January 7, 2022

Shenzhen Taikang Medical Equipment Co., Ltd.
Shigui Du
General Manager
3F East, Building 4, Lanzhu East Road 8, Grand Industrial
Park, Pingshan District
Shenzhen, Guangdong 518015
CHINA

Re: K211940
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: December 6, 2021
Received: December 6, 2021

Dear Shigui Du:

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/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)*
K211940

Device Name
Fetal Doppler

Indications for Use *(Describe)*
The Fetal Doppler is used to detect the fetal heart rate. The device should be used by health care professionals including nurses, midwives, and specialized technicians in hospital, clinic, community and home. The device is intended for use at or after 16 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.

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510(k) Summary
K211940

Prepared in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Information of Submitter and Correspondent

Submitter's information:

Company Name: Shenzhen Taikang Medical Equipment Co., Ltd.
Street Address: 3F East, Building 4, Lanzhu East Road 8, Grand Industrial Park, Pingshan District
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Country: China
Telephone: +86(755)-89664986
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Contact Person: Shigui Du
Contact Title: General Manager
Contact Email: dushigui@taikang-medical.com

Submission correspondent's information:

Name: Shenzhen Reanny Medical Devices Management Consulting Co., Ltd
Address: Room 2012#, Gebu Commercial Building, Hongxing Community Songgang Street, Baoan District, Shenzhen 518000, China
Contact Person: Reanny Wang
E-mail: reanny@reanny.com

Date Summary Prepared: January 5, 2022

2.0 Device Information

Trade/Device Name	Fetal Doppler
Model:	TK-T802CR
Regulation Name:	Fetal ultrasonic monitor and accessories
Regulation Number:	21 CFR 884.2660
Common Name:	Fetal Doppler
Product Code:	KNG (monitor, ultrasonic, fetal)
Regulatory Class:	Class II
Review Panel:	Obstetrics/Gynecology

3.0 Predicate Device Information

Sponsor:	Vcomin Technology Limited Company
Device:	Fetal Doppler, Model: FD-200D
510(K) Number:	K182526 The predicate device has not been subject to a design-related recall.

4.0 Device Description

The Fetal Doppler, model TK-T802CR, is a hand-held, battery powered audio Doppler device used for detecting fetal heart beats and sounds. The Fetal Doppler is used for non-invasive detection and display of the fetal heart rate (FHR) utilizing Doppler ultrasound. It has two hand-held components, a main unit and a probe. The main unit consists of the main board, power module, battery, speaker, and LCD screen. The probe consists of the ultrasonic transducers for transmission and for signal reception. The ultrasonic signal is continuously transmitted at a frequency of 2.0, 2.5, or 3.0 MHz, depending on the probe settings selected.

5.0 Indications for Use

The Fetal Doppler is used to detect the fetal heart rate. The device should be used by health care professionals including nurses, midwives, and specialized technicians in hospital, clinic, community and home. The device is intended for use at or after 16 weeks gestation.

6.0 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):	**Subject Device** K211940 Fetal Doppler Model: TK-T802CR	**Predicate Device** K182526 Fetal Doppler Model: FD-200D	**Comparison**
Indications for Use	The Fetal Doppler is used to detect the fetal heart rate. The device should be used by health care professionals including nurses, midwives, and specialized technicians in hospital, clinic, community and home. The device is intended for use at or after 16 weeks gestation.	The device is used to detect the fetal heart rate. The device should be used by health care professionals including nurses, midwives, and specialized technicians in hospital, clinic, community and home.	Same
Design	A main unit and a probe. The main unit displays FHR	A main unit and a probe. The main unit displays FHR	Same
Mode of action	Doppler ultrasound, continuous wave	Doppler ultrasound, continuous wave	Same
Ultrasound frequency	2.0 MHz, 2.5 MHz, and 3.0 MHz	2.0 MHz, 2.5 MHz, and 3.0 MHz	Same

FHR Specifications	FHR Measuring Range: 50-210 bpm Accuracy: ±2 bpm Resolution: 1 bpm	FHR Measuring Range: 50-210 bpm Accuracy: ±2 bpm Resolution: 1 bpm	Same
Acoustic output	2.0MHz – ISATA: 6.01mW/cm^2 2.5MHz – ISATA: 6.67mW/cm^2 3.0MHz – ISATA: 6.87mW/cm^2	2.0MHz – ISATA: 17.24 mW/cm^2 2.5MHz – ISATA: 18.57 mW/cm^2 3.0MHz – ISATA: 11.496 mW/cm^2	**Different**
Material - Patient Contacting Components	ABS	ABS, Silicone, Colorants	Same

The subject and predicate device have the same intended use (i.e., to detect the fetal heartbeat). The subject and predicate device have different technological characteristics, including different acoustic output specifications, physical dimensions, and weight. The differences in technological characteristics do not raise new questions of safety and effectiveness.

7.0 Performance Summary

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

a. Biocompatibility
Biocompatibility testing on the patient-contacting components of the subject device in accordance with the FDA guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" dated September 4, 2020. Testing included the following assessments:
- Cytotoxicity per ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitization per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Irritation per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

The patient-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

b. Electrical Safety, Electromagnetic Compatibility, and Wireless Technology
- IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012.
- IEC 60601-1-11:2015, 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.
- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
- IEC 62133:2012 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

c. Software Verification

Software verification and validation was conducted and software documentation was provided in accordance with the 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.

d. Performance Testing
The following testing was provided to support the safety and effectiveness of the subject device:
    i. Use-Life Testing
    ii. Fetal Heart Rate Accuracy Testing
    iii. 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
    iv. Acoustic output testing per NEMA UD 2-2004(R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and 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 non-clinical 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.