May 29, 2019

Vcomin Technology Limited
% Lucy Yan
Consult
Shenzhen Joyantech Consulting Co., Ltd.
1122#, International Mayor Communication Center
55 Shizhou Zhong Road, Nanshan District
Shenzhen, Guangdong 518100
China

Re: K182526
Trade/Device Name: Fetal Doppler ((Models: FD-231B, FD-231D, FD-640B, FD-640D, FD-200B, FD-200D, FD-591B,and FD-591D)
Regulation Number: 21 CFR§ 884.2660
Regulation Name: Fetal Ultrasonic Monitor and Accessories
Regulatory Class: II
Product Code: KNG
Dated: April 15, 2019
Received: April 29, 2019

Dear Lucy Yan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

Sharon M. Andrews
Assistant Division 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)*
K182526

Device Name
Fetal Doppler (Models: FD-231B, FD-231D, FD-640B, FD-640D, FD-200B, FD-200D, FD-591B,and FD-591D)

Indications for Use *(Describe)*
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.

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
K182526

1. Submitter Information

Manufacturer information	Company Name: Vcomin Technology Limited Company address: 2&3 Fl., No.1, Kangzheng Rd., Buji Town, Shenzhen, Guangdong 518110, P. R. China Contact person: Han JieLin Phone: +86-755-33826016 Fax: +86-755-61658248 E-mail: info@vcomin.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: Room 1122, International Mayors Communication Centre, 55 Shizhou Zhong Rd., Nanshan District, Shenzhen, Guangdong 518000, P. R. China Contact person: Ms. Lucy Yan; Mr. Field Fu E-Mail: lucy@cefda.com; field@cefda.com

2. Date Prepared: May 29, 2019

3. Device Identification

Trade Name	Fetal Doppler (Models: FD-231B, FD-231D, FD-640B, FD-640D, FD-200B, FD-200D, FD-591B, and FD-591D)
Common Name	Fetal Doppler
Regulation name	Fetal Ultrasonic Monitor and Accessories
Regulation Number	21 CFR 884.2660
Product Code	KNG (Monitor, Ultrasonic, Fetal)
Regulatory Class	II

4. Predicate Device

Fetal Doppler (K131457) manufactured by Shenzhen Jumper Medical Equipment Co., Ltd. This predicate has not been subject to any design related recalls.

5. Device Description

The 510(k) covers four series of Fetal Doppler devices, including FD-200, FD-231, FD-591, and FD-640. Each series contains two models, and four series consists of a total of eight individual models (FD-231B, FD-231D, FD-640B, FD-640D, FD-200B, FD-200D, FD-591B, and FD-591D).

The subject devices are used for non-invasive measurement and display of the fetal heart rate (FHR) utilizing Doppler ultrasound. All models have two hand-held components, a main unit and a probe. The main unit consists of the main board, power module, battery, speaker, and LED screen. The probe consists of the ultrasonic transducers for transmission and one for signal reception. The ultrasonic signal is continuously transmitted at a frequency of 2.0, 2.5, or 3.0 MHz, depending on the probe selected. The reflected continuous signal is received, and detected Doppler shift is presented to the user. These devices are intended for use at or after 12 weeks' gestation.

6. Indications for Use

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.

7. Substantial Equivalence Discussion

Devices	Subject devices (K182526)	Predicate device (K131457)
Indications for Use	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.	The fetal doppler JPD-100B is a hand-held, battery powered audio doppler device used for detecting fetal heart beats.
Intended population	Same as the predicate device	Women with pregnancy at or after 12 weeks
Design	Same as the predicate device	A main unit and a probe. The main unit can display FHR
Mode of action	Same as the predicate device	Doppler ultrasound, continuous wave
Ultrasound frequency	2.0 MHz, 2.5 MHz, and 3.0 MHz	2.5 MHz
Performance	- FHR Measuring Range: 50-210 bpm - Resolution: 1 bpm - Accuracy: ±2 bpm	- FHR Measuring Range: 50-230 bpm - Resolution: 1 bpm - Accuracy: ±2 bpm
Acoustic output (statistical maximum limit)	- 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	I_{SATA}: <20 mW/cm^2
Patient contact material	ABS, silicone, colorants	ABS, polypropylene (PP)

Both subject and predicate devices are indicated for detection of fetal heart rate. They also have the same intended patient population. Therefore, the subject and predicate devices have the same intended use.

The subject and predicate devices have the same design and mode of action. They have different acoustic output, but both meet FDA recommendations (I_{SATA}: <20 mW/cm^2). They also have different ultrasound frequency, FHR measuring range, and patient contacting materials. These differences do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate devices:

- Biocompatibility:
  - Cytotoxicity Test per ISO 10995-5:2009
  - Skin Irritation Test per ISO 10993-10:2010
  - Guinea Pig Maximization Sensitization Test per ISO 10993-10:2010
- Cleaning and disinfection validation testing in accordance with FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued March 17, 2015
- Software verification and validation testing in accordance with FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005
- Electrical safety testing per ANSI/AAMI ES60601-1:2005(R)2012 + A1:2012 and IEC 60601-1-11:2015
- Electromagnetic compatibility (EMC) testing per IEC 60601-1-2:2014
- Ultrasound testing per IEC 60601-2-37:2015
- Battery testing per EN 62133:2013
- Acoustic output testing FDA guidance "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 9, 2008
- Use-life testing:

  In this study, the devices under simulated repeated use conditions were evaluated for pressing-key performance and FHR measurement accuracy. The results demonstrated that the subject device can be used for three years under normal use conditions.

9. Conclusion

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.