K112911

OCT 27 2011

Section III 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 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission:
   Sep 26, 2011

2. Sponsor
   Beijing Choice Electronic Technology Co., Ltd
   No.9 Shuangyuan Road, Badachu Hi-Tich Zone, Shijingshan District, Beijing, China, 100041
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
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   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Fetal Doppler
   Proposed Device Model: MD800
   Classification: II
   Product Code: KNG
   Regulation Number: 21 CFR 884.2660
   Review Panel: Obstetrics/ Gynecology
   Intended Use Statement:

The Fetal Doppler is a hand-held, battery powered audio Doppler device used for detecting fetal heart beats.

5. Predicate Device Identification

510(k) Number: K100626
Product Name: Doppler Fetal Heart Rate Detector
Manufacturer: Shenzhen Biocare Electronics Co., Ltd

6. Device Description

The Fetal Doppler is a hand-held, battery powered audio Doppler device integrated with 2MHz probe for detecting fetal heart beat. The device is normally applied to pregnancy as early as 12 weeks through the principle of ultrasound shift in hospital or homecare environment.

The Fetal Doppler includes the following components: Power supply module, Display module, User interface, Signal collection and process module and Control module

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1 2005+ CORR.1 (2006) + CORR.2 (2007), Medical Electrical Equipment – Part 1: General Requirements for Safety.
IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility – Requirements and Tests
IEC 61266:1994 Ultrasonic- Hand-held probe Doppler fetal heartbeat detectors- Performance requirements and methods of measurement and reporting.
ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.
ISO 10993-10:2010 Standard, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity

8. Substantially Equivalent Conclusion

The proposed device, Fetal Doppler, is determined to be Substantially Equivalent (SE) to the predicate device, Doppler Fetal Heart Rate Detector, K100626, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -- WO66-G609
Silver Spring, MD 20993-0002

Beijing Choice Electronic Technology Co., Ltd.
Ms. Diana Hong
General Manager
MID-Link Consulting Co., Ltd.
P.O. Box 237-023
Shanghai, 200237
CHINA

OCT 27 2011

Re: K112911
Trade/Device Name: Fetal Doppler
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: September 30, 2011
Received: October 3, 2011

Dear Ms. Hong:

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. 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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section II Indications for Use

510(k) Number:
Device Name: Fetal Doppler

Indications for Use:

The Fetal Doppler is a hand-held, battery powered audio Doppler device used for detecting fetal heart beats.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K112911