July 19, 2018

Shenzhen IMDK Medical Technology Co., Ltd.
Yuan Xia
Administrative Director
C Zone, 10F, Building16, Yuanshan Industrial B Area
Gongming Street, Guangming District
Shenzhen, 518106
CHINA

Re: K180419
Trade/Device Name: Ultrasonic Doppler (Model YM-2T8)
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: Class II
Product Code: KNG
Dated: June 8, 2018
Received: June 21, 2018

Dear Yuan Xia:

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,

Sharon M. Andrews -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180419

Device Name
Ultrasonic Doppler
Model YM-2T8

Indications for Use *(Describe)*
The Ultrasonic Doppler uses continuous-wave Doppler to detect fetal heart beats, display fetal heart rate and play the fetal heart sound from early gestation thru delivery for singleton pregnancies. The Ultrasonic Doppler is intended for use by trained healthcare professionals only in a clinical setting.

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
K180419

1. Submitter

Name and Address: Shenzhen IMDK Medical Technology Co., Ltd.
C Zone,10F, Building 16, Yuanshan Industrial B Area, Gongming Street,
Guangming District, 518106, P.R. China
Telephone: +86 13662694320
Contact Person: Yuan Xia
Date Prepared: July 5, 2018

2. Device Information

Trade Name: Ultrasonic Doppler
Model: YM-2T8
Classification Name: Fetal ultrasonic monitor and accessories
Regulation Number: 21 CFR 884.2660
Device Classification: Class II
Product Code: KNG
Review Panel: Obstetrics/Gynecology

3. Predicate Device

510(k) Number: K153475
Device Name: SD5 Ultrasonic Tabletop Doppler
Manufacturer: Edan Instruments, Inc.

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

4. Device Description

The Ultrasonic Doppler is a hand-held device for non-invasive measurement and display of the fetal heart beat utilizing the principle of Doppler shift of an ultrasound. The device consists of two main components, the main unit and probe. The main unit consists of the main board, power module, battery, speaker, and organic light-emitting diode screen. The wired probe consists of the transducer and includes two angled semi-circle ultrasonic crystals, one for transmission and one for reception. The ultrasonic signal is continuously transmitted at a frequency of 2 MHz. The reflected continuous wave signal is received by one of the crystals and then any detected Doppler shift is presented to the user.

The main unit is powered by two 1.5V AA alkaline batteries.

5. Indications for Use

The Ultrasonic Doppler uses continuous-wave Doppler to detect fetal heart beats, display fetal heart rate and play the fetal heart sound from early gestation thru delivery for singleton pregnancies. The Ultrasonic Doppler is intended for use by trained healthcare professionals only in a clinical setting.

6. Predicate Comparison

The following table compares the Ultrasonic Doppler to the predicate device with respect to the indications for use and technological characteristics:

Device	**Subject Device** Ultrasonic Doppler Model: YM-2T8	**Predicate Device** SD5 Ultrasonic Tabletop Doppler
510(k) Number	K180419	K153475
Manufacturer	Shenzhen IMDK Medical Technology Co., Ltd.	EDAN Instruments, Inc.
Classification Name	Fetal ultrasonic monitor and accessories	Fetal ultrasonic monitor and accessories
Regulation Number	844.2660	844.2660
Device Class	Class II	Class II
Product Code	KNG	KNG
Indications for Use	The Ultrasonic Doppler uses continuous-wave Doppler to detect fetal heart beats, display fetal heart rate and play the fetal heart sound from early gestation thru delivery for singleton pregnancies. The Ultrasonic Doppler is intended for use by trained healthcare professionals only in a clinical setting.	The SD5 Ultrasonic TableTop Doppler (hereinafter called "SD5") and SD6 Ultrasonic TableTop Doppler (hereinafter 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 well being. They can also be used to verify fetal heart viability.
Gestational Age	12 weeks	12 weeks
Gestational Type	Singleton	Singleton
Technical Characteristics		
Display Type	Digital Display; LCD	Digital Display; LCD
Power Suppler	Two 1.5V AA Alkaline Batteries	100 V – 240 V~, 50 Hz/60 Hz or 7.2 V/2000 mAh (Ni-MH Battery)
Probe connection	Wired	Wired
Acoustic Output Power	3 W	3 W
Nominal Frequency	2 MHz	2 MHz
Working Frequency	(2.0 ± 10%) MHz	(2.0 ± 10%) MHz
I_{ob}	< 20 mW/cm^2	< 20 mW/cm^2
p_r	1 MPa	1 MPa
Ispta	< 100 mW/cm^2	< 100 mW/cm^2
Isata	< 20 mW/cm^2	< 20 mW/cm^2

W_o	50 mW	50 mW
Mode of operation	Continuous Wave Doppler	Continuous Wave Doppler
Effective Radiating Area	(157±30%) mm^2	(245±15%) mm^2
FHR Measuring Range	50 bpm ~ 210 bpm	50 bpm ~ 240 bpm
Accuracy	± 2bpm	± 2bpm
Resolution	1 bpm	1 bpm

7. Non-Clinical Performance Testing

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

Biocompatibility
The biocompatibility evaluation was conducted in accordance with 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:

i. Cytotoxicity (ISO 10993-5)

ii. Skin Sensitization (ISO 10993-10)

iii. Irritation (ISO 10993-10)

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted and the device was found to comply with the requirements of the following standards:

i. IEC 60601-1, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance with US deviations per AAMI/ANSI ES 60601-1

ii. IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances– requirements and tests

iii. IEC 60601-1-11, 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

Ultrasound and Acoustic Testing
Bench testing was conducted on the Ultrasonic Doppler and the system was found to comply with the following:

i. IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

ii. Acoustic Output testing per NEMA UD2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

The acoustic output measurement methodology as recommended in FDA guidance document "*Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers,*" dated September 9, 2008 was followed for Track 1 devices.

Software Verification and Validation Testing
Software verification and validation testing was conducted and completed with no outstanding anomalies. 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.

8. Clinical Performance Testing

Not Applicable

9. Conclusion

Based on the comparison and analysis above, the Ultrasonic Doppler is substantially equivalent to the predicate device.