November 14, 2019

HeraMED Ltd.
% Sheila Hemeon-Heyer, JD, RAC
President and Founder
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 91002

Re: K191110
Trade/Device Name: HeraBEAT™US
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: April 24, 2019
Received: April 26, 2019

Dear Sheila Hemeon-Heyer:

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.
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191110

Device Name

HeraBEAT™ US

Indications for Use *(Describe)*

HeraBEAT™ US is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound. HeraBEAT™ US is indicated for use by medical professionals in clinical or home care settings for singleton pregnancies from 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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**510(k) SUMMARY**
**K191110**

| | |
|---|---|
| **Device Manufacturer:** | HeraMED Ltd.<br>6 Meir Ariel Street<br>Netanya, 4059300, Israel |
| **510(k) Contact:** | Sheila Hemeon-Heyer<br>President and Founder<br>Heyer Regulatory Solutions LLC<br>413-330-8578<br>Sheila@Heyer-Regulatory.com |
| **Date Prepared:** | November 13, 2019 |
| **Name of Device:** | HeraBEAT™ US |
| **Common or Usual Name:** | Fetal Ultrasonic Monitor and Accessories |
| **Classification:** | Product Code: KNG<br>Regulation No: 21 C.F.R. §884.2660<br>Regulatory Class: II<br>Classification Panel: Obstetrics/Gynecology |
| **Predicate Device:** | MD800, cleared under K112911 |

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

**Intended Use / Indications for Use**

HeraBEAT™ US is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound. HeraBEAT™ US is indicated for use by medical professionals in clinical or home care settings for singleton pregnancies from 12 weeks gestation.

**Device Description**

HeraBEAT™ US is a hand-held, battery powered audio Doppler device integrated with 2MHz probe, used for detecting and displaying the fetal heart rate (FHR) and FHR sound. The device uses an optical sensor to distinguish between the FHR and the maternal heart rate (MHR) to eliminate “crosstalk” in the FHR display.

HeraBEAT™ US includes the following components:

- The handheld HeraBEAT™ US device that incorporates an ultrasound transducer, rechargeable battery, and internal microcontroller and Bluetooth Low Energy (BLE) chip for wireless data transfer from the HeraBEAT™ US device to the user’s smartphone.
- The HeraBEAT™ application, which is downloaded from an app store to the user's

smartphone. The HeraBEAT™ application is used to communicate with the HeraBEAT™ US device using wireless BLE. It controls the operation of the device and receives the FHR values for numerical display to the user. It plays the FHR sound and stores the FHR values in a history log.

HeraBEAT™ US is supplied with a battery charger (power supply), two tubes of commercially available Aquasonic 100 Ultrasound Transmission Gel (cleared under K802146), carry case and User Manual.

**Substantial Equivalence Discussion**

| **Device & Predicate Device(s):** | K191110 | K112911 |
|---|---|---|
| General Device Characteristics | | |
| Device Name | HeraBEAT™ US | MD800 |
| Indications for Use | HeraBEAT™ US is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound. HeraBEAT™US is indicated for use by medical professionals in clinical or home care settings for singleton pregnancies from 12 weeks gestation. | The Fetal Doppler is a hand-held, battery powered audio Doppler device used for detecting fetal heart beats. |
| Intended patient population | Pregnant women | Pregnant women |
| Intended device operator | Healthcare professionals | Healthcare professionals |
| Gestational age | 12 weeks | 12 weeks |
| Environment of use | Professional and home healthcare environment | Professional and home healthcare environment |
| FHR measurement method | Doppler ultrasound | Doppler ultrasound |
| Device Features | | |
| Battery/Power Supply | Lithium ion rechargeable battery supplied with charger | 2 AA alkaline batteries, assumed replaceable |
| Display | Smart phone application | LCD |
| Bluetooth | Yes | - |
| Technical Specifications | | |
| Working mode | Continuous wave | Continuous wave |
| Ultrasound nominal frequency | 2 MHz | 2 MHz |
| FHR measuring range | 50-240 bpm | 50-210 bpm |
| Resolution | 1bpm | 1 bpm |
| Accuracy | +/- 2bpm | +/- 2bpm |
| Ingress protection | IP22 | IPX4 |

The HeraBEAT™ US device has the same intended use and similar technological characteristics and principles of operation as the MD800 fetal ultrasonic monitor. Different technological features include the use of Bluetooth technology, different battery/power supply,

different ingress protection, and different display modalities. The technological differences between the HeraBEAT™US device and the predicate device do not raise different questions of safety and effectiveness.

**Non-clinical Performance Data**

Bench Performance Testing

Clinical measurement accuracy was conducted per the acoustic output measurement methodology as recommended in the FDA guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," dated September 9, 2008.

Biocompatibility

HeraBEAT™ US is a surface contact device with a short-term (<24 hours) contact duration with intact skin. Per the recommendations of the 2016 FDA guidance document “Biological Evaluation of Medical Devices - Part 1: Evaluation and testing Within A Risk Management Process,” the following tests were performed:

- Cytotoxicity Test per ISO 10995-5:2009
- Intracutaneous Irritation Test per ISO 10993-10:2010
- Guinea Pig Maximization Sensitization Test per ISO 10993-10:2010

Software Validation

The HeraBEAT™ US software meets the requirements of IEC 62304:2015-06 (ed. 1.1) Medical device software - Software life cycle processes. Software documentation, including software verification and validation testing is in accordance with FDA’s 2005 guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”.

Electrical Safety and EMC Testing

The HeraBEAT™ US device was tested to and found to be in compliance with the following safety tests:

- IEC 60601-1:2005/A1:2012 (ed. 3.1) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 (ed. 2.0) 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 60601-2-37:2015 (ed. 2.1) Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical

diagnostic and monitoring equipment

- IEC 60601-1-2:2014 (ed. 4.0) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- IEC 62471:2006-07 (ed. 1.0) Photobiological safety of lamps and lamp systems. The device was confirmed to meet the EXEMPT category of light emissions.

Use-life testing:

Devices underwent simulated repeated use conditions and were evaluated for key performance and FHR measurement accuracy. The results demonstrated that the subject device can be used for three years under normal use conditions.

RF Wireless Transmission

The HeraBEAT™ US Bluetooth communication between the device and mobile app was subjected to wireless co-existence and quality of service (QoS) testing in accordance with FDA's guidance document, "Radio Frequency Wireless Technology in Medical Devices," August 13, 2013, and was found to be compliant for the device's intended use and indications for use.

**Conclusion**

The results of the performance testing described above demonstrate that the HeraBEAT™ US is as safe and effective as the predicate device and supports a determination of substantial equivalence.