JUN 24 2011

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Submitter

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Company Contact: Amy M.H. Kim
Date Summary Prepared: October 26, 2010

Device Name

Trade Name:	F10 Fetal Doppler
Common Name:	Monitor, Ultrasonic, Fetal
Classification Name:	Monitor, Ultrasonic, Fetal (21CFR 884.2660, KNG)
Classification:	Class 2

Predicate Device (Legally Marketed Devices)

The predicate devices for Fetal Doppler, Model F10 are:

- Edan Instruments, Inc. Ultrasonic Pocket Doppler, Sonotrax
  cleared by FDA through 510(k) No. K040480 (Decision Date - May. 25. 2004), and
- Bistos Co., Ltd. Ultrasonic Pocket Doppler, BT-200
  cleared by FDA through 510(k) No. K05219 (Decision Date - Oct. 4. 2005)

Device Description

F10 is a pocket-size fetal Doppler that measures the fetal heat rate and outputs the fetal heart sound through built-in speaker. By measuring fetal heart rate(FHR), you are able to predict fetal well-being. F10 irradiates fetal wave to the abdomen of a pregnant woman to detect the Doppler frequency signal and analyze, and displays the heart rate on LCD screen. The device also provides the heart sound from the heart of fetus

Indications for Use

The F10 Fetal Doppler measures heart rate, which is displayed on a LCD display and provides fetal heart sounds. The fetal heart rate is measured using Doppler ultrasound.

Comparison with predicate device

Mediana Co., Ltd. believes that the F10 Fetal Doppler is substantially equivalent to the Sonotrax of Edan Instruments, Inc. and BT-200 of Bistos Co., Ltd.

The F10 Fetal Monitors described in this 510(k) submissions has the same intended use and similar technical characteristics as the Sonotrax of Edan Instruments, Inc., and the BT-200 of Bistos Co., Ltd..

- The similarities are as below;

'Mode of operation', 'System characteristics', 'FHR Monitoring', 'Transducer Type', 'Ultrasound Frequency', 'FHR Detection Method', 'FHR Range', 'Display method', and 'Intended use', etc.

- The differences are as below;

'Ultrasound Frequency' – Ultrasound frequency has a little difference. But there is not a difference to basic function.

'Battery type, voltage and life' – Battery type, voltage and life have a little difference. But it has not effect on efficiency, effectiveness and safety.

Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Mediana Co., Ltd. concludes that F10 are safe and effective and substantially equivalent to predicate devices as described herein.

Mediana Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mediana Co., LTD.
% Mr. Marc M. Mouser
Engineering Leader & FDA Office
Coordinator, Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

JUN 24 2011

Re: K110630
Trade Name: F-10 Fetal Doppler
Regulation Number: 21 CFR §884.2660
Regulation Name: Fetal Ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: June 16, 2011
Received: June 16, 2011

Dear Mr. Mouser:

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, M.D., Director (Acting)
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): K110630

Device Name: F10 Fetal Doppler

Indications for Use:

The F10 Fetal Doppler measures heart rate, which is displayed on a LCD display and provides fetal heart sounds. The fetal heart rate is measured using Doppler ultrasound.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110630

F10 Fetal Doppler
510(k) Submission

K110630

Appendix F

Diagnostic Ultrasound Indications For Use Form

Fill out one form for each ultrasound system and each transducer.

2MHz PW DOPPLER FETAL PROBE – MODEL : F10
Intended use : Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (Specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Pheperial Vascular										
Lapaloscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments :

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110630