



January 8, 2026

Zhongshan Xiaolan Town Senlan Electronic Factory
% Ailing Fu
Consultant
Shenzhen Aisnwei Medical Technology Service Co., Ltd.
Room B07, 3rd Floor, No.690, Dongmen Building
Xinniu Community, Minzhi Street, Longhua District
Shenzhen, \ 518131
CHINA

Re: K252669
Trade/Device Name: Fetal Doppler U8-25, U9-25
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal Ultrasonic Monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: December 5, 2025
Received: December 8, 2025

Dear Ailing Fu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

510(k) Number (if known)
K252669

Device Name
Fetal Doppler U8-25, U9-25

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.

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510(k) Summary

K252669

Prepared in accordance with the requirements of 21 CFR 807.92

1. Date Prepared

January 7, 2026

2. Submitter's Information

Sponsor/510(k) Owner:

Company name: Zhongshan Xiaolan Town Senlan Electronic Factory

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Correspondent:

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Contact Name: Ms. Fu Ailing

Telephone No.: +86-13538216349

Email Address: fuailing@aisnwei.com

3. Device Information

Trade Name/Model: Fetal Doppler U8-25, U9-25

Common Name: Fetal Doppler

Regulation Number: 21 CFR 884.2660

Regulation Name: Fetal ultrasonic monitor and accessories

Product code: KNG (Monitor, Ultrasonic, Fetal)
Classification Panel: Obstetrics/Gynecology
Device Class: II

4. Predicate Device

510(k) Number: K211940
Device Name: Fetal Doppler, Model TK-T802CR
Manufacturer: Shenzhen Taikang Medical Equipment Co., Ltd.,

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

5. Device Description

The Fetal Doppler U8-25, U9-25 is a handheld ultrasound device that employs the Doppler principle to detect the fetal heart rate (FHR) from a pregnant woman's abdomen.

The fetal doppler has a main unit and a probe. The main unit consists of main board, power module, battery, speaker and display screen. The probe integrated into the main unit consists of the ultrasonic transducers for signal transmission and reception. The ultrasonic signal is continuously transmitted at a frequency of 2.5 MHz.

The difference between U8-25 and U9-25 is their appearance. Except their appearances, there are no other differences between the fetal dopplers. They have the same intended use, power supply, and discharge holes close to a speaker.

6. 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.

7. Substantial Equivalence Discussion

The following table compares the intended use and technological characteristics of the subject and predicate devices:

**Table 1. Comparison of Intended Use and Technological Characteristics
Between Fetal Doppler U8-25, U9-25 and Fetal Doppler TK-T802CR**

| ID | Comparison Item | Subject Device (K252669) Fetal Doppler U8-25, U9-25 | Predicate Device (K211940) Fetal Doppler TK-T802CR | Explanation of Differences |
|----|----------------------------------|--|--|----------------------------|
| 1 | Manufacturer | Zhongshan Xiaolan Town Senlan Electronic Factory | Shenzhen Taikang Medical Equipment Co., Ltd. | N/A |
| 2 | Intended use/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 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. | Same |
| 8 | Gestational Age | 16 weeks | 16 weeks | Same |

| | | | | |
|----|-------------------------|---|---|--|
| 9 | Design | A main unit and a probe. The probe is integrated into the main unit. | A main unit and a probe. | Same |
| | | The main unit displays FHR. | The main unit displays FHR. | Same |
| 10 | Principles of Operation | Doppler Ultrasound, Continuous wave | Doppler Ultrasound, Continuous wave | Same |
| 27 | Ultrasound Frequency | 2.5MHz | 2.0 MHz, 2.5 MHz, and 3.0 MHz | Similar |
| 28 | FHR Specifications | FHR Measuring Range: 65bpm ~ 210bpm Accuracy: ± 2 bpm Resolution: 1 bpm | FHR Measuring Range: 50bpm ~ 210bpm Accuracy: ± 2 bpm Resolution: 1 bpm | Same |
| 29 | Acoustic Output | 2.5MHz – P-: 30.7KPa | Not available | Different The subject and predicate devices have different acoustic outputs, but both devices meet FDA recommendations for acoustic output (I_{SATA} : < 20 mW/cm ²). In addition, the differences do |
| | | 2.5MHz – I_{ob} : 2.99mW/cm ² | Not available | |
| | | 2.5MHz – I_{SPTA} : 10.08mW/cm ² | Not available | |

| | | | | |
|----|--|---|--|---|
| | | 2.5MHz – I _{SATA} : 2.99mW/cm ² | 2.0MHz – ISATA: 6.01mW/cm ² 2.5MHz – ISATA: 6.67mW/cm ² 3.0MHz – ISATA: 6.87mW/cm ² | not raise safety concerns according to IEC 60601-2-37 and NEMA UD2-2004 Acoustic Output Test Reports. |
| 31 | Material-patient Contacting Components | ABS | ABS, Silicone, Colorants | Similar |

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 different questions of safety and effectiveness.

8. Non-clinical Performance Testing

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

Biocompatibility Testing

The biocompatibility was evaluated in accordance with the 2023 FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*.

The following tests were performed for patient contacting materials:

- Cytotoxicity
- Skin Sensitization
- Irritation

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

Software Verification and Validation Testing

The software was verified and validated according to the 2023 FDA guidance document "Guidance for the Content of Premarket submissions for Device Software Functions".

Electrical Safety and Electromagnetic Compatibility

Electrical safety and EMC testing were conducted, and the device was found to comply with the requirements of the following standards.

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

- 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
- 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

Ultrasound and Acoustic testing

All measurements were conducted in accordance with the measurement procedures of the NEMA Standard Publications UD-2, and with the measurement methodology for Track 1 devices in the 2023 FDA guidance document "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers".

Use Life testing

Use life testing was conducted to verify the device maintains functionality and structural integrity over a 5-year service life. The device operated normally and maintained accuracy and showed no degradation.

9. Conclusion

The results of the testing described above demonstrate that the Fetal Doppler U8-25, U9-25 is as safe and effective as the predicate device and supports a determination of substantial equivalence.