June 6, 2018

Edan Instruments, Inc.
Alice Yang
Regulatory Engineer
#15 Jinhui Road, Jinsha Community
Kengzi Sub-District, Pingshan District
Shenzhen, Guangdong 518067
China

Re: K172780
Trade/Device Name: SD1 Ultrasonic Pocket Doppler
Regulation Number: 21 CFR§ 884.2660
Regulation Name: Fetal Ultrasonic Monitor and Accessories
Regulatory Class: II
Product Code: KNG
Dated: May 3, 2018
Received: May 7, 2018

Dear Alice Yang:

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.

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,

Joyce M. Whang -S

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)*
K172780

Device Name
SD1 Ultrasonic Pocket Doppler

Indications for Use *(Describe)*
The SD1 is a pocket Doppler device used for detecting the fetal heartbeat from the 10th week of gestation. It is intended to be used by medical professionals only.

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
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*"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 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.: (0755) 26856469 Fax: +1 (408) 418-4059

**Contact Person:** Alice Yang

**Date Prepared:** 2018-5-30

**2. Device name and classification:**

**Device Name:**SD1 Ultrasonic Pocket Doppler

**Model:**SD1(with or without Bluetooth/APP)

**Common Name:** Fetal Doppler

**Classification Number and Name:**

21 CFR 884.2660 Fetal ultrasonic monitor and accessories

**Product code:** KNG (monitor, ultrasonic, fetal)

**Regulatory Class:** Class II

**3. Predicate Device(s):**

1. K131457, FETAL ULTRASONIC MONITOR AND ACCESSORIES /JPD-100B, Shenzhen Jumper Medical Equipment Co. (Primary)
2. K140579, SD3 ULTRASONIC POCKET DOPPLER, Edan Instruments, Inc. (Secondary)

The predicate devices were not subjected to design-related recalls.

**4. Device Description:**

SD1 Ultrasonic Pocket Doppler is a device prescribed by a licensed physician for use by professional healthcare providers. It is a hand-held, battery powered audio Doppler device integrated with 3 MHz probe and with optional use of Bluetooth/app, used for detecting fetal heart beats. The device is for prescription use and is intended for use at or after 10 weeks gestation.

**5. Indications for Use:**

The SD1 is a pocket Doppler device used for detecting the fetal heartbeat from the $10^{th}$ week of gestation. It is intended to be used by medical professionals only.

## 6. Predicate Device Comparison

The subject device shares the same characteristics with the predicate device except as shown in the table below. The following differences in technological characteristics do not raise different questions of safety and effectiveness.

| Item | JPD-100B | SD3 | SD1 | Comparison Result |
|---|---|---|---|---|
| **Manufacturer/K#** | SHENZHEN JUMPER MEDICAL EQUIPMENT CO., LTD / K131457 | EDAN INSTRUMENTS, INC./K | EDAN INSTRUMENTS, INC./current submission | —— |
| Indications for use | The device is ultrasonic fetal heart detector, which can detect the Fetal Heart Rate. The built-in speaker of the device allows for listening of the fetal heartbeat. It can display values of fetal heart rate. The Fetal Doppler JPD-100B is a hand-held, battery powered audio Doppler device used for detecting fetal heart beats. | The SD3 Series Ultrasonic Pocket Dopplers are intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices. The 2 MHz and 3 MHz waterproof probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. Specifically, the 3 MHz probe is used for more than 9-week gestation and the 2 MHz is used for 12-week gestation. The 4 MHz, 5 MHz and/or 8 MHz waterproof vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease. | The SD1 is a pocket Doppler device used for detecting the fetal heartbeat from the $10^{th}$ week of gestation. It is intended to be used by medical professionals only. | Different, but the subject and predicate devices have the same intended use |

| | | | | |
|---|---|---|---|---|
| Device Description | JPD-100B Fetal Doppler is device prescribed by a licensed physician for use in hospitals and the homecare environment. It is a hand-held, battery powered audio Doppler device integrated with 2.5 MHz probe, used for detecting fetal heart beats. And the device is for prescription use and is intended for use at or after 12 weeks gestation. | The SD3 series Ultrasonic Pocket Doppler is a hand-held device for non-invasive measurement and display of fetal heart rate and blood flow velocity utilizing the principle of Doppler shift of an ultrasound. The ultrasound is transmitted from the probe to patient body (maternal abdominal wall), and moves through biophysical objects. The acoustic ultrasound is reflected by blood and moving objects such as the fetal heart. The reflected ultrasound is received by the probe and is converted into electric signals. The waveform data are applied to the CPU for all the digital processing on OLED Display, operation keys. The audio signal is taken off for the routing to the speaker to generate the analogue signals before digital processing. The following probes are supplied with the SD3 series Ultrasonic Pocket Doppler:<br>1. 2 MHz for fetal heart rate.<br>2. 3 MHz for fetal heart rate<br>3. 4 MHz for detections of arterial and venous blood flow velocity.<br>4. 5 MHz for detections of arterial and venous blood flow velocity. | SD1 Ultrasonic Pocket Doppler is a device prescribed by a licensed physician for use by professional healthcare providers. It is a hand-held, battery powered audio Doppler device integrated with 3 MHz probe and with optional use of Bluetooth/app, used for detecting fetal heart beats. The device is for prescription use and is intended for use at or after 10 weeks gestation. | Different, minor differences in the device description, but the intended use is the same. |

| | | | | |
|---|---|---|---|---|
| | | 5. 8 MHz for detections of arterial and venous blood flow velocity.<br>FHR Performance: Sensitivity: 9 weeks gestation (3 MHz) | | |
| Intended patient population | Pregnant woman | Pregnant woman | Pregnant woman | Same |
| Application site | Indoor | Indoor | Indoor | Same |
| Contacting location | Abdomen surface | Abdomen surface | Abdomen surface | Same |
| **Operational characteristics** | | | | |
| Operation principle | Ultrasonic Doppler/Continuous Wave | Ultrasonic Doppler/Continuous Wave | Ultrasonic Doppler/Pulsed Wave | Different, clinical tests show that the performance is substantially equivalent. |
| Installation and use | hand-held | hand-held | hand-held | Same |
| Mode of operation | Continuous operation | Continuous operation | Continuous operation | Same |
| **Specifications** | | | | |
| Ultrasound Working Frequency | 2MHz, 2.5MHz, 3MHz | 2MHz, 3MHz, 4MHz, 5MHz, 8MHz | 3MHz<br><br>Pulse repetition frequency: 5kHz | Different, but bench and clinical performance tests demonstrate substantial equivalence. |
| Size | 128 mm× 91.5 mm× 37.5 mm | 168 mm x 31 mm x 67 mm | 48mm× 39 mm× 147 mm | Different, but the subject device conforms to IEC 60601-1. |
| Weight | 530g | about 350 g (including the battery) | < 180g | |
| Battery Supply | NI-MH 300mAh 9.6v | 3*LR6 AA<br>18650 Lithium battery | 2*LR6AA | |
| Display | LCD display | LCD display | LCD display | Same |
| Resolution | 1 bpm | 1 bpm | 1 bpm | Same |
| Accuracy | ±2bpm | ±2bpm | ±2bpm | Same |
| FHR Measuring Range | 50bpm ~ 210bpm | 50bpm ~ 240bpm | 50bpm ~ 240bpm | Different, but measuring range is the same as the SD3 predicate. |
| Acoustic output （3MHz） | <20mW/cm2 | <20mW/cm2 | <10mW/cm2 | Different, but the |

| | | | | |
|---|---|---|---|---|
| | | | | subject device has lower acoustic output and performance comparable to predicates. |
| Wireless function | Not support | Not support | Bluetooth/APP function (optional). | Different, Wireless technology testing per the FDA guidance, "Radio Frequency Wireless Technology in Medical Devices" dated August 14, 2013 and Part 15 of the FCC rules. |
| **Safety Classifications** | | | | |
| Anti-electric Shock Type | Internally powered equipment | Internally powered equipment | Internally powered equipment | Same |
| Anti-electric Shock Degree | Type BF equipment | Type B equipment | Type BF equipment | Same |
| Degree of Protection against Harmful Ingress of Water: | Probes：IPX4 | Probes：IPX8 | IP22 | Different, but the subject device conforms to IEC 60529:2001. |
| The degree of safety of application in the presence of a flammable gas | Equipment not suitable for use in presence of flammable gases | Equipment not suitable for use in presence of flammable gases | Equipment not suitable for use in presence of flammable gases | Same |
| EMC | CISPR 11 Group 1 Class B | CISPR 11 Group 1 Class B | CISPR 11 Group 1 Class B | Same |

## 7. Summary of Performance Data:

### Clinical Performance Data:

Clinical testing was conducted at a Chinese hospital to demonstrate that the SD1 Ultrasonic Pocket Doppler, which uses the pulse-wave mode of Doppler ultrasound, is as safe and effective for finding and measuring the fetal heart rate as the SD3 Ultrasonic Pocket Doppler, which uses the continuous-wave

mode of Doppler ultrasound. The results showed that it did not take more time to find the fetal heart rate in pregnant patients, from 10 weeks of gestation onward, using the SD1 Pocket Doppler in comparison to the predicate SD3 Ultrasonic Pocket Doppler. Therefore, the fetus would not be exposed to a longer duration of ultrasound radiation during the course of an exam with the SD1 Ultrasonic Pocket Doppler.

**Non-clinical Performance Data:**

Bench testing was conducted per the following standards, and all the results met pre-defined acceptance criteria as applicable and were acceptable.

(1) IEC 60601-1 Electrical Safety
(2) IEC 60601-1-2 Electromagnetic Compatibility
(3) IEC 60601-2-37 Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
(4) IEC 61266 ULTRASONICS Hand-Held probe Doppler fetal heartbeat detectors Performance requirements and methods of measurement and reporting
(5) NEMA UD 2 Standard for Acoustic output measurement standard for diagnostic ultrasound equipment.
(6) Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.
(7) Biocompatibility, ISO 10993-5 (cytotoxicity) and ISO 10993-10 (irritation and sensitization)
(8) Wireless technology testing per the FDA guidance, "Radio Frequency Wireless Technology in Medical Devices" dated August 14, 2013 and Part 15 of the FCC rules.

**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 to have 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.

## 8. Conclusion:

Verification and validation testing was conducted on the SD1 Ultrasonic Pocket Doppler with optional use of Bluetooth/app and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the SD1Ultrasonic Pocket Doppler is substantially equivalent to the predicate devices.