June 14, 2024

Contec Medical Systems Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District,
Beijing, Beijing 102401
CHINA

Re: K232893
Trade/Device Name: Pocket Fetal Doppler (CONTEC 10D),
Pocket Fetal Doppler (CONTEC 10E),
Pocket Fetal Doppler (CONTEC 10F)
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal Ultrasonic Monitor And Accessories
Regulatory Class: II
Product Code: KNG
Dated: May 11, 2024
Received: May 13, 2024

Dear Ray Wang:

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.

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, PhD
Assistant Director
DHT3B: Division of Reproductive,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232893

Device Name

Pocket Fetal Doppler (CONTEC 10D);
Pocket Fetal Doppler (CONTEC 10E);
Pocket Fetal Doppler (CONTEC 10F)

Indications for Use *(Describe)*

The Pocket Fetal Doppler (Models CONTEC 10D, CONTEC 10E and CONTEC10F) is used to detect the fetal heart rate. The device should be used by health care professionals including nurses, midwives, and specialized technicians in the hospital, clinic, community and home. The device is intended for use at or after 12 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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The assigned 510(k) Number: K232893

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: June 14, 2024

2. 510(k) Owner

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3. Designated Submission Correspondent

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4. Identification of Subject Device

Trade Name: Pocket Fetal Doppler (CONTEC 10D), Pocket Fetal Doppler (CONTEC 10E), Pocket Fetal Doppler (CONTEC 10F)
Common Name: Fetal Doppler

Regulatory Information
Regulation Name: Fetal ultrasonic monitor and accessories
Regulation Number: 21 CFR 884.2660

Regulatory Class: II
Product Code: KNG (Monitor, Ultrasonic, Fetal)
Review Panel: Obstetrics/Gynecology

5. Predicate Device

Predicate Device:
510(k) Number: K220245
Product Name: Pocket Fetal Doppler (Models CONTEC10C and CONTEC10CL)
Manufacturer: Contec Medical Systems Co., Ltd.

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

6. Device Description:

The Pocket Fetal Doppler is a hand-held fetal Doppler used for non-invasive measurement and numerical display of the fetal heart rate (FHR) utilizing pulsed-wave Doppler ultrasound. The Pocket Fetal Doppler includes three models: CONTEC10D, CONTEC10E and CONTEC10F. All models have four components: upper shell, lower shell, display and probe. The material for probe cap and shell is ABS. The device contains an ultrasonic signal transmitter and receiver, analog signals processing unit, FHR calculating unit, and LCD display control unit. 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. This device can detect a fetal heart rate value at or after twelve weeks gestation.

The CONTEC10D is powered by a 3.7V lithium battery, the ultrasonic signal is continuously transmitted at a frequency of 2.5MHz.

The CONTEC10E and CONTEC10F is powered by two 1.5V batteries (AA LR6), the ultrasonic signal is continuously transmitted at a frequency of 2.5MHz.

7. Indications for use Statement:

The Pocket Fetal Doppler (Models CONTEC 10D, CONTEC 10E and CONTEC10F) is used to detect the fetal heart rate. The device should be used by health care professionals including nurses, midwives, and specialized technicians in the hospital, clinic, community and home. The device is intended for use at or after 12 weeks gestation.

8. Substantial Equivalence Discussion
The following table compares the intended use and technological characteristics of the subject and predicate device.

Table 1 General Comparison

Item	**Subject Device K232893**	**Predicate Device K220245**	**Remark**

Device name	Pocket Fetal Doppler (CONTEC 10D), Pocket Fetal Doppler (CONTEC 10E), Pocket Fetal Doppler (CONTEC 10F	Pocket Fetal Doppler	/
Model	CONTEC 10D; CONTEC 10E; CONTEC 10F	CONTEC10C and CONTEC10CL	/
Classification Regulation	21 CFR 884.2660	21 CFR 884.2660	Same
Classification	II	II	Same
Product Code	KNG	KNG	Same
Regulation Name	Fetal ultrasonic monitor and accessories.	Fetal ultrasonic monitor and accessories.	Same
Indications for use	The Pocket Fetal Doppler (Models CONTEC 10D, CONTEC 10E and CONTEC10F) is used to detect the fetal heart rate. The device should be used by health care professionals including nurses, midwives, and specialized technicians in the hospital, clinic, community and home. The device is intended for use at or after 12 weeks gestation.	The Pocket Fetal Doppler (Models CONTEC10C and CONTEC10CL) is used to detect the fetal heart rate. The device should be used by health care professionals including nurses, midwives, and specialized technicians in the hospital, clinic, community and home. The device is intended for use at or after 12 weeks gestation.	Same
Intended population	Women with pregnancy at or after 12 weeks	Women with pregnancy at or after 12 weeks	Same
Design	A main unit and a probe. The main unit can display a numerical FHR value	A main unit and a probe. The main unit can display a numerical FHR value	Same
Mode of action	Doppler ultrasound, pulsed wave	Doppler ultrasound, continuous wave	Different
Ultrasound frequency	2.5MHz Pulse repetition frequency: 5556Hz (CONTEC 10D) 5560Hz (CONTEC 10E/F)	2.0 MHz, 3.0 MHz	Different
Performance	-FHR Measuring Range: 50 BPM ~ 240 BPM	-FHR Measuring Range: 50 BPM ~ 240 BPM	Same
	-Resolution: 1 BPM	-Resolution: 1 BPM	
	Accuracy: ±2 BPM	Accuracy: ±2 BPM	

Acoustic output (statistical maximum limit)	CONTEC 10D: I_{SATA} < 10 mW/cm^2 CONTEC 10E: I_{SATA} < 20 mW/cm^2 CONTEC 10F: I_{SATA} < 20 mW/cm^2	I_{SATA}< 20 mW/cm^2	Different
Patient contact material	ABS	ABS, Silica, PVC	Different
Biocompatibility	Meets Attachment G recommendations (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" (issued September 2023))	No cytotoxicity, sensitization or irritation (ISO 10993-5 & ISO 10993-10)	Same
Electrical Safety	IEC 60601-1 and IEC 60601-1-11	IEC 60601-1 and IEC 60601-1-11	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Performance	IEC 60601-2-37	IEC 60601-2-37	Same
Battery	EN 62133	EN 62133	Same

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

The subject device and predicate device have different mode of action, but they both utilize doppler ultrasound. The subject device has the same mode of action (pulsed-wave Doppler) as another cleared handheld fetal doppler (K172780) and passed the same performance testing as the predicate device.

The subject device and predicate device have different ultrasound frequencies, but the ultrasound frequencies of subject device (2.5MHz) are included in the scope ultrasound frequencies of the predicate device (2.0 MHz and 3.0 MHz).

The subject and predicate device have different acoustic output and FHR measuring range, but both meet FDA recommendations for acoustic output (I_{SATA}: <20 mW/cm^2).

The subject and predicate device also have different patient contacting materials; the patient

contacting materials of the predicate device passed testing for the recommended biocompatibility endpoints per ISO 10993 standards (cytotoxicity, sensitization, irritation) and the subject device met Attachment G recommendations per the 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" (issued September 2023).

The technological differences do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the subject device met all design specifications and to support device safety and effectiveness. The test results demonstrated that the subject device complies with the following standards:

- AAMI/ANSI/ES 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- Acoustic output testing per the 2019 FDA guidance *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*
  - 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;
- IEC 62133-2 Edition1.0 2017-02 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 - Part 2: Lithium systems
- This device meets the recommendations of Attachment G of the 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" (issued September 2023). Therefore, this device is considered biocompatible.
- IEC 62359: 2017 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- Software verification and validation documentation consistent with a Basic level of documentation per the 2023 FDA guidance Content of Premarket Submissions for Device Software Functions (fda.gov)

In addition, the following performance testing was performed on the subject device:

- Use Life testing
- Battery life testing
- Battery indicator testing

10. Conclusion

The non-clinical performance testing described above demonstrates that the device is as safe and effective as the predicate device (K220245) and supports a determination of substantial equivalence.