October 5, 2018

Edan Instruments, Inc
% Alice Yang
Regulatory Engineer
Edan Medical
1200 Crossman Ave, Suite 200
Sunnyvale, California 94089

Re: K173042
Trade/Device Name: Fetal & Maternal Monitor: Models F6, F6 Express, F9, F9 Express; Fetal Monitor: Models F2, F3
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: Class II
Product Code: HGM, HGL, DSI, DRT, DXN, FLL, DQA, DPS
Dated: September 20, 2017
Received: September 28, 2017

Dear Alice Yang:

This letter corrects our substantially equivalent letter of August 30, 2018.

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 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173042

Device Name
Fetal & Maternal Monitor
Model: F6, F6 Express, F9, F9 Express

Indications for Use *(Describe)*

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 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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173042

Device Name
Fetal Monitor
Model: F2, F3 Fetal Monitor

Indications for Use *(Describe)*
F3/F2 Fetal 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.
The 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.

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

Submitter:

Edan Instruments, Inc
#15 Jinhui Road,Jinsha Community,
Kengzi Sub-District, Pingshan District,
Shenzhen, 518122 P.R.China.
Tel.: (0755) 28340011
Fax: +1 (408) 418-4059

Contact Person: Alice Yang

Date Prepared: August 30, 2018

Device Name and Classification:

Device Name: Fetal & Maternal Monitor
Model: F6, F6 Express, F9, F9 Express
Common Name: Fetal & Maternal Monitor
Classification Name:
884.2740 Perinatal monitoring system and accessories
Product Codes:
HGM (system, monitoring, perinatal)
DSI (detector and alarm, arrhythmia)
DRT (monitor, cardiac (incl. cardiotachometer & rate alarm))
DXN (system, measurement, blood-pressure, non-invasive)
FLL (thermometer, electronic, clinical)
DQA (oximeter)
DPS (electrocardiograph)

Device Name: Fetal Monitor
Model: F2, F3
Common Name: Fetal Monitor
Classification Name
884.2740 Perinatal monitoring system and accessories
Product codes:
HGM (system, monitoring, perinatal)
HGL (transducer, ultrasonic, obstetric)

Regulatory Class: Class II

Predicate Device(s):

1. Fetal & Maternal Monitor, F9 Express, Edan Instruments, Inc., K150901 (Primary for F6, F6 Express, F9, F9 Express)

2. Fetal Monitor, F3, Edan Instruments, Inc., K102140 (Primary for F2 and F3))

3. Patient Monitor, iM20, Edan Instruments, Inc., K152552 (Secondary)

The predicate devices have not been subject to a design related recall.

Device Description:

The subject devices are bedside fetal and maternal monitors, which are used to monitor the physiological parameters of pregnant women including the fetus from 28 weeks gestation. The devices may be used antepartum as well as during labor and delivery. The submission seeks clearance for several devices and their accessories, which were modified since their last 510(k) clearance.

The subject devices of the present submission include the F2/F3 and F6/F9 fetal monitors as well as the F6/F9 Express, which provide both fetal and maternal monitoring capabilities.

The fetal and maternal physiological parameters that are supported by the EDAN bedside monitors are as follows:

- Fetal heart rate (FHR)
- Tocodynamometry (TOCO) for external monitoring of uterine contractions
- Fetal Movement (FM)
- Automated Fetal Movement (AFM)
- Direct ECG (DECG) for internal monitoring of fetal heart rate
- Intrauterine pressure catheter (IUP) for internal monitoring of uterine contractions
- Maternal ECG (MECG)
- Noninvasive blood pressure (NIBP) was added to F6/F9 Express in this submission
- Maternal Sp02 (MSp02) for monitoring pulse rate (PR)
- Temperature (TEMP) for monitoring maternal temperature

The following table summarizes the fetal and maternal physiological parameters measured by each fetal monitor.

Model / Measurement	F3	F2	F6	F9	F6 Express	F9 Express
Single-FHR	√	√	√	√	√	√
Dual-FHR	√	√	√	√	√	√
TOCO	√	√	√	√	√	√
FM	√	√	√	√	√	√
AFM	√	√	√	√	√	√
DECG/IUP	Opt	Opt	Opt	Opt	×	Opt
MECG	×	×	×	×	√	√
NIBP	×	×	×	×	√	√
MSpO2	×	×	×	×	√	√
TEMP	×	×	×	×	√	√
	NOTE: √ = Standard; Opt = Optional; × = Not Available					

The following features are available for the F6/F9 and F6/F9 Express bedside fetal and maternal monitors:

- Basic parameters: FHR, TOCO, Event Mark, AFM
- Dual FHR monitoring
- Internal parameters: IUP/DECG
- FHR limit alarm
- Software for data transmission to PC
- Quick printing for stored waveform
- Lithium battery for continuous operation
- Maternal ECG, Sp02, NIBP, and temperature monitoring
- Used with FTS-3 Fetal Telemetry System (hereinafter called FTS-3)

The following features are available for the F2/F3 bedside fetal monitors:

- Basic parameters: FHR, TOCO, Event Mark, AFM
- Dual FHR monitoring
- Internal parameters: IUP/DECG
- FHR limit alarm
- Software for data transmission to PC
- Quick printing for stored waveform
- Lithium battery for continuous working

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 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.

F3/F2 Fetal 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.

The 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.

Predicate Device Comparison:

Comparison between the subject F9 series and the previously cleared F9 Express

Item	F6 / F6 Express/ F9 / F9 Express	F9 Express	Comparison
Manufacturer	Edan Instruments, Inc.	Edan Instruments, Inc.	
K#	K174042	K150901	
Intended use	**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 is intended for monitoring physiological parameters of pregnant women during	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	Same

	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.	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.	
Electrical Safety			
Anti-electric-shock degree:	FHR1, FHR2, TOCO, FM, IUP: BF; SpO2, NIBP: BF (Defibrillator-proof); DECG:CF; ECG, TEMP: CF (Defibrillator-proof); FTS-3: FHR1, FHR2, TOCO: BF (Defibrillator-proof).	FHR1, FHR2, TOCO, FM, IUP: BF; SpO2, NIBP: BF (Defibrillator-proof); DECG: CF; ECG, TEMP: CF (Defibrillator-proof). FTS-3: FHR1,FHR2, TOCO: BF (Defibrillator-proof).	Same
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
Degree of Protection against Harmful Ingress of Water	Main Unit: IPX1, protected against vertically falling water drops (provided recorder drawer is shut and the monitor is not mounted on the wall vertically)	Main Unit: IPX1, protected against vertically falling water drops (provided recorder drawer is shut and the monitor is not mounted on the wall vertically)	Same

	US/TOCO Transducers: IPX8, protected against the effects of continuous emersion in water FTS-3: Base station: IPX1 (protected against vertically falling water drops) Transducers: IPX8 (Protected against the effects of continuous immersion in water 1.1m deep for 24 hours)	US/TOCO Transducers: IPX8, protected against the effects of continuous emersion in water FTS-3: Base station: IPX1 (protected against vertically falling water drops) Transducers: IPX8 (Protected against the effects of continuous immersion in water 1.1m deep for 24 hours)	
Working mode:	Continuous running equipment	Continuous running equipment	Same
FHR (F6 / F6 Express/ F9 / F9 Express)			
Technique:	Pulse Doppler with autocorrelation processing	Pulse Doppler with autocorrelation processing	Same
Pulse Repetition Frequency:	2 KHz	2 KHz	Same
Effective Radiating Area:	942 mm^2 ± 15%(F9/F9 Express/ FTS-3, 12 ultrasound crystals) 628 mm^2 ± 15%(F6/F6 Express, 8 ultrasound crystals) 549.5 mm^2± 15%(F6/F6 Express /FTS-3, 7 ultrasound crystals)	942 mm^2 ± 15%(F9/F9 Express /FTS-3, 12 ultrasound crystals) 628 mm^2 ± 15%(F6/F6 Express, 8 ultrasound crystals)	Different
TOCO (F6 / F6 Express/ F9 / F9 Express)			
TOCO Range:	0-100	0-100	Same
Resolution:	1	1	Same
DECG (F6 / F9 / F9 Express)			
Technique:	Peak-peak detection technique	Peak-peak detection technique	Same
Heart Rate Counting Range:	30 bpm ~ 240 bpm	30 bpm ~ 240 bpm	Same
IUP **(F6 / F9 / F9 Express)**			

Pressure Range:	0 ~ 100mmHg(0.0~13.3 kPa)	0 ~ 100mmHg(0.0~13.3 kPa)	Same
Sensitivity:	5uV/V/mmHg	5uV/V/mmHg	Same
Resolution:	1mmHg (0.1 kPa)	1mmHg (0.1 kPa)	Same
Zero Mode:	Automatic (TOCO value becomes zero or below lasting for 30 seconds) / Manual	Automatic (TOCO value becomes zero or below lasting for 30 seconds)/ Manual	Same
MECG (F6 Express / F9 Express)			
Heart Rate Range	30-240BPM	30-240BPM	Same
Defibrillator Protection	YES	YES	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
SpO_2 (F6 Express/ F9 Express)			
Measuring Range:	50% ~ 100%	50% ~ 100%	Same
Resolution:	1%	1%	Same
Pulse Rate Measurement Range:	30-240BPM	30-240BPM	Same
Pulse Rate Measuring Accuracy:	±3BPM	±3BPM	Same
Emitted light energy	< 15 mW	< 15 mW	Same
NIBP (F6 Express/ F9 Express)			
Blood Pressure Range	Systolic Pressure: 40 mmHg ~ 270 mmHg (5.3 kPa~36.0 kPa) Diastolic Pressure: 10 mmHg ~ 215 mmHg (1.3 kPa~28.7 kPa)	Systolic pressure:40mmHg ~ 270mmHg Diastolic pressure:10mmHg ~ 215mmHg	Different
Measuring Accuracy:	Max. average deviation ≤±5mmHg (≤±0.8 kPa) Max. standard deviation ≤8mmHg (≤1.2 kPa)	Max. average deviation ≤±5mmHg Max. standard deviation ≤8mmHg	Different
Cuff Pressure measuring range	0 mmHg ~ 300 mmHg (0.0 kPa~40.0 kPa)	0 mmHg ~ 300 mmHg	Different
TEMP (F6 Express/ F9 Express)			

Channel:	1	1	Same
Measurement Range:	0 ºC ~ +50 ºC	0 ºC ~ +50 ºC	Same
Accuracy:	±0.3 °C (Transducer error excluded: ±0.1 °C) (Transducer: ≤ ±0.2 °C)	0ºC ~ +25ºC (+32ºF ~ +77ºF): ± 0.2ºC (±0.36ºF) +25ºC ~ +45ºC (+77ºF ~ +113ºF): ± 0.1ºC (±0.18ºF) +45ºC ~ +50ºC (+113ºF ~ +122ºF): ± 0.2ºC (±0.36ºF)	Different
Printer (F6 / F6 Express/ F9 / F9 Express)			
Paper width:	152mm (GE), 150mm (PHILIPS)	152mm (GE), 150mm (PHILIPS)	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
Physical Specification (F6 / F6 Express/ F9 / F9 Express)			
Screen	LCD	LCD	Same
Screen Diagonal:	F9 Express / F9: 12.1” F6 Express / F6: 10.1”	F9 Express / F9: 12.1” 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 F6 Express: Approx. 6.1 kg F9: Approx. 5.5 kg F9 Express: Approx. 6.3 kg	F6: Approx. 5.3 kg F6 Express: Approx. 6.1 kg F9: Approx. 5.5 kg F9 Express: Approx. 6.3 kg	Same
Operating Temperature:	+5 ºC ~ + 40 ºC (+41 ºF ~ +104 ºF)	+5 ºC ~ + 40 ºC (+41 ºF ~ +104 ºF)	Same
Transport/ Storage Temperature:	-20 ºC ~ +55 ºC (-4ºF ~ +131 ºF)	-20 ºC ~ +55 ºC (-4 ºF ~ +131 ºF)	

Operating Humidity:	15% ~ 93% (non-condensing)	15% ~ 93% (non-condensing)	Same
Transport/ Storage Humidity:	15% ~ 93% (non-condensing)	15% ~ 93% (non-condensing)	
Operating atmospheric pressure:	86 kPa ~ 106 kPa	860 hPa ~1060 hPa	Different
Transport/Storage atmospheric pressure:	70 kPa ~ 106 kPa	700 hPa ~1060 hPa	
FTS-3 compatible transducers	Wireless US Transducer Wireless TOCO Transducer	Wireless US Transducer Wireless TOCO Transducer	Same

Comparison between the subject F9 series and iM20

Item	**F6 Express/ F9 Express**	**iM20**	**Comparison**
Manufacturer	Edan Instruments, Inc.	Edan Instruments, Inc.	
K#	K174042	K152552	
Pulse Rate (PR) by NIBP module	Measurement Range：40bpm ~ 240bpm Measuring Accuracy：±3 bpm or 3.5%, take the maximum value	Measurement Range：40bpm ~ 240bpm Measuring Accuracy：±3 bpm or 3.5%, take the maximum value	Same

Comparison between the subject F2&F3 and the previously cleared F3

Item	**F2&F3**	**F3**	**Comparison**
Manufacturer	Edan Instruments, Inc.	Edan Instruments, Inc.	
K#	K174042	K102140	
Intended use	F3/F2 Fetal 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	The F3 & F2 Fetal Monitors are intended for non-invasive and invasive monitoring of fetus during antepartum examination, labor and delivery. They are intended to be used	Same

	qualified personnel in antepartum examination rooms, labor and delivery rooms. The 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.	only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms. They provide non-stress testing for pregnant women from the 28th week of gestation. They can externally monitor the FHRs using ultrasound and uterine activity via a TOCO transducer. Alternatively, they can internally monitor one of the FHRs with DECG and uterine activity with an IUPC.	
Electrical Safety			
Anti-electric-shock degree:	FHR1, FHR2, TOCO, FM, IUP: BF; DECG:CF;	FHR1, FHR2, TOCO, FM: B; IUP: BF; DECG: CF;	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
Degree of Protection against Harmful Ingress of Water	US/TOCO Transducers: IPX8, protected against the effects of continuous emersion in water	US/TOCO Transducers: IPX8, protected against the effects of continuous emersion in water	Same
Working mode:	Continuous running equipment	Continuous running equipment	Same
FHR			

Technique:	Pulse Doppler with autocorrelation processing	Pulse Doppler with autocorrelation processing	Same
Pulse Repetition Frequency:	2 KHz	2 KHz	Same
Effective Radiating Area:	628 mm^2 ± 15%(8 ultrasound crystals) 549.5 mm^2± 15%(7 ultrasound crystals)	628 mm^2 ± 15%(8 ultrasound crystals)	Different
TOCO			
TOCO Range:	0-100	0-100	Same
Resolution:	1	1	Same
DECG			
Technique:	Peak-peak detection technique	Peak-peak detection technique	Same
Heart Rate Counting Range:	30 bpm ~ 240 bpm	30 bpm ~ 240 bpm	Same
IUP			
Pressure Range:	0 ~ 100mmHg(0.0 kPa~13.3 kPa)	0 ~ 100mmHg	Different
Sensitivity:	5uV/V/mmHg	5uV/V/mmHg	Same
Resolution:	1mmHg (0.1 kPa)	1mmHg (0.1 kPa)	Same
Physical Specification			
Screen	LCD	LCD	Same
Screen Diagonal:	5.6”	5.6”	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:	70VA	70VA	Same
Battery:	Rechargeable Lithium-ion Battery	Rechargeable Lithium-ion Battery	Same
Dimensions:	350mm x 300mm x 104mm	350mm x 300mm x 104mm	Same
Weight:	Approx. 3.5kg	Approx. 3.5kg	Same
Operating Temperature:	+5 ºC ~ + 40 ºC (+41 ºF ~ +104 ºF)	5 ºC ~ 40 ºC	Different
Transport/ Storage Temperature:	-20 ºC ~ +55 ºC (-4ºF ~ +131 ºF)	-20 ºC ~ 55 ºC	
Operating Humidity:	15% ~ 93% (non-condensing)	25%～80%（non-condensing）	Different
Transport/ Storage	15% ~ 93%	25%～93%	

Humidity:	(non-condensing)	（non-condensing）	
Operating atmospheric pressure:	86 kPa ~ 106 kPa	860 hPa ~1060 hPa	Different
Transport/Storage atmospheric pressure:	70 kPa ~ 106 kPa	700 hPa ~1060 hPa	

The subject devices and their respective primary predicate device have the same intended use. The subject devices and their respective primary predicate devices have different technological characteristics as evidenced by the preceding table. The differences in technological characteristics do not raise different questions for safety or effectiveness.

Performance Data:

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

- Software validation per the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- Electrical safety testing per IEC 60601-1
- Electromagnetic compatibility testing per IEC 60601-2
- Evaluation of NIBP sensor
- Evaluation of ultrasound transducer

The remaining performance tests were leveraged from the predicate device.

The results of all completed performance testing were acceptable.

Conclusion:

The subject devices are substantially equivalent to their respective primary predicate devices.