August 27, 2025

Edan Instruments, Inc.
Yue Tracy
Official Correspondent
15 Jinhui Road, Jinsha Community, Kengzi Sub-district,
Pingshan Distrct
Shenzhen, 518122
China

Re: K241882
Trade/Device Name: Fetal & Maternal Monitor (F15A, F15A Air)
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: II
Product Code: HGM
Dated: June 28, 2024
Received: February 25, 2025

Dear Yue Tracy:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241882

Device Name
Fetal & Maternal Monitor (F15A, F15A Air)

Indications for Use *(Describe)*
Fetal & Maternal Monitor (Model: F15A, F15A Air) is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.
Fetal & Maternal Monitor (Model: F15A, F15A Air) is intended for real time monitoring of fetal and maternal physiological parameters, including non-invasive monitoring and invasive monitoring:
Non-invasive physiological parameters:
• Maternal heart rates (MHR)
• Maternal ECG (MECG)
• Maternal temperature (TEMP)
• Maternal oxygen saturation (SpO2) and pulse rates (PR)
• Fetal heart rates (FHR)
• Fetal movements (FM)
• FTS-3
Note: SpO2 and PR are not available in F15A Air.
Invasive physiological parameters:
• Uterine activity
• Direct ECG (DECG)

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 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) 84513592
Fax: +86(0755) 26882223

2. Contact person: Tracy Yue

Preparing date: August 27, 2025

3. Device name and classification:

Trade name: Fetal & Maternal Monitor (F15A, F15A Air)
Common name: Perinatal monitoring system
Regulation Number/Classification Name/Product Code:
21 CFR 884.2740 Perinatal monitoring system and accessories,HGM
21 CFR 884.2960 Obstetric ultrasonic transducer and accessories, HGL
21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm), DRT
21 CFR 880.2910 Clinical electronic thermometer, FLL
21 CFR 870.2700 Oximeter, DQA
21 CFR 870.2340 Electrocardiograph,DPS
21 CFR 870.2700 Intrauterine pressure monitor and accessories, HFN
21 CFR 884.2720 External uterine contraction monitor and accessories, HFM
Regulatory Class: Class II

4. Predicate Device:

1) Edan Instruments, Inc., F9 Express Fetal & Maternal Monitor, cleared under K173042 (Predicate device)

The predicate device has not been subject to a design related recall.

5. Device Description:

The F15A series fetal and maternal monitor can monitor multiple physiological parameters of the fetus/mother in real time. F15A series can display, store, and print patient information and parameters, provide alarms of fetal and maternal parameters, and transmit patient data and parameters to Central Monitoring System.

F15A series fetal and maternal monitors mainly provide following primary feature:

Non-invasive physiological parameters:

- Maternal heart rates (MHR)
- Maternal ECG (MECG)
- Maternal temperature (TEMP)
- Maternal oxygen saturation (SpO2) and pulse rates (PR)
- Fetal heart rates (FHR)
- Fetal movements (FM)
- FTS-3

Note: SpO2 and PR are not available in F15A Air.

Invasive physiological parameters:

- Uterine activity
- Direct ECG (DECG)

6. Indication for Use

Fetal & Maternal Monitor (Model: F15A, F15A Air) is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

Fetal & Maternal Monitor (Model: F15A, F15A Air) is intended for real time monitoring of fetal and maternal physiological parameters, including non-invasive monitoring and invasive monitoring:

Non-invasive physiological parameters:

- Maternal heart rates (MHR)
- Maternal ECG (MECG)
- Maternal temperature (TEMP)
- Maternal oxygen saturation (SpO2) and pulse rates (PR)
- Fetal heart rates (FHR)
- Fetal movements (FM)
- FTS-3

Note: SpO2 and PR are not available in F15A Air.

Invasive physiological parameters:

- Uterine activity
- Direct ECG (DECG)

7. Predicate Device Comparison

The subject device is technologically equivalent to predicate devices. Any differences are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness. The table below compares the intended use and technological characteristics of the subject and primary predicate device:

Item	< **Subject Device** > EDAN Instrument Inc.	< **Predicate Device** > EDAN Instrument Inc.	**Comparison Result**

	F15A series Fetal & Maternal Monitor	F9 Express Fetal & Maternal Monitor	
K#	K241882	K173042	——
Intended Use/Indications for Use	Fetal & Maternal Monitor (Model: F15A, F15A Air) is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms. Fetal & Maternal Monitor (Model: F15A, F15A Air) is intended for real time monitoring of fetal and maternal physiological parameters, including non-invasive monitoring and invasive monitoring: Non-invasive physiological parameters: • Maternal heart rates (MHR) • Maternal ECG (MECG) • Maternal temperature (TEMP) • Maternal oxygen saturation (SpO2) and pulse rates (PR) • Fetal heart rates (FHR) • Fetal movements (FM) • FTS-3 Note: SpO2 and PR are not available in F15A Air. Invasive physiological parameters: • Uterine activity • Direct ECG (DECG)	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. 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.	Similar
Physical Specification			
Power Supply:	AC or battery	AC or battery	Same
Operating Voltage:	a.c.100 V-240 V	a.c.100 V-240 V	Same
Operating Frequency:	50/60 Hz	50/60 Hz	Same
Power Supply Input Power:	1.2A-0.5A	1.0A-0.5A	Different
Battery :	Rechargeable Lithium-ion	Rechargeable Lithium-ion	Same

	Battery	Battery	
Dimensions:	389mm×296mm×82.5mm, ±5mm	347mm x 330mm x 126mm	Different
Weight:	≤ 8kg	Approx. 6.3 kg	
Electrical Safety			
Anti-electric-shock degree:	CF: FHR1, FHR2, AFM/MFM, DECG, IUP， CF(defibrillation-proof): MECG, SpO_2, TEMP	BF:FHR1, FHR2, TOCO, AFM/MFM,IUP BF (defibrillation-proof): NIBP, SpO_2 CF :DECG CF (defibrillation-proof) : MECG, TEMP	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 Operation equipment	Continuous Operation equipment	Same
FHR			
Technique:	Pulse Doppler with autocorrelation processing	Pulse Doppler with autocorrelation processing	Same
Ultrasound Frequency:	(1.0±10%) MHz	(1.0±10%) MHz	Same
Spatial-Peak Temporal Average Intensity:	Ispta < 100 mW/cm2	Ispta < 100 mW/cm2	Same
Effective Radiating Area:	942 mm^2 ± 15%(12 ultrasound crystals) 550 mm^2 ± 15%(7 ultrasound crystals)	942 mm^2 ± 15%(12 ultrasound crystals)	Different
DECG			
Heart Rate Counting Range:	30 bpm ~ 240 bpm	30 bpm ~ 240 bpm	Same
IUP			
Pressure Range:	0 ~ 100mmHg	0 ~ 100mmHg	Same
Resolution:	1mmHg	1mmHg	Same
FM			
FM Mode	Automatic(AFM)/Manual(MFM)	Automatic(AFM)/Manual(MFM)	Same
MECG			
MHR	30bpm ~ 240bpm	30bpm ~ 240bpm	Same

Measurement Range			
Number of electrodes	Three leads	Three leads	Same
SpO_2 (Nellcor, F15A only)			
Resolution	1 %	1 %	Same
Measurement Range	50% ~ 100%	50% ~ 100%	Same
PR Measurement	Range: 30~240bpm Resolution: 1 bpm Accuracy:±3bpm	Range: 30~240bpm Resolution: 1 bpm Accuracy: ±3 bpm	Same
TEMP(Only applicable for F15A)			
Measurement Range	0°C ~ +50°C	0°C ~ +50°C	Same
Resolution	0.1°C	0.1°C	Same
Printer			
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
FTS-3			
Operating Voltage	100V-240V~	100V-240V~	Same
Battery	14.8VDC/5000mAh	14.8VDC/5000mAh	Same
FHR Measurement Range	50 bpm ～ 240 bpm	50 bpm ～ 240 bpm	Same
FHR Resolution	1 bpm	1 bpm	Same
Ultrasound Frequency	(1+10%) MHz	(1+10%) MHz	Same
TOCO Range	0~ 100	0~ 100	Same

The subject device and predicate device have the same intended use – monitoring of fetal and maternal physiological parameters. The subject device and predicate device have different technological characteristics, including differences in power supply input power, physical dimensions, weight, electrical safety classification, and effective radiating area. However, the differences in technological characteristics do not raise different questions for safety or effectiveness.

8. Performance Data:

Non-clinical test:

Electrical safety and electromagnetic compatibility (EMC)

F15A Series Fetal & Maternal Monitor was assessed for conformity with the relevant requirements of the following standards and found to comply:

- IEC 60601-1:2005/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: electromagnetic disturbances – Requirements and tests.

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." issued June 14, 2023.

Cybersecurity Testing

Cybersecurity testing was conducted, and documentation was provided as recommended by FDA's "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued September 27, 2023.

Bench Testing:

Edan has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets relevant consensus standards.

- IEC 60601-1-8:2006, AMD1:2012, AMD2:2020 Medical electrical equipment - part 1-8: 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
- IEC 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 60601-2-37:2015 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 80601-2-49:2018 Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-56:2017+A1:2018 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02): Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ANSI IEEE USEMCSC C63.27-2021 American National Standard for Evaluation of Wireless Coexistence
- IEC 62359:2017 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- ANSI AAMI EC53:2013/(R)2020 ECG trunk cables and patient leadwires

9. Conclusion

The results of the performance testing described above demonstrate that the Fetal & Maternal Monitor (F15A, F15A Air) is as safe and effective as the predicate device and supports a determination of substantial equivalence.