceleration, sine curve and other parameters.	Same

The subject device shares the same characteristics in most items with the predicate device except in the following one aspect: The predicate device prints the CIV ob ™ (plus) data base definition (e.g. item names) but the subject device does not. MFM-CNS only prints fetal and/or maternal reports such as fetal monitoring graphs or maternal trend lists.

The comparison above shows that the differences do not affect the safety and

effectiveness of the MFM-CNS and there are no safety and effectiveness issues relating to the MFM-CNS.

8. Effectiveness and Safety Considerations:

Clinical test:

Clinical testing is not required.

Non-clinical test:

Since the subject is a software only product, EMC and Electrical Safety Evaluation are not required. But the following quality assurance measures were applied to the development of the MFM-CNS to ensure its safety and effectiveness:

- Software testing according to FDA Guidance *General Principles of Software Validation* dated on Jan. 11, 2002.
- Risk analysis according to ISO 14971: 2007
- Usability analysis according to IEC 62366: 2007
- Software life cycle management according to IEC 62304: 2006

The subject device passed all testing. The tests and analysis were all conducted to ensure the safety and effectiveness, and results show substantial equivalence between the subject device and the predicates.

9. Substantially Equivalent Determination

Verification and validation testing was done on the MFM-CNS and all testing passed pre-specified criteria. Since the testing passed, this premarket notification submission demonstrates that the subject device MFM-CNS is substantially equivalent to the predicate device.