September 6, 2017

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

Re:   K171178  
Trade/Device Name: Central Monitoring System  
MFM-CNS Lite v1.1 and MFM-CNS v3.91  
Regulation Number:  21 CFR 884.2740  
Regulation Name:  Perinatal Monitoring System and Accessories  
Regulatory Class:  Class II  
Product Code:  HGM  
Dated:  August 4, 2017  
Received:  August 7, 2017

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 (DICE) 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 (DICE) 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
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.

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.

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

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

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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Indications for Use

MFM-CNS Lite (hereinafter called "Lite") is a clinical data managing software application and is indicated for antepartum monitoring of pregnant women in a healthcare setting.

Lite is intended to manage antepartum-monitoring data acquired from bedside monitors and produce electronic medical records.

Lite has display fields for the following obstetric data:
- patient demographics
- provider notes
- fetal heart rate (FHR)
- uterine activity
- fetal movement

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)
510(K) Summary
Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

1. Submitter: Edan Instruments, Inc.
   #15 Jinhui Road, Jinsha Community,
   Kengzi Sub-District, Pingshan District,
   Shenzhen, 518122 P.R.China.
   Tel: +86(0755) 26858736
   Fax: +1 (408) 418-4059

2. Device name and classification:
   **Device Name:** Central Monitoring System
   **Model:** MFM-CNS v3.91, MFM-CNS Lite v1.1
   **Classification Name/Product code:**
   884.2740 Perinatal monitoring system and accessories / HGM
   **Regulatory Class:** Class II

3. Predicate Device(s):
   1. EDAN Instrument, Inc. Central Monitoring System, model MFM-CNS v3.82, K143695. The predicate device was not the subject of a recall and no reference devices were used in this submission.

4. Device Description: MFM-CNS v3.91 and MFM-CNS Lite v1.1
   The MFM-CNS v3.91 and MFM-CNS Lite v1.1 are clinical data managing software applications. Both applications manage clinical data of fetal monitoring and uterine activity, and the MFM-CNS v3.91 additional monitors maternal vital signs. Data are 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. They provide electronic medical records and operate with off-the-shelf software and hardware.

   The MFM-CNS v3.91 and MFM-CNS Lite v1.1 are intended to be
used in hospital clinical areas such as monitor units, delivery room, etc. They are 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 v3.91 and MFM-CNS Lite v1.1 system interface. The user cannot only depend on the MFM-CNS v3.91 and MFM-CNS Lite v1.1 system to obtain monitoring data, because whether the data provided by the system are accurate depends on the stability of the operating system, the performance of PC station and the network.

5. Indications for Use

**MFM-CNS v3.91:**
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.
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.
MFM-CNS has display fields for the following obstetric data:
- patient demographics
- provider notes
- fetal heart rate (FHR)
- uterine activity
- fetal movement
- maternal heart rate
- SpO2
- non-invasive blood pressure (NIBP)
- respiratory rate
- temperature
- pulse rate

**MFM-CNS Lite v1.1:**
MFM-CNS Lite (hereinafter called "Lite") is a clinical data managing software application and is indicated for antepartum monitoring of pregnant women in a healthcare setting.
Lite is intended to manage antepartum-monitoring data acquired from
bedside monitors and produce electronic medical records. Lite has display fields for the following obstetric data:
- patient demographics
- provider notes
- fetal heart rate (FHR)
- uterine activity
- fetal movement

### 6. Predicate Device Comparison

The subject device shares the same characteristics in most items with the predicate device except in the following aspects:

<table>
<thead>
<tr>
<th>Item</th>
<th>MFM-CNS v3.82</th>
<th>MFM-CNS v3.91</th>
<th>MFM-CNS Lite v1.1</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer/K#</td>
<td>EDAN Instruments/K143695</td>
<td>EDAN Instruments/N/A</td>
<td>EDAN Instruments/N/A</td>
<td></td>
</tr>
<tr>
<td>Indication for Use</td>
<td>MFM-CNS v3.82 The Maternal Fetal Monitoring – Central Nurse System (hereinafter called &quot;MFM-CNS&quot;) 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</td>
<td>MFM-CNS v3.91 The Maternal Fetal Monitoring – Central Nurse System (hereinafter called &quot;MFM-CNS&quot;) is a clinical data managing software application and is indicated for antepartum and intrapartum monitoring of pregnant women in a healthcare setting.</td>
<td>MFM-CNS Lite v1.1 MFM-CNS Lite (hereinafter called &quot;Lite&quot;) is a clinical data managing software application and is indicated for antepartum monitoring of pregnant women in a healthcare setting. MFM-CNS Lite is intended to manage antepartum-monitoring data acquired from bedside monitors and produce electronic medical records. The MFM-CNS Lite has display fields for</td>
<td>Different</td>
</tr>
</tbody>
</table>

Different
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, fetal movement.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Class II</th>
<th>Class II</th>
<th>Class II</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Network and Hardware</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hardware</td>
<td>Off-the-shelf computers and accessories</td>
<td>Off-the-shelf computers and accessories</td>
<td>Off-the-shelf computers and accessories</td>
<td>Same</td>
</tr>
<tr>
<td>Network connecting to bedside monitor</td>
<td>Ethernet</td>
<td>Ethernet</td>
<td>Ethernet</td>
<td>Same</td>
</tr>
<tr>
<td>Software</td>
<td>16 client</td>
<td>32 client</td>
<td>1 client</td>
<td>Different</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>------------------------------------------------</td>
<td>------------------------------------------------</td>
<td>------------------------------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td><strong>User Access / Authentication</strong></td>
<td>Fetal heart rate, TOCO, maternal vital signs, patient demography data, and notes. Providing the means to display multiple beds simultaneously.</td>
<td>Fetal heart rate, TOCO, maternal vital signs, patient demography data, and notes. Providing the means to display multiple beds simultaneously.</td>
<td>Fetal heart rate, TOCO, patient demography data, and notes. Providing the means to display multiple beds simultaneously.</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>Print (locally or remotely) CTG and patient records.</td>
<td>Print (locally or remotely) CTG and patient records.</td>
<td>Print (locally) CTG and patient records.</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Supporting beds</strong></td>
<td>32</td>
<td>128</td>
<td>6</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Archive</strong></td>
<td>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.</td>
<td>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.</td>
<td>CTG. Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk). Saving data automatically.</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Alarm</strong></td>
<td>Visual alerts of fetal/maternal monitor such as out-of-limit heart rate or poor signal quality.</td>
<td>Visual alerts of fetal/maternal monitor such as out-of-limit heart rate or poor signal quality.</td>
<td>Visual alerts of fetal monitor such as poor signal quality.</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Electronic patient record</strong></td>
<td>Interfaces with HL7 patient record systems for data</td>
<td>Interfaces with HL7 patient record systems for data acquisition,</td>
<td>Interfaces with the Gerätedatenträger -Transfer (GDT) patient record systems</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Notes</strong></td>
<td>Providing the user the ability to enter comments and specific data.</td>
<td>Providing the user the ability to enter comments and specific data.</td>
<td>Providing the user the ability to enter comments and specific data.</td>
<td>Same</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>CTG</strong></td>
<td>The MFM-CNS can analyze signal loss, contractions, basal heart rate, accelerations, decelerations, short term variation, long term variation and other parameters.</td>
<td>The MFM-CNS can analyze signal loss, contractions, basal heart rate, accelerations, decelerations, short term variation, long term variation and other parameters.</td>
<td>The MFM-CNS Lite can analyze signal loss, contractions, basal heart rate, accelerations, decelerations, short term variation, long term variation and other parameters.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>NICHD</strong></td>
<td>The MFM-CNS can analyze FHR baseline and its scope, FHR baseline variation and its scope, acceleration number, early deceleration, late deceleration, variable deceleration, prolonged deceleration, sine curve and other parameters.</td>
<td>The MFM-CNS can analyze FHR baseline and its scope, FHR baseline variation and its scope, acceleration number, early deceleration, late deceleration, variable deceleration, prolonged deceleration, sine curve and other parameters.</td>
<td>The MFM-CNS Lite can analyze FHR baseline and its scope, FHR baseline variation and its scope, acceleration number, early deceleration, late deceleration, variable deceleration, prolonged deceleration, sine curve and other parameters.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Remote Access</strong></td>
<td>Review fetal/maternal monitor data remotely over the</td>
<td>Review fetal/maternal monitor data remotely over the</td>
<td>Local Access</td>
<td>Different</td>
</tr>
<tr>
<td></td>
<td>TCP/IP.</td>
<td>TCP/IP.</td>
<td></td>
<td></td>
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<tr>
<td>---------------</td>
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<td>----------------------------------</td>
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<td>----------------------</td>
</tr>
<tr>
<td><strong>Storage capacity</strong></td>
<td>100 thousand records</td>
<td>Capacity depends on the size of the hard disk</td>
<td>Capacity depends on the size of the hard disk</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Windows OS Support</strong></td>
<td>XP, Win7, Win8.1</td>
<td>XP, Win7, Win8.1, Win10</td>
<td>XP, Win7, Win8.1, Win10</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Standards compliance</strong></td>
<td>IEC 62304, IEC 62366</td>
<td>IEC 62304, IEC 62366</td>
<td>IEC 62304, IEC 62366</td>
<td>Same</td>
</tr>
</tbody>
</table>

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

7. **Performance Data:**

**Non-clinical data:**

Since the subject is a software only product, the following quality assurance measures were applied to the development of the MFM-CNS v3.91 and MFM-CNS Lite v1.1 to evaluate safety and effectiveness:

1. Risk analysis according to ISO 14971: 2007
2. Software life cycle management according to IEC 62304: 2006. The subject device passed all testing.
3. Bench testing was conducted per IEC 60601-1-8: 2006 (Medical electrical equipment 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), and all the results show pass.

**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.” The software for this device was considered as a “major” level of concern, since a failure or latent flaw in the software could result in serious injury or death to the patient or operator.

**Summary**

The non-clinical performance testing showed that the subject devices are as safe and as effective as the predicate device.

8. **Conclusion**

The non-clinical data and software verification and validation demonstrate that MFM-CNS v3.91 and MFM-CNS Lite v1.1 are substantially equivalent to the predicate device.