510(K) SUMMARY

This summary of 5 10(k) safety a nd ef fectiveness information is be ing s ubmitted i n accordance with 21 CFD part 807.92.

The assigned 510(k) number is: K090510

APR 2 9 2010

1. Submitter's name, address, phone number, contact person and preparation data:

Name: Shenzhen Bestman Instrument Co., Ltd.

Address: 4/F, Block 210, 2nd Industrial Area of Nanyou, Xiangnan Rd., Nanshan Dist., Shenzhen, P.R.China
Phone: 86-755-26713783/26713784
Fax: 86-755-26495167/26713783
Contact Person: Bai Yong

- **Official correspondent:**

Bai Yong
General Manager
Shenzhen Bestman Instrument Co., Ltd.
Address: 4/F, Block 210, 2nd Industrial Area of Nanyou, Xiangnan Rd., Nanshan Dist., Shenzhen, P.R.China
Tel: 86-755-26713783/26713784
Fax: 86-755-26495167/26713783
Email: bestm@public.szptt.net.cn

- **Date of Preparation:** April 27, 2010

2. Device:

- **Proprietary Name: Doppler fetal heartbeat rate detector**
- **Common Name: Ultrasonic Fetal Monitor**
- **Classification Name: Fetal Ultrasonic Monitor and Accessories**
- **Product Code: KNG**

- **Manufactured By: Shenzhen Bestman Instrument Co., Ltd., China**

3. Predicate Device:

K040480 SONOTRAX

4. Classification Names:

Class II as per 21CFR 884-2660, Ultrasonic Fetal Monitor and accessories.

5. Description:

Doppler fetal heartbeat rate detector uses Doppler principle of ultrasound signal to detect the fetal heart rate. Doppler fetal heartbeat rate detector uses a split D piezoelectric transducer. A high frequency oscillator supplies a continuous high frequency voltage to one half of the split D transmitter transducer. The high frequency voltage is converted to an ultrasound acoustic wave by the transducer and is transmitted to biophysical objects through an applied coupling water based medium and moves through biophysical objects. The acoustic ultrasound is reflected by body and moving objects such as the fetal heart. The reflected ultrasound is received by the second split D receiver transducer and is converted via the piezoelectric effect into a high frequency electronic signal. The received electronic signal is amplified and detected. The result is a base band audio Doppler shifted signal which is filtered and converted to audio via a loudspeaker. At the same time the fetal heart rate is displayed on a liquid crystal arithmometer display.

6. Indications for use:

This Doppler can be used for the detection of average fetal heartbeat rate.
Models List Form: (Please see the attached "Diagnostic Ultrasound Indications For Use Format" forms for detail.)

Series	Models	Attached Transducers
1	BF-500B	CW20 (fc=2.0MHz)
2	BF-500+	CW25 (fc=2.5MHz)
	BF-500++	

7. Contra-indications:

Not be discovered till now.

8. Comparison to Predicate Devices:

Doppler fetal heartbeat rate detector has the same device characteristics as the above predicate approved device.

9. Test Data:

Doppler fetal heartbeat rate detector has been subjected to extensive safety, performance test and validations before release. Final test of the Doppler fetal heartbeat rate detector includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the devices comply with applicable industry and safety standards. Doppler fetal heartbeat rate detector includes instructions for safe and effective use, warnings, cautions and guidance for use.

10. Literature Review:

A review of the literature pertaining to the safety of fetal Doppler has been conducted and appropriate safeguards have been incorporated in the design of the Doppler fetal heartbeat rate detector.

11. Conclusion:

The conclusions drawn from the test of the Doppler fetal heartbeat rate detector demonstrates that the device is substantially equivalent to the predicate device.

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

Shenzhen Bestman Instrument Co., Ltd
% Mr. Marc M. Mouser
Manager/FDA Office Coordinator
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

APR 29 2010

Re: K090510
Trade/Device Name: Doppler fetal heartbeat detector
Models: BF-500B, BF-500+, and BF500++
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: April 2, 2010
Received: April 8, 2010

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 Doppler fetal heartbeat detector - Models: BF-500B, BF-500+, and BF500++as described in your premarket notification:

Transducer Model Number

Model BF-500+ & BF-500++
CW25

Model BF-500B
CW20

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 Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K090510

Device Name: **Doppler fetal heartbeat rate detector**

Indications for Use:

This Doppler can be used for the detection of average fetal heartbeat rate.

Models List Form:

Series	Models	Attached Transducers
1	BF-500B	CW20 (fc=2.0MHz)
2	BF-500+	CW25 (fc=2.5MHz)
	BF-500++	

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

Robert A Becker

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

510(k) Number K090510

Diagnostic Ultrasound Indications For Use Format

System: X
Transducer:
Model: BF-500B
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 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 this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Robert J Beckey
K090510

Diagnostic Ultrasound Indications For Use Format

System: X
Transducer: _____
Model: BF-500+
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 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 this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Robert A Becker
K090510

Diagnostic Ultrasound Indications For Use Format

System: X
Transducer: _____
Model: BF-500++
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 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 this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Robert Reeder
K090510

Diagnostic Ultrasound Indications For Use Format

System: _____
Transducer: _____X_____
Model: CW25(This probe applies to BF-500+ & BF-500++ Model)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 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 this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

K090510

Diagnostic Ultrasound Indications For Use Format

System: _____

Transducer: _____X_____

Model: CW20(This probe applies to BF-500B Model)_____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 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 this appendix

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

Robert Becker
K090510