December 19, 2018

Shenzhen AOJ Medical Technology Co., Ltd.
Qihuan Zhao
General Manager
Room 202, HaoGu Industry Park, 2037 Guanguang Road,
Guangming district
Shenzhen, 518105
China

Re: K182190
Trade/Device Name: Fetal Doppler (Models AOJ-50A and AOJ-50B)
Regulation Number: 21 CFR§ 884.2660
Regulation Name: Fetal Ultrasonic Monitor and Accessories
Regulatory Class: II
Product Code: KNG
Dated: November 8, 2018
Received: November 19, 2018

Dear Qihuan Zhao:

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); 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,

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)*
K182190

Device Name
Fetal Doppler (Models AOJ-50A and AOJ-50B)

Indications for Use *(Describe)*
The Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate and play the fetal heart sound from early gestation thru delivery for singleton pregnancies. The Fetal 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 – K182190

1. Submitter

Name and Address Shenzhen AOJ Medical Technology Co., Ltd.

Room 202, HaoGu industry park, 2037 Guanguang road, Guangming district, 518105, Shenzhen, P.R. China

Tel.: +86 18603031299

Contact Person: Qihuan Zhao, General Manager, Shenzhen AOJ Medical Technology Co., Ltd.

Date Prepared: December 17, 2018

2. Device Information

Trade Name:	Fetal Doppler (Models AOJ-50A, AOJ-50B)
Common Name:	Fetal doppler
Classification Name:	Fetal ultrasonic monitor and accessories
Regulation Number:	21 CFR 884.2660
Device Classification:	Class II
Product Code:	KNG (monitor, ultrasonic, fetal)
Review Panel:	Obstetrics/Gynecology

3. Predicate Device

510(k) Number:	K180419
Device Name:	YM-2T8 Ultrasonic Doppler
Manufacturer:	Shenzhen IMDK Medical Technology Co., Ltd.

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

4. Device Description

The Fetal 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. The use-life of the device is five years.

5. Indications for Use

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

6. Predicate Comparison

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

Comparison Items	**Predicate Device** Ultrasonic Doppler Model: YM-2T8	**Subject Device** Fetal Doppler	**Comparison Result**
510(k) Number	K180419	K182190	----
Manufacturer	Shenzhen IMDK Medical Technology Co., Ltd.	Shenzhen AOJ Medical Technology Co., Ltd.	----
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	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 Ultrasonic Doppler is intended 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.	Same
Gestational Age	12 weeks	12 weeks	Same
Gestational Type	Singleton	Singleton	Same
Technical Characteristics			Same
Display Type	Digital Display; LCD	Digital Display; LCD	Same
Power Suppler	2* 1.5V AA Alkaline batteries	2* 1.5V AA Alkaline batteries	Same
Probe connection	Wired	Wired	Same
Acoustic Output Power	3 W	3 W	Same
Nominal Frequency	2 MHz	2 MHz	Same
Working Frequency	(2.0 ± 10%) MHz	(2.0 ± 10%) MHz	Same
I_{ob}	< 20 mW/cm^2	< 20 mW/cm^2	Same
p_r	1 MPa	1 MPa	Same
lspta	< 100 mW/cm^2	< 100 mW/cm^2	Same
lsata	< 20 mW/cm^2	< 20 mW/cm^2	Same
W_o	50 mW	50 mW	Same
Mode of operation	Continuous Wave Doppler	Continuous Wave Doppler	Same
Effective Radiating Area	(157±30%) mm^2	(157±30%) mm^2	Same
FHR Measuring Range	50 bpm -210 bpm	50 bpm - 210 bpm	Same
Accuracy	± 2bpm	± 2bpm	Same
Resolution	1 bpm	1 bpm	Same

As evidenced by the table above, the subject and predicate device have similar technological characteristics. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety or effectiveness.

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:

- Cytotoxicity (ISO 10993-5)
- Skin Sensitization (ISO 10993-10)
- 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:

- 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
- 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

Ultrasound and Acoustic Testing

Bench testing was conducted on the Fetal Doppler and the system was found to comply with the following:

- 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
- 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. Conclusion

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