K110124

Attachment II 510(k) Summary

As Required by CFR 870.92

FEB - 4 2011

Preparing Date	November 23, 2010
Sponsor	Shenzhen Jumper Medical Equipment Co., Ltd 5th Floor, Building No.34, Baoyuan Industrial Zone, Xixiang Street, Baoan District, Shenzhen, Guangdong 518067, P.R. China Boley He Quality Manager Tel: +86-755-2669 6279 Fax: +86-755-2685 2678 Email: rd@jumper-medical.com
Submission Correspondent	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd P.O. BOX 237-023 Shanghai, 200237, China Tel: +86-21-64264467 Fax: 240-238-7587 Email: diana.hong@mid-link.net
Proposed Product	
Trade Name	Fetal Doppler
Model	JPD-100S
Product Code:	KNG
Regulation Number:	21 CFR 884.2660
Device Class:	Class II
Submission Purpose:	New Device
Submission Type	Traditional 510(k)
Predicate Device:	
Device Name	Contec Pocket Fetal Doppler Baby Sound A
K Number	K082480
Manufacturer	Contec Medical Systems Co., LTD
Intended Use	The Fetal Doppler JPD-100S is a hand-held, battery powered audio

	Doppler device used for detecting fetal heart beats.
Device Description	JPD-100S Fetal Doppler is a prescription from licensed physician in hospitals, clinics and private offices. It is a hand-held, battery powered audio Doppler device integrated with 3MHz probe, used for detecting fetal heart beats. And the device is normally applied to pregnancy for more than twelve weeks.
Test Conclusion	Laboratory testing was conducted to validate and verify that the proposed devices met all design specifications, including electrical safety, EMC, specification per following standards. IEC60601-1(1988; Amendment 1, 1991-11, Amendment 2, 1995): Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC60601-1-2 (2001): Medical electrical equipment - Part 1-2: General requirements for basic 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 10993-5 (2009): Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity ISO 10993-10 (2002; Amd. 1:2006): Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity Results of these tests demonstrate compliance to the requirements of all consensus standards.
Comparison Summary	The proposed device shares same classification, intended use, similar technical specifications, same safety specifications and skin-contact material with the predicate device. The main difference includes battery, operation and storage conditions, transducer frequency and /sata, but the difference is considered to have no effect on effectiveness and safe. The SE analysis of the difference is provided as following. The batteries of proposed and predicate device are different. But both of them comply with the requirements of electrical safety and EMC of IEC 60601-1 and IEC 60601-1-2. Therefore, this diference is

	considered has no effect on effectiveness and safety. The operation and storage conditions of the proposed device have slight differences with those of the predicate device. But these conditions are considered to be able to cover the normal working and storage environment. In addition, these conditions are clearly on the proposed labeling, to remind the user handle and operate with these conditions. Therefore, this difference is considered to have no effect on effectiveness and safe. The transducer frequency of proposed device and predicate device is different. But the proposed transducer was tested for its acoustic output, and the result demonstrates that it complies with the standard criteria. In addition, 3MHz transducer of fetal doppler is very common in clinical use, such as, 3MHz normal transducer of Contec Pocket Fetal Doppler SONOLINE A and SONOLINE B (**k082480**). Therefore, this difference is considered to have no effect on effectiveness and safe. The *I*sata of proposed device and predicate device is different. But the proposed transducer was tested for its acoustic output, and the result demonstrates that it complies with the standard criteria. In addition, transducer of fetal doppler with *I*sata <5 mW/cm^2 is very common in clinical use, such as, CMS-150-T2 and CMS-150-T5 transducer of Contec Pocket Fetal Doppler SONOLINE A and SONOLINE B (**k082480**). Therefore, this difference is considered to have no effect on effectiveness and safe.
SE Determination	The proposed device, Fetal Doppler JPD-100S, is substantially equivalent (SE) to the predicate device Contec Pocket Fetal Doppler Baby Sound A (K082480).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Shenzhen Jumper Medical Equipment Co., Ltd
% Mr. Marc M. Mouser
Engineering Leader/FDA Office Coordinator
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

FEB - 4 2011

Re: K110124
Trade/Device Name: Fetal Doppler JPD-100s
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasound monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: December 17, 2010
Received: January 18, 2011

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Fetal Doppler JPD-100s, as described in your premarket notification:

Transducer Model Number

3.0MHz CW

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

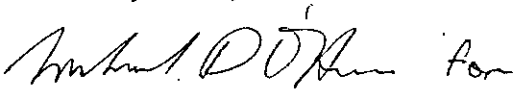
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 market.

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.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours,



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

Enclosure(s)

Section II **Indications for Use Statement**

510(k) Number: _____

Device Name: Fetal Doppler JPD-100S

Indications for Use:

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

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

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

_____
(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K110124

Diagnostic Ultrasound Indications for Use Form

Device Name: Fetal Doppler JPD-100S

Transducer: 3.0MHz CW inherent of the main unit

Intended Use: Detect fetal heart beats as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal				N			
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E Comments:

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110624