JAN 24 2014

VOL 05 510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

5.1 Administrative Information

Date of Summary prepared	May, 09, 2013
Manufacturer information	Company title: Shenzhen Jumper Medical Equipment Co., Ltd. Company address: 5th Floor, Building No.34, Baoyuan Industrial Zone, Xixiang Street, Baoan District, Shenzhen 518102, P.R. China. Phone: +86-755-2669 2192 Fax: +86-755-2685 2025 Contact Person: E-mail: info@jumper-medical.com
Submission Correspondent	Shenzhen ZYTC Consulting Co., Ltd. 4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District, Shenzhen, Guangdong, China. Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com
Establishment registration number	3008973759

5.2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Fetal doppler
Model:	JPD-100B
Classification name:	Monitor, ultrasonic, fetal
Review Panel:	Obstetrics/Gynecology
Product Code:	KNG

Device Class:	II
Regulation Number:	884.2660

5.3 Predicate Device Information

Sponsor:	Beijing Choice Electronic Technology Co., Ltd.
Device:	Fetal Doppler MD800
510(K) Number:	K112911

5.4 Device Description

JPD-100B Fetal Doppler is device prescribed by a licensed physician for use in hospitals and the homecare environment. It is a hand-held, battery powered audio Doppler device integrated with 2.5 MHz probe, used for detecting fetal heart beats. And the device is for prescription use and is intended for use at or after 12 weeks gestation.

5.5 Intended Use

The device is ultrasonic fetal heart beat detector, which can detect the Fetal Heart Rate. The built in speaker of the device allows for listening of the fetal heartbeat. It can display values of fetal heart rate.

5.6 Indications for Use:

The Fetal Doppler JPD-100B is a hand-held, battery powered audio Doppler device used for detecting fetal heart beats.

5.7 Technological characteristics of the proposed device compared to the predicate device

The proposed device and the Predicate device have the same intended use, design principle, and similar material composition. The differences do not exert adverse effect on the proposed device. An itemized comparison between the proposed device and the cited predicate devices demonstrates that the proposed device is substantially equivalent to the predicate devices. The differences and/or similarities are as follow:

1) In terms of intended use, differences in wording are minor and do not impact the equivalence of the statements;

2) Energy used: the predicate is powered by alkaline batteries, and the subject device is powered by Ni-HM rechargeable batteries, the differences in battery type do not have a significant impact on device operation;

3) The working frequency of transducer:
   - 2MHz for the predicate device
   - 2.5MHz for the subject,
   - 3MHz another model on the market, JPD-100S fetal Doppler (Shenzhen Jumper, K110124) ,

2.5MHz falls in the range of 2MHZ to 3MHz, thus, it is believed to be similar to products on the market;

4) Materials:
   - patient contact materials of predicate are unknown,
   - materials for subject device are either
     - the same as the aforementioned Doppler JPD-100S, K110124 (for ABS),
     - Complied with ISO 10993-5 and -10. (for PP);

5) Acoustic output: The output is different, but the value of both the predicate and the subject are less than 20 mW/cm^2, complies with sub-section 2.1.2 of FDA Guidance--- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

5.8 Brief discussion of the nonclinical tests

JPD-100B Fetal Doppler conforms to the following standards:

- ✧ IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, 2005, CORR.1:2006 + CORR.2: 2007;
- ✧ IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – 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 10993-1:2009 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.

5.9 Brief discussion of clinical tests

Not applicable.

5.10 Other information (such as required by FDA guidance)

No other information.

5.11 Conclusions

The subject device JPD-100B Fetal Doppler is substantially equivalent to MD800 Fetal Doppler whose 510(k) number is K112911.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 24, 2014

Shenzhen Jumper Medical Equipment Co., Ltd.
% Field Fu
Shenzhen ZYTC Consulting Co., Ltd.
4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District
Shenzhen, Guangdong 518052
China

Re: K131457
Trade/Device Name: Fetal Doppler JPD-100B
Regulation Number: 21 CFR§ 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: December 6, 2013
Received: December 23, 2013

Dear Field Fu,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -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

VOL 04 Indications for Use

510(k) Number (if known): K131457

Device Name: Fetal Doppler JPD-100B

Indications for Use:
The Fetal Doppler JPD-100B is a hand-held, battery powered audio Doppler device used for detecting fetal heart beats.

Prescription Use ☒ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Diagnostic Ultrasound Indications For Use

Device Name: Fetal Doppler JPD-100B
Transducer: 2.5MHz CW inherent of the main unit
Intended Use: Detect fetal heart beats as follows:

Clinical Application		Mode of Operation						
General (Track 1	Specific (Tracks 1 &	B	M	PWD	CWD	Color Dopple	Combine d	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal				N			
Cardiac	Cardiac							
Peripheral Vessel	Peripheral							
	Peripheral							

Note: N = new indication; P = previously cleared by FDA; E = added under appendix E

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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