



June 26, 2025

Shenzhen Bestman Instrument Co., Ltd.
Yong Bai
Head of Firm
8th floor, Yifang Building, No.315, Shuangming Avenue,
Dongzhou Community, Guangming Street, Guangming District
Shenzhen, GD 518107
CHINA

Re: K242846
Trade/Device Name: Doppler FHR Detector (BF-500D+, BF-560)
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal Ultrasonic Monitor and accessories
Regulatory Class: Class II
Product Code: KNG
Dated: May 23, 2025
Received: May 23, 2025

Dear Yong Bai:

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
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K242846

Device Name
Doppler FHR Detector (BF-500D+, BF-560)

Indications for Use (Describe)

The Doppler FHR Detector (Model BF-500D+ and BF-560) is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound in patients with singleton pregnancies after 12 weeks of gestation. The device is intended to be used by health care professionals in a hospital, clinic, community, and home 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

1. Submitter

Name and Address Shenzhen Bestman Instrument Co., Ltd.
8th floor, Yifang Building, No.315, Shuangming Avenue, Dongzhou Community,
Guangming Street, Guangming District, Shenzhen, China, 518107
Tel.: 86 755-26713784

Contact Person: Bai Yong
Date Prepared: June 11, 2025

2. Device Information

Trade Name: Doppler FHR Detector (BF-500D+ and BF-560)
Common Name: Fetal Doppler
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Product Code: KNG (Monitor, Ultrasonic, Fetal)
Device Classification: Class II
Review Panel: Obstetrics/Gynecology

3. Predicate Device

510(k) Number: K090510
Device Name: BF-500B Doppler Fetal Heart Rate Detector
Manufacturer: Shenzhen Bestman Instrument 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 Doppler 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 liquid crystal display(LCD) 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 one frequency.

The difference between BF-500D+ and BF-560 are shown as below:

- BF-500D+ is powered by a 9V rechargeable Ni-MH battery, and adapter is packaged with the unit; BF-560 is powered by three pieces of 1.5V AA alkaline disposable batteries.
- BF-500D+ will display Fetal heart rate, sound volume, and battery indicator; BF-560 will also display the selected working frequency besides in addition to the features of the BF-500D+.
- the two models have different probe shapes.

5. Indications for Use

The Doppler FHR Detector (Model BF-500D+ and BF-560) is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound in patients with singleton pregnancies after 12 weeks of gestation. The device is intended to be used by health care professionals in a hospital, clinic, community, and home setting.

6. Substantial Equivalence Discussion

The following tables compare the intended use and technological characteristics of the subject and predicate devices:

Table 6-1: Comparison between the predicate device BF-500B and the subject device BF-500D+

Comparison Items	Predicate Device Doppler Fetal Heart Rate Detector Model: BF-500B	Subject Device Doppler FHR Detector Model: BF-500D+	Comparison Result
510(k) Number	K090510	K242846	----
Manufacturer	Shenzhen Bestman Instrument Co., Ltd.	Shenzhen Bestman Instrument 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 Doppler Fetal Heart Rate Detector can be used for the detection of average fetal heartbeat rate.	The Doppler FHR Detector is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound in patients with singleton pregnancies after 12 weeks of gestation. The device is intended to be used by health care professionals in a hospital, clinic, community, and home setting.	Different
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 Supply	9.6 V	9 V	Different
Battery Type	Rechargeable Ni-MH battery	Rechargeable Ni-MH battery	Same
Probe connection	Wired	Wired	Same
Acoustic Output Power	Less than 1.8W	Less than 1.8 W	Same
Nominal Frequency	2 MHz	2 MHz	Same
Working Frequency	(2.0 ± 10%) MHz	(2.0 ± 10%) MHz	Same
I_{ob}	≤ 10 mW/cm ²	≤ 10 mW/cm ²	Same
p_r	1 MPa	1 MPa	Same
I_{spta}	< 100 mW/cm ²	< 100 mW/cm ²	Same
I_{sata}	< 20 mW/cm ²	< 20 mW/cm ²	Same
W_o	10 mW	<u>26.31 mW</u>	Different
Mode of operation	Continuous Wave Doppler	Continuous Wave Doppler	Same

Coupling Medium Impedance	1.5-1.6 (10 ⁵ g/cm ² .s)	1.5-1.6 (10 ⁵ g/cm ² .s)	Same
Effective Radiating Area	(6±0.5) cm ²	<u>(3.08±3.6%) cm²</u>	Different
FHR Measuring Range	50 bpm ~ 210 bpm	65 bpm ~ 210 bpm	
Accuracy	± 2bpm	± 2bpm	Same
Resolution	1 bpm	1 bpm	Same
Working Time	≥5 hours	≥2 hours	Different
Working Environment	Temperature: +5°C ~ +40 °C Humidity: ≤ 80% Atmospheric pressure: 86kPa ~ 106kPa	Temperature: +5 °C ~ +40 °C Humidity: ≤ 80% Atmospheric pressure: 86kPa ~ 106kPa	Same
Transport and Storage Environment	Temperature: -10 °C ~ +40 °C Humidity: ≤ 80%	Temperature: -10 °C ~ +40 °C Humidity: ≤ 80%	Same

Table 6-2: Comparison between the predicate device BF-500B and the subject device BF-560

Comparison Items	Predicate Device Doppler Fetal Heart Rate Detector Model: BF-500B	Subject Device Doppler FHR Detector Model: BF-560	Comparison Result
510(k) Number	K090510	K242846	----
Manufacturer	Shenzhen Bestman Instrument Co., Ltd.	Shenzhen Bestman Instrument 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 Doppler Fetal Heart Rate Detector can be used for the detection of average fetal heartbeat rate.	The Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound from early gestational. The device should only be used by a trained medical professional in a clinical setting and not intended for operated by the pregnant at home.	Different
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 Supply	9.6 V	4.5V	Different

Battery Type	Rechargeable Ni-MH battery	Alkaline battery	
Probe connection	Wired	Wired	Same
Acoustic Output Power	Less than 1.8W	Less than 1.5 W	Different
Nominal Frequency	2 MHz	2 MHz, 3MHz	Same
Working Frequency	(2.0 ± 10%) MHz	(2.0 ± 10%) MHz (3.0 ± 10%) MHz	Different
I_{ob}	≤ 10 mW/cm ²	≤ 10 mW/cm ²	Same
p_r	1 MPa	1 MPa	Same
I_{spta}	< 100 mW/cm ²	< 100 mW/cm ²	Same
I_{sata}	< 20 mW/cm ²	< 20 mW/cm ²	Same
W_o	10 mW	21.54 mW (for 2 MHz probe) 22.49 mW (for 3 MHz probe)	Different
Mode of operation	Continuous Wave Doppler	Continuous Wave Doppler	Same
Coupling Medium Impedance	1.5-1.6 (10 ⁵ g/cm ² .s)	1.5-1.6 (10 ⁵ g/cm ² .s)	Same
Effective Radiating Area	(6±0.5) cm ²	(1.57±5%) cm ²	Different
FHR Measuring Range	50 bpm ~ 210 bpm	65 bpm ~ 210 bpm	
Accuracy	± 2bpm	± 2bpm	Same
Resolution	1 bpm	1 bpm	Same
Working Time	≥5 hours	≥2 hours	Different
Working Environment	Temperature: +5°C ~ +40 °C Humidity: ≤ 80% Atmospheric pressure: 86kPa ~ 106kPa	Temperature: +5 °C ~ +40 °C Humidity: ≤ 80% Atmospheric pressure: 86kPa ~ 106kPa	Same
Transport and Storage Environment	Temperature: -10 °C ~ +40 °C Humidity: ≤ 80%	Temperature: -10 °C ~ +40 °C Humidity: ≤ 80%	Same

The subject and predicate devices have similar indications for use statements and have the same intended use – to detect the fetal heart rate.

The subject and predicate devices have different technological characteristics, including different ultrasound frequency, output power, effective area and measuring range, power supply, and working time. These differences in technology do not raise different questions of safety or effectiveness and can be evaluated through performance testing.

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)

These tests were selected based on the nature and duration of patient contact, as outlined in Attachment G of the FDA guidance.

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

Ultrasound and Acoustic Testing

Bench testing was conducted on the Fetal 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 IEC 62359:2017, Guidance for Industry and Food and Drug Administration Staff:2019, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

The acoustic output measurement methodology as recommended in FDA guidance document “*Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Guidance for Industry and Food and Drug Administration Staff*,” dated June 27, 2019 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.

Use Life

Use life testing to validate the device performance and durability over the proposed service life of 609 hours was conducted. Testing was conducted on three samples (n=3) for each device model, in compliance with FDA recommendations for adequate sample sizes in medical device testing.

The use life testing protocol encompassed the following key elements:

- i. Continuous device operation for the entire 609-hour service life period.
- ii. Simulated cleaning and disinfection processes, replicating expected maintenance procedures over the device's lifespan.
- iii. Battery cycling for rechargeable batteries and key-fatigue testing of device buttons to assess long-

- term durability of these components.
- iv. Utilization of a fetal heart rate simulator to evaluate device performance under worst-case operational scenarios.

The device successfully passed all aspects of the use life testing, including continuous operation, simulated maintenance, and stress testing under various conditions.

8. Conclusion

The results of the testing described above demonstrate that the Doppler FHR Detector (BF-500D+ and BF-560) is safe and effective as the predicate device and supports a determination of the substantial equivalence.