November 3, 2021

Shenzhen Mericonn Technology Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District,
Shenzhen, Guangdong 518067
CHINA

Re: K212084
Trade/Device Name: Fetal Doppler
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: September 30, 2021
Received: October 4, 2021

Dear Kevin Wang:

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. 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 and Part 809); 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/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 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 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, 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)*
K212084

Device Name
Fetal Doppler

Indications for Use *(Describe)*
Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound. Fetal Doppler is indicated for use by health care professionals in hospital, clinic, community and home for singleton pregnancies after 12 weeks gestation.

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.

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510(K) Summary – K212084

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: November 2, 2021

1. Submission sponsor

Name: Shenzhen Mericonn Technology Co., Ltd.
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2. Submission correspondent

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Contact person: Kevin Wang
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3. Subject Device Information

Trade/Device Name	Fetal Doppler
Common Name	Fetal Doppler
Model	FD 100, FD 200, FD 300, FD 400
Regulatory Class	II
Regulation Name:	Fetal ultrasonic monitor and accessories
Regulation Number:	21 CFR 884.2660
Product Code	KNG

4. Predicate Device

EDAN Instruments, Inc, SD5 Ultrasonic Tabletop Doppler (K153475)
The predicate device has not been subject to a design-related recall

5. Device Description

Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound. Fetal Doppler is indicated for use by used by health care professionals in hospital, clinic, community and home for singleton pregnancies after 12 weeks gestation.

It is comprised of an ultrasonic signal transmitter and receiver, analog signal processing unit, FHR calculating unit, and LCD/TFT display control unit.
It has audio output and can be connected with headphones or to a recorder with audio input.
The Fetal Doppler is powered by a standard 1.5 V DC alkaline battery.

6. Indication for use

Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound. Fetal Doppler is indicated for use by health care professionals in hospital, clinic, community and home for singleton pregnancies after 12 weeks gestation.

7. Comparison to the Predicate Device

The following table compares the subject device to the predicate device with respect to the intended use and technological characteristics:

Device & Predicate Device(s):	K212084	K153475	Comment
Device Name	Fetal Doppler, Model: FD 100, FD 200, FD 300, FD 400	SD5 Ultrasonic TableTop Doppler	-
Manufacturer	Shenzhen Mericonn Technology Co., Ltd.	EDAN Instruments	-
Classification name	Fetal ultrasonic monitor and accessories	Fetal ultrasonic monitor and accessories	Same
Regulation Number	844.2660	844.2660	Same
Device Class	Class II	Class II	Same
Product Code	KNG	KNG	Same
Indications for Use	Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound. Fetal Doppler is indicated for use by medical professionals in clinical or home care settings for singleton	The SD5 Ultrasonic TableTop Doppler (hereinafter called “SD5”) and SD6 Ultrasonic TableTop Doppler (hereinafter	Similar

	pregnancies from 12 weeks gestation.	called “SD6”) 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/or 3 MHz obstetrical probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal wellbeing. They can also be used to verify fetal heart viability.	
Gestational Age	12 weeks	12 weeks	Same

Gestational Type	Singleton	Singleton	Same
Display Type	FD100,FD200,FD300: LCD	Digital Display LCD	Similar
	FD400: TFT		
Power Supply	Two 1.5V AA Alkaline	100V-240V, 50Hz/60Hz	**Different**
Probe Connection	Wired	Wired	Same
Nominal Frequency	2.5 MHz	2 MHz	Similar
Working Frequency	2.5 MHz ±10%	(2.0±10%)MHz	Similar
Iob	<10 mW/cm^2	<20 mW/cm^2	**Different**
Ispta	<50 mW/cm^2	<100 mW/cm^2	**Different**
Isata	<20 mW/cm2	<20 mW/cm2	Same
Mode of Operation	Continuous Doppler	Continuous Doppler	Same
Effective Radiating Area	208mm^2 ±15%	245mm^2 ±15%	**Different**
FHR Measuring Range	50 – 240 BPM	50 – 240 BPM	Same
Accuracy	±2BPM	±2BPM	Same
Resolution	1BPM	1BPM	Same

The subject and predicate device have the same intended use (i.e., to detect the fetal heart beat). The Fetal Doppler and SD5 Ultrasonic TableTop Doppler have different technological characteristics, including different battery/power supply, and ultrasound performance (Iob, Ispta, Isata). The differences in technological characteristics do not raise new questions of safety and effectiveness.

8. Performance Data

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

Biocompatibility testing

The biocompatibility evaluation was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Patient contacting materials were subjected to testing that included the following tests:

- Cytotoxicity (ISO 10993-5:2019)

- Skin Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)

Software Verification and Validation Testing

Software verification and validation testing was conducted and completed and software documentation was provided as recommended by FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005 for a moderate software level of concern.

Electromagnetic Compatibility and Electrical Safety

The subject device models were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.
- IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Performance Testing

The following testing is provided to support the safety and performance of the subject device:

- Use Life Testing
- Battery Life Testing
- Battery Indicator Testing
- Testing per IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- The acoustic output measurement methodology as recommended in FDA guidance document "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated June 27, 2019 was followed for Track 1 devices.

9. Conclusion

The nonclinical performance data described above demonstrate that the Fetal Doppler is as safe and effective as the predicate device and supports a determination of substantial equivalence.