September 28, 2022

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.,
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Beijing, Beijing 102401
China

Re: K220245
Trade/Device Name: Pocket Fetal Doppler (Models CONTEC10C and CONTEC10CL)
Regulation Number: 21 CFR§ 884.2660
Regulation Name: Fetal Ultrasonic Monitor and Accessories
Regulatory Class: II
Product Code: KNG
Dated: August 24, 2022
Received: August 24, 2022

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 (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)*
K220245

Device Name
Pocket Fetal Doppler (Models CONTEC10C and CONTEC10CL)

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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The assigned 510(k) Number: K220245

Tab #4 510(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: September 27, 2022

2. 510(k) Owner

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Subject Device

Trade Name: Pocket Fetal Doppler (Models CONTEC10C and CONTEC10CL)
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
Review Panel: Obstetrics/Gynecology

5. Predicate Device

510(k) Number: K182526
Product Name: Fetal Doppler
Manufacturer: Vcomin Technology Limited

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

Device Description:

The Pocket Fetal Doppler is a hand-held FHR detection device, it is used for non-invasive measurement and display of the fetal heart rate (FHR) utilizing Doppler ultrasound. The Pocket Fetal Doppler consists of two models (CONTEC10C, CONTEC10CL). Both models have two hand-held components, a main unit and a probe. The device contains components of ultrasonic signal transmitter and receiver, analog signals processing unit, FHR calculating unit, and LCD display control unit.

The CONTEC10C is powered by three AA batteries, and the ultrasonic signal is continuously transmitted at a frequency of 2.0MHz.

The CONTEC10CL is powered by a 3.7V lithium battery, and the ultrasonic signal is continuously transmitted at a frequency of 3.0MHz.

Indications for use Statement:

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.

6. Substantial Equivalence Discussion

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 1 General Comparison

Item	Subject Device	Predicate Device K182526
Device name	Pocket Fetal Doppler	Fetal Doppler
Classification Regulation	21 CFR 884.2660	21 CFR 884.2660
Classification	II	II
Product Code	KNG	KNG
Regulation Name	Fetal ultrasonic monitor and accessories.	Fetal ultrasonic monitor and accessories.
Indications for use	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.	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.
Intended population	Women with pregnancy at or after 12 weeks	Women with pregnancy at or after 12 weeks
Design	A main unit and a probe. The main unit can display FHR	A main unit and a probe. The main unit can display FHR
Mode of action	Doppler ultrasound, continuous wave	Doppler ultrasound, continuous wave
Ultrasound frequency	2.0 MHz, 3.0 MHz	2.0 MHz, 2.5 MHz, and 3.0 MHz
Performance	-FHR Measuring Range: 50 BPM ~ 240 BPM	-FHR Measuring Range: 50-210 bpm
	-Resolution: 1 BPM	-Resolution: 1 bpm
	Accuracy: ±2 BPM	-Accuracy: ±2 bpm
Acoustic output (statistical maximum limit)	I_{SATA}< 20 mW/cm^2	-2.0MHz – I_{SATA}: 17.24 mW/cm^2 -2.5MHz – I_{SATA}: 18.57 mW/cm^2 -3.0MHz – I_{SATA}: 11.496 mW/cm^2
Patient contact material	ABS, Silica, PVC	ABS, silicone, colorants
Biocompatibility	ISO 10993-5 & ISO 10993-10	ISO 10993-5 & ISO 10993-10
Electrical Safety	IEC 60601-1 and IEC 60601-1-11	ANSI/AAMI ES60601-1

		and IEC 60601-1-11
EMC	IEC 60601-1-2	IEC 60601-1-2
Performance	IEC 60601-2-37	IEC 60601-2-37
Battery	EN 62133	EN 62133

The subject and predicate device have similar indications for use statements and have the same intended use – to detect the fetal heart rate. The subject device and predicate device have different ultrasound frequencies, but the ultrasound frequencies of subject device (2.0 MHz, 3.0 MHz) are included in the ultrasound frequencies of the predicate device (2.0 MHz, 2.5 MHz, and 3.0 MHz). The subject and predicate devices 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 devices also have different patient contacting materials; both the patient contacting materials of subject device and predicate device passed testing for the recommended biocompatibility endpoints per ISO 10993 standards (cytotoxicity, sensitization, irritation). Therefore, these differences do not raise different questions of safety and effectiveness.

7. 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:

- Recommended biocompatibility endpoints per the 2020 FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*
  - ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
  - ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- IEC 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 Compatibility-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

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

- Use Life Testing
- Battery Life Testing
- Battery Indicator Testing

8. Conclusion

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