



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

July 1, 2015

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

Re: K150901

Trade/Device Name: Fetal & Maternal Monitor, models F6, F6 Express, F9, F9 Express  
Regulation Number: 21 CFR 884.2740  
Regulation Name: Perinatal monitoring system and accessories  
Regulatory Class: Class II  
Product Code: HGM  
Dated: March 27, 2015  
Received: April 3, 2015

Dear Mr. 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,

  
**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

510(k) Number (if known)

K150901

Device Name

Fetal & Maternal Monitor, models F6, F6 Express, F9, F9 Express

Indications for Use (Describe)

F6/F9 Fetal & Maternal Monitor (hereinafter called F6/F9):

F6/F9 Fetal & Maternal Monitor is intended for non-invasive and invasive monitoring of fetus during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

F6/F9 Fetal & Maternal Monitor provides Non-Stress testing for pregnant women from the 28th week of gestation. It can externally monitor the FHRs using ultrasound and uterine activity via a TOCO transducer. Alternatively, it can internally monitor one of the FHRs with DECG and uterine activity with an IUPC.

F6 Express/F9 Express Fetal & Maternal Monitor (hereinafter called F6 Express/F9 Express):

F6 Express/F9 Express Fetal & Maternal Monitor is intended for monitoring physiological parameters of pregnant women during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

F6 Express/F9 Express Fetal & Maternal Monitor is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation. In addition, it provides a solution for maternal vital signs monitoring.

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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"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."*

## 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:** June 29, 2015
- 2. Device name and classification:** **Device Name:** Fetal & Maternal Monitor, models F6, F6 Express, F9, F9 Express (hereinafter called F series)  
**Classification Name/ Product code:**  
884.2740 Perinatal monitoring system and accessories/ HGM  
**Regulatory Class:** Class II
- 3. Premarket Notification Class III Certification and Summary** Not applicable, the subject device is Class II.
- 4. Predicate Device(s):** 1) Edan Instruments, Inc., Fetal & Maternal Monitor/F9 Express /K100797.  
2) Philips Medical Systems, Inc./Avalon CTS cordless Fetal Transducer System/K023931
- 5. Reason for Submission** Modification for previous cleared product Fetal & Maternal Monitor, models F6, F6 Express, F9, F9 Express.
- 6. Pre-Submission, IDE** Not applicable, there is no prior submission.
- 7. Device Description:** F series Fetal & Maternal Monitor, including F6, F6 Express, F9, F9 Express which provides the following primary features that can be available for the multiple configurations:
- Basic parameters: FHR, TOCO, Event Mark, AFM
  - Dual FHR monitoring
  - Internal parameters: IUP/DECG
  - FHR limit alarm

- Software for data transmission to PC, which means the subject device can be connected to Central Nursing System provided by EDAN, which has been cleared by K100358.
- Quick printing for stored waveform
- Lithium battery for continuous working
- Maternal ECG monitoring
- Maternal SpO2 monitoring
- Maternal NIBP
- Maternal temperature monitoring
- Used with FTS-3 Fetal Telemetry System (hereinafter called FTS-3)

The above is the maximum configuration for F series Fetal & Maternal Monitor, the user may select different measurement parameters in according with their requirements, which is also show in the following table.

| Measurement \ Model                                   | F6  | F9  | F6 Express | F9 Express |
|---|-----|-----|------------|------------|
| Single-FHR  | √   | √   | √          | √          |
| Dual-FHR  | √   | √   | √          | √          |
| TOCO  | √   | √   | √          | √          |
| FM  | √   | √   | √          | √          |
| AFM   | √   | √   | √          | √          |
| DECG/IUP  | Opt | Opt | ×          | Opt        |
| MECG  | ×   | ×   | √          | √          |
| NIBP  | ×   | ×   | √          | √          |
| MSpO2   | ×   | ×   | √          | √          |
| TEMP  | ×   | ×   | √          | √          |
| NOTE: √ = Standard; Opt = Optional; × = Not Available |     |     |            |            |

### **8. Indications for Use:**

F6/F9 Fetal & Maternal Monitor (hereinafter called F6/F9):  
 F6/F9 Fetal & Maternal Monitor is intended for non-invasive and invasive monitoring of fetus during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

F6/F9 Fetal & Maternal Monitor provides Non-Stress testing for pregnant women from the 28<sup>th</sup> week of gestation. It can externally monitor the FHRs using ultrasound and uterine activity via a TOCO transducer. Alternatively, it can internally monitor one of the FHRs with DECG and uterine activity with an IUPC.

F6 Express/F9 Express Fetal & Maternal Monitor (hereinafter called F6 Express/F9 Express):

F6 Express/F9 Express Fetal & Maternal Monitor is intended for monitoring physiological parameters of pregnant women during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

F6 Express/F9 Express Fetal & Maternal Monitor is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation. In addition, it provides a solution for maternal vital signs monitoring.

### **9. Predicate Device Comparison**

The subject devices share the same characteristics in all items with the predicate device, concluding from using the same technology and principle. All the technological differences existed between the subject and predicate devices are only some performance parameters items, detailed comparison information can be found in the following tables.

#### **Comparison between the subject F9 series and the previous cleared F9 Express**

| <b>Item</b>         | <b>F6 / F6 Express/ F9 / F9 Express</b>   | <b>F9 Express</b>   | <b>Substantial Equivalence (SE)</b> |
|---------------------|---|---|-------------------------------------|
| <b>Manufacturer</b> | Edan Instruments, Inc.  | Edan Instruments, Inc.  | /                                   |
| <b>K#</b>           | N/A   | K100797   | /                                   |
| <b>Intended use</b> | The F9 Express fetal & maternal monitor is intended for monitoring physiological parameters of pregnant women during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms. It is not intended for use in intensive care units, operating rooms or for home use.<br>F9 Express fetal & maternal monitor is intended for providing | The F9 Express fetal & maternal monitor is intended for monitoring physiological parameters of pregnant women during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms. It is not intended for use in intensive care units, operating rooms or for home use.<br>F9 Express fetal & maternal monitor is intended for providing | Same                                |

|   |   |   |           |
|---|---|---|-----------|
|   | Non-Stress testing or fetal monitoring for pregnant women .In addition, it provides a solution for maternal vital signs monitoring.   | Non-Stress testing or fetal monitoring for pregnant women. In addition, it provides a solution for maternal vital signs monitoring. |           |
| <b>Electrical Safety</b>  |   |   |           |
| Anti-electric-shock degree:                                       | FHR1, FHR2, TOCO, FM, IUP: BF;<br>SpO2, NIBP: BF (Defibrillator-proof);<br>DECG:CF;<br>ECG, TEMP: CF (Defibrillator-proof);<br>FTS-3: FHR1, FHR2, TOCO: BF (Defibrillator-proof). | FHR1, FHR2, TOCO, FM, IUP: BF;<br>SpO2, NIBP: BF (Defibrillator-proof);<br>DECG: CF;<br>ECG, TEMP: CF (Defibrillator-proof).        | Different |
| Degree of safety of application in the presence of flammable gas: | Equipment not suitable for use in presence of flammable gases   | Equipment not suitable for use in presence of flammable gases   | Same      |
| Working mode:   | Continuous running equipment  | Continuous running equipment  | Same      |
| <b>FHR</b>  |   |   |           |
| Technique:  | Pulse Doppler with autocorrelation processing   | Pulse Doppler with autocorrelation processing   | Same      |
| Pulse Repetition Frequency:                                       | 2 KHz   | 2 KHz   | Same      |
| Pulse Duration:   | 92 $\mu$ s  | 92 $\mu$ s  | Same      |
| Ultrasound Frequency:   | 1.0MHz $\pm$ 10%  | 1.0MHz $\pm$ 10%  | Same      |
| Spatial-Peak Temporal Average Intensity:                          | Ispta < 100 mW/cm2  | Ispta < 100 mW/cm2  | Same      |
| FHR Range:  | 50 bpm-240 bpm  | 50 bpm-240 bpm  | Same      |
| Resolution:   | 1 bpm   | 1 bpm   | Same      |
| Accuracy:   | $\pm$ 1 bpm(F9)<br>$\pm$ 2 bpm(F6,FTS-3)  | $\pm$ 1 bpm(F9)<br>$\pm$ 2 bpm(F6)  | Same      |
| <b>TOCO</b>   |   |   |           |
| TOCO Range:   | 0%-100%   | 0%-100%   | Same      |
| Resolution:   | 1%/   | 1%/   | Same      |
| <b>ECG</b>  |   |   |           |
| Technique:  | Peak-peak detection technique   | Peak-peak detection technique   | Same      |

|   |  |  |      |
|---|--|--|------|
| Heart Rate Counting Range:                | 30 bpm ~ 240 bpm   | 30 bpm ~ 240 bpm   | Same |
| Heart Rate Resolution:                    | ±1 BPM   | ±1 BPM   | Same |
| Input Impedance:                          | >10MΩ (Differential),<br>>20MΩ (Common Mode)   | >10MΩ (Differential),<br>>20MΩ (Common Mode)   | Same |
| Countable Input Signal Range:             | 20uV-3mV peak-to-peak  | 20uV-3mV peak-to-peak  | Same |
| Pressure Range:                           | 0 ~ 100mmHg  | 0 ~ 100mmHg  | Same |
| Sensitivity:                              | 5uV/V/mmHg   | 5uV/V/mmHg   | Same |
| Resolution:                               | 1%   | 1%   | Same |
| Zero Mode:                                | Automatic / Manual   | Automatic / Manual   | Same |
| Heart Rate Range                          | 30-240BPM  | 30-240BPM  | Same |
| Heart Rate Resolution                     | ±1 BPM   | ±1 BPM   | Same |
| Input Signal Range                        | ± 8 mV PP  | ± 8 mV PP  | Same |
| Defibrillator Protection                  | YES  | YES  | Same |
| Tall T-wave Rejection                     | 1.2mV(12mm)  | 1.2mV(12mm)  | Same |
| HR averaging method                       | Heart rate is computed by averaging the 12 most recent RR intervals.   | Heart rate is computed by averaging the 12 most recent RR intervals.   | Same |
| Accuracy and Response to Irregular Rhythm | Ventricular bigeminy:<br>80bpm±1bpm<br>Slow alternating ventricular bigeminy:<br>60bpm±1bpm<br>Rapid alternating ventricular bigeminy:<br>120bpm±1bpm<br>Bidirectional systoles:<br>91bpm±1bpm | Ventricular bigeminy:<br>80bpm±1bpm<br>Slow alternating ventricular bigeminy:<br>60bpm±1bpm<br>Rapid alternating ventricular bigeminy:<br>120bpm±1bpm<br>Bidirectional systoles:<br>91bpm±1bpm | Same |
| Response time to Change in HR             | HR range: 80bpm ~ 120bpm<br>Range: 7s ~ 8s (average: 7.5s)<br>HR range: 80bpm ~ 40bpm<br>Range : 7s ~ 8s (average: 7.5s)   | HR range: 80bpm ~ 120bpm<br>Range: 7s ~ 8s (average: 7.5s)<br>HR range: 80bpm ~ 40bpm<br>Range : 7s ~ 8s (average: 7.5s)   | Same |
| <b>SpO<sub>2</sub></b>                    |  |  |      |
| Measuring Range:                          | 50% ~ 100%   | 50% ~ 100%   | Same |
| Resolution:                               | 1%   | 1%   | Same |

|                                |   |   |      |
|--------------------------------|---|---|------|
| Measuring Accuracy (EDAN):     | 90% ~ 100% ± 2%<br>70% ~ 90% ± 4%<br>< 70%<br>unspecified   | 90% ~ 100% ± 2%<br>70% ~ 90% ± 4%<br>< 70%<br>unspecified   | Same |
| Measuring Accuracy (Nellcor):  | 70% ~ 100% ± 2%<br>< 70%<br>unspecified   | 70% ~ 100% ± 2%<br>< 70%<br>unspecified   | Same |
| Pulse Rate Measurement Range:  | 30-240BPM   | 30-240BPM   | Same |
| Pulse Rate Measuring Accuracy: | ±ulse   | ±ulse   | Same |
| Emitted light energy           | < 15 mW   | < 15 mW   | Same |
| <b>NIBP</b>                    |   |   |      |
| Blood Pressure Range           | Systolic pressure:40mmHg ~ 270mmHg<br>Diastolic pressure:10mmHg ~ 215mmHg   | Systolic pressure:40mmHg ~ 270mmHg<br>Diastolic pressure:10mmHg ~ 215mmHg   | Same |
| Measuring Accuracy:            | ≤ 8mmHg   | ≤ 8mmHg   | Same |
| Cuff Pressure Protection       | 300mmHg   | 300mmHg   | Same |
| <b>TEMP</b>                    |   |   |      |
| Channel:                       | 1   | 1   | Same |
| Measurement Range:             | 0 °C ~ 50 °C  | 0 °C ~ 50 °C  | Same |
| Accuracy:                      | 0°C ~ +25°C (+32°F ~ +77°F): ± 0.2°C (±0.36°F)<br>+25°C ~ +45°C (+77°F ~ +113°F): ± 0.1°C (±0.18°F)<br>+45°C ~ +50°C (+113°F ~ +122°F): ± 0.2°C (±0.36°F) | 0°C ~ +25°C (+32°F ~ +77°F): ± 0.2°C (±0.36°F)<br>+25°C ~ +45°C (+77°F ~ +113°F): ± 0.1°C (±0.18°F)<br>+45°C ~ +50°C (+113°F ~ +122°F): ± 0.2°C (±0.36°F) | Same |
| <b>Printer</b>                 |   |   |      |
| Paper width:                   | 152mm (GE), 150mm (PHILIPS)   | 152mm (GE), 150mm (PHILIPS)   | Same |
| Effective printing width:      | 110mm (American Standard)<br>120mm (International)  | 110mm (American Standard)<br>120mm (International)  | Same |

|                                     |   |  |      |
|-------------------------------------|---|--|------|
|                                     | Standard)   | Standard)  |      |
| FHR printout width:                 | 70mm (American Standard)<br>80mm (International Standard)   | 70mm (American Standard)<br>80mm (International Standard)  | Same |
| FHR scaling:                        | 30bpm/cm (American Standard)<br>20bpm/cm (International Standard)   | 30bpm/cm (American Standard)<br>20bpm/cm (International Standard)                                    | Same |
| TOCO printout width:                | 40mm  | 40mm   | Same |
| TOCO scaling:                       | 25%/cm  | 25%/cm   | Same |
| Standard Speed (Real-Time Traces ): | 1 cm/min, 2 cm/min, 3 cm/min  | 1 cm/min, 2 cm/min, 3 cm/min   | Same |
| Paper:                              | Z-fold, thermosensitive (compatible with GE and PHILIPS record papers)  | Z-fold, thermosensitive (compatible with GE and PHILIPS record papers)                               | Same |
| <b>Physical Specification</b>       |   |  |      |
| Screen                              | LCD   | LCD  | Same |
| Screen Diagonal:                    | F9 Express / F9 : 12.1”<br>F6 Express / F6 : 10.1”  | F9 Express / F9 : 12.1”<br>F6 Express / F6 : 10.1”   | Same |
| Power Supply:                       | AC or battery   | AC or battery  | Same |
| Operating Voltage:                  | a.c.100 V-240 V   | a.c.100 V-240 V  | Same |
| Line Frequency:                     | 50/60 Hz  | 50/60 Hz   | Same |
| Pmax :                              | 1.0A-0.5A   | 1.0A-0.5A  | Same |
| Battery :                           | Rechargeable Lithium-ion Battery  | Rechargeable Lithium-ion Battery   | Same |
| Dimensions:                         | 347mm × 330mm × 126mm   | 347mm × 330mm × 126mm  | Same |
| Weight:                             | F6: Approx. 5.3 kg<br>F6 Express: Approx. 6.1 kg<br>F9: Approx. 5.5 kg<br>F9 Express: Approx. 6.3 kg<br>FTS-3: 1.8 kg | F6: Approx. 5.3 kg<br>F6 Express: Approx. 6.1 kg<br>F9: Approx. 5.5 kg<br>F9 Express: Approx. 6.3 kg | Same |
| Operating Temperature:              | 5 °C ~ 40 °C  | 5 °C ~ 40 °C   | Same |

|   |   |  |           |
|---|---|--|-----------|
| Transport/ Storage Temperature:         | -20 °C ~ 55 °C  | -20 °C ~ 55 °C   |           |
| Operating Humidity:                     | 15% ~ 93%<br>(non-condensing)   | 25%~80%<br>( non-condensing )  | Different |
| Transport/ Storage Humidity:            | 15% ~ 93%<br>(non-condensing)   | 25%~93%<br>( non-condensing )  |           |
| Operating atmospheric pressure:         | 860 hPa ~1060 hPa   | 860 hPa ~1060 hPa  | Same      |
| Transport/Storage atmospheric pressure: | 700 hPa ~1060 hPa   | 700 hPa ~1060 hPa  | Same      |
| <b>Complied Standards</b>               |   |  |           |
| Detail                                  | IEC 60601-1:2005, EN 60601-1:2006/AC:2010, IEC 60601-1-2:2007, EN 60601-1-2:2007/AC:2010, IEC/EN 60601-2-27, IEC/EN 60601-2-37, IEC/EN 60601-2-49, IEC 80601-2-30, ISO 80601-2-61, ISO 80601-2-56, EN 12470-4 AAMI/ANSI EC13 UD 2 FCC 47 CFR Part 15 FCC 47 CFR Part 95 | MDD93/42/EEC, EN60601-1:1990+A1:1993 + A2:1995, EN 60601-2-37:2001, EN 60601-1-1:2001, EN 60601-1-2:2001, EN 61157:1995 EN ISO 9919, EN 12470-4 UD 2 FCC 47 CFR Part 15 FCC 47 CFR Part 95 | Different |

### Comparison between FTS-3 and Avalon CTS

| Items                               | FTS-3                 | Avalon CTS cordless Fetal Transducer System | Substantial Equivalence (SE) |
|-------------------------------------|-----------------------|---|------------------------------|
| Transmission Power:                 | < 10 mW ERP           | 0.1mW ERP (Classic Value)                   | Different                    |
| Frequency Range:                    | 608.00 MHz~614.00 MHz | 608.0125 MHz to 613.9875 MHz                | Same                         |
| Transmission Range (line of sight): | >110 m                | >100 m                                      | Different                    |
| Modem Mode:                         | FSK                   | FSK   | Same                         |
| Transmission Rate:                  | About 25kbps          | 200 bits/s                                  | Different                    |

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The main technological differences between the subject and predicate devices are related to the wireless transmission characteristics. These minor differences, however, do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical testing, the different technological characteristics do not affect the safety and effectiveness of the Edan Fetal & Maternal Monitors.

## **10. Performance Data:**

### **Non-clinical data:**

The following performance data were provided in support of the substantial equivalence determination.

#### **Biocompatibility testing**

The biocompatibility evaluation for the F series Fetal & Maternal Monitor were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The worst case of the whole system is considered tissue contacting for a duration of less than 24 hours. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Irritation or Intracutaneous Reactivity

#### **Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the F series Fetal & Maternal Monitor device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012 standards for safety and the IEC 60601-1-2: 2007 for EMC.

#### **Bench Testing**

Bench testings were conducted on the F series Fetal & Maternal Monitor device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1-8: 2006, IEC 60601-2-27: 2011, IEC 60601-2-37: 2007, IEC 60601-2-49: 2011, IEC 80601-2-30: 2009, ISO 80601-2-56: 2009, ISO 80601-2-61: 2011, ISO 81060-2: 2013 and IEC 62366: 2007 standards.

#### **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 “moderate” level of concern, since a failure or latent flaw in the software will not directly result in serious injury or death to the patient or operator, and the software device is an accessory to a medical device that has a Moderate Level of Concern.

### **Acoustic testing**

All measurements were conducted in accordance with the measurement procedures of the NEMA Standard Publications UD-2 and IEC 62359 and following the calibration procedures given in Section 4 of UD-2, and the reporting requirements of the September 9, 2008 FDA Guide for Track 1.

**Clinical data:** Not applicable.

### **Summary**

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

### **11. Conclusion**

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the F series Fetal & Maternal Monitor device should perform as intended in the specified use conditions, and all the data demonstrate that the subject devices perform comparably to the predicate device that is currently marketed for the same intended use. In other words, the subject F series Fetal & Maternal Monitor devices are substantially equivalent to the predicate devices.