K100358

510（K）Summary of Safety and Effectiveness

JAN - 6 2011

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

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Contact person: Jiang yucai
Edan Instruments, Inc.

Preparing date: 2010-08-23

Proprietary Name: Central Monitoring System (model MFM-CNS)

Classification information: 21 CFR 884.2740 Perinatal monitoring system and accessories
Class II

Product code: HGM

Review Panel: Obstetrics/Gynecology

Predicate Devices: CIV-ob Obstetrical Monitoring Software Application (K051175)

Device Description: MFM-CNS is a software production who runs on PC station with Microsoft Windows XP operating system. MFM-CNS by connecting one central station with some bedside fetal / maternal monitors, carries out centralized monitoring management for many beds. It can monitor a pregnant woman during the whole parturition process, and all the monitoring information can be recorded, saved and printed, and alarm when the parameter exceed the user defined limit and poor signal quality. At the same time, the old records can be searched conveniently and quickly.

Device features:

- Connect maximum 32 bedside fetal / maternal monitors with Ethernet.
- Display FHR, UA, Maternal HR, PR, SpO2, NIBP, RR and TEMP numerics on the screen.
- The screen displays all the monitors simultaneously, or displays one monitor in full screen.
- 24-hour CTG, 1440-group Maternal Vital Sign data, 200-group NIBP data review.
- Print CTG report, Maternal Vital Sign list, NIBP list on the paper
- Audible & visible alarm when FHR or maternal vital sign exceeds the user defined limit or poor signal quality.
- Patient information, CTG, Maternal Vital Sign list and NIBP list can be saved, and burned into CDs for backup.
- Support user accessing control.

1.2 Indications for Use

The Maternal Fetal Monitoring – Central Nurse System (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
- FHR
- uterine activity (via tocodynamometry or IUP)
- maternal heart rate
- SpO2
- NIBP
- respiratory rate
- temperature
- pulse rate

K100358

Test Summary: The following quality assurance measures were applied to the development of the MFM-CNS Electrocardiograph:

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

Conclusion: Verification and validation testing was done on MFM-CNS. This premarket notification submission demonstrates that the subject device MFM-CNS is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Edan Instruments, Inc.
c/o Mr. William Stern
Official Correspondent
Multigon Industries, Inc.
1 Odell Plaza
YONKERS NY 10701

JAN - 6 2011

Re: K100358
Trade Name: MFM-CNS (Central Monitoring System)
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: December 20, 2010
Received: December 23, 2010

Dear Mr. Stern:

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 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K100358

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Device Name: Central Monitoring System (model MFM-CNS)

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Prescription Use X Or Over the Counter Use ____.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100358