March 1, 2019

ShenzZhen Luckcome Technology Inc., Ltd.
Linli He
Regulatory Manager
Floor 6A, 6th Building
Tongfuyu Industrial Park
Nanshan District
Shenzhen, 518055
China

Re: K182710
Trade/Device Name: Fetal Doppler, Model FD88
Regulation Number: 21 CFR§ 884.2660
Regulation Name: Fetal Ultrasonic Monitor and Accessories
Regulatory Class: II
Product Code: KNG
Dated: January 28, 2019
Received: January 31, 2019

Dear Linli He:

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

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K182710

Device Name
Fetal Doppler, Model FD88

Indications for Use (Describe)
The Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound from early gestation. The device should only be used by a trained medical professional in a clinical setting and is not intended for operated by the patient at 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
(K182710)

1. Submitter

Name and Address  ShenZhen Luckcome Technology Inc., Ltd.
Floor 6A, 6th Building
Tongfuyu Industrial Park, Nanshan District
Shenzhen, 518055
P. R. China
Telephone: +86 755-26853526

Contact Person:  Linli He

2. Date Prepared:  February 28, 2019

3. Device Information

Trade Name:  Fetal Doppler, Model FD88
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

Ultrasonic Doppler (Model YM-2T8) (K180419) manufactured by Shenzhen IMDK Medical Technology Co., Ltd. This predicate device has not been subject to any design-related recalls.

5. Device Description

The subject device (model FD88) is a hand-held device for non-invasive measurement and display of the fetal heart rate (FHR) utilizing Doppler ultrasound. It includes two major components: main unit and probe. The main unit consists of the main board, power module, battery, speaker, and LCD screen. The main unit is supplied by a rechargeable 3.7V/500mAh Li-ion battery. The wired probe contains two angled semi-circle ultrasonic crystals, one for transmission and the other for reception. The ultrasonic signal is continuously transmitted (at a frequency of 2.5 MHz), received and presented to the user as numerical display. This device is intended to be used after 12 weeks gestation for singleton by a trained health professional in a clinical setting.

6. Indications for Use

The Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound from early gestation. The device should only be used by a trained medical professional in a clinical setting and is not intended for use by the patient at home.
7. Predicate Device Comparison

<table>
<thead>
<tr>
<th>Devices</th>
<th>Subject device (K182710)</th>
<th>Predicate device (K180419)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The Fetal Doppler is intended to detect fetal heart beats, display fetal heart rate, and play the fetal heart sound from early gestation. The device should only be used by a trained medical professional in a clinical setting and is not intended for use by the patient at home.</td>
<td>The Ultrasonic Doppler uses continuous-wave Doppler to detect fetal heart beats, display fetal heart rate and play the fetal heart sound from early gestation through delivery for singleton pregnancies. The Ultrasonic Doppler is intended for use by trained healthcare professionals only in a clinical setting.</td>
</tr>
<tr>
<td>Intended patients</td>
<td>Same as the predicate device</td>
<td>Women with pregnancy at 12 weeks or onward</td>
</tr>
<tr>
<td>Design</td>
<td>Same as the predicate device</td>
<td>A main unit and a wired probe. The main unit can display the FHR.</td>
</tr>
<tr>
<td>Mode of action</td>
<td>Same as the predicate device</td>
<td>Doppler ultrasound</td>
</tr>
<tr>
<td>Ultrasound frequency</td>
<td>2.5 MHz</td>
<td>2.0 MHz</td>
</tr>
<tr>
<td>Performance</td>
<td>Same as the predicate device</td>
<td>– FHR Measuring Range: 50-210 bpm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– Resolution: 1 bpm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– Accuracy: ±2 bpm</td>
</tr>
<tr>
<td>Acoustic output</td>
<td>Same as the predicate device</td>
<td>$I_{SATA}$: &lt;20 mW/cm²</td>
</tr>
<tr>
<td>Patient contact material</td>
<td>Acrylonitrile butadiene styrene (ABS), thermoplastic polyurethane (TPU)</td>
<td>Acrylonitrile butadiene styrene (ABS), thermoplastic elastomer (TPE)</td>
</tr>
</tbody>
</table>

Both subject and predicate devices are indicated for detection of fetal heart beats, display of fetal heart rate, and play of the fetal heart sound from early gestation. 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, mode of action, and performance specifications. They have different acoustic output, but both meet FDA requirements ($I_{SATA}$: <20 mW/cm²). They also use different patient contact 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
- Electromagnetic compatibility (EMC) testing per IEC 60601-1-2:2014
- Battery performance testing:
  In this test, battery life, operation time, recharging time and battery status indicator function were evaluated. The test showed that all design specifications were met.
- Ultrasound testing per IEC 60601-2-37:2015
- Acoustic output testing per NEMA UD2 and 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 appearance, deformation, malfunction, fetal heart rate measurement range and accuracy of fetal heart rate measurement. The results demonstrated that the subject device can be used for five 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.