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:	FM20
Common Name:	System, Monitoring, Perinatal
Classification Name:	System, Monitoring, Perinatal (21CFR 884.2740, HGM,)
Classification:	Class 2

Predicate Device (Legally Marketed Devices)

The predicate devices for Fetal Doppler, Model FM20 are:

- Biosys Co., Ltd. Ultrasonic fetal Monitor, IFM-500
  cleared by FDA through 510(k) No. K994008 (Decision Date - Sep. 29. 2000), and
- Bistos Co., Ltd. Ultrasonic Fetal Monitor, BT-300
  cleared by FDA through 510(k) No. K05219 (Decision Date - Oct. 4. 2005)

Device Description

FM20 is the fetal monitor that measures uterine contractions and fetal heart rate (FHR) which may be used to predict fetal status. To detect the Doppler frequency signal reflected from the heart of the fetus, FM20 irradiates ultrasound wave to the abdomen of a pregnant woman. FM20 analyzes this signal and displays the heart rate by LCD. Also, FM20 provides the sound from the heart of fetus.

FM20 measures the uterine contraction of a pregnant woman by pressure sensors and

displays the numerical values.

And FM20 prints the heart rate of the fetus and the values of uterine contraction.

- FM20 records the heart rate of the fetus, the uterine contraction of a pregnant woman, and basic information of the equipment with a provided thermal printer.
- FM20 is capable of Twin Monitoring with two pulsed Ultrasound Transducers.
- FM20 has a free voltage(100 – 240VAC input) power adaptor.
- FM20 has Fetal movement detection function. To extract fetal movement signal, FM20 uses a circuit and digital filter.
- FM20 has Event marker function so that the patient can record the time of important events.
- FM20 has the capability to alert the caregiver in the event a heart rate goes above or below limit for a preset time delay.

Indications for Use

The FM20 is a Fetal Monitor for measuring and recording maternal contraction and fetal heart rate. Data is displayed on a front panel LCD(7") Display, recorded on a strip chart recorder. Single/Twin fetal heart rates may be measured by means of Doppler Ultrasound. Uterine Activity is measured with an external TOCO transducer. The FM20 is intended to be used during the antepartum periods on pregnant woman.

Summary of Indications and Technical characteristics of the Device compared to the Predicate Device (Legally Marketed Devices)

The Mediana Fetal Doppler, Model FM20 is substantially equivalent to the Bistos Co.,Ltd. Model BT-300, and BiOSYS Co.,Ltd, Model IFM-500.

- **Indications**

  The intended use and indications are equivalent to the Bistos Co.,Ltd. Model BT-300, and BiOSYS Co.,Ltd, Model IFM-500. The mode of operation(Ultrasound mode, Uterine Contraction), System characteristics(Portable, Strip chart recorder, Power sources) of Mediana Model FM20 is same as those of the Bistos Co.,Ltd. Model BT-300, and BiOSYS Co.,Ltd, Model IFM-500.

- **Technical characteristics**

  The specifications and performances(FHR monitoring, UC monitoring, Transducer type, ultrasound frequency, FHR range, FHR accuracy, Detection of fetal movement via ultrasound transducer) of Mediana Model FM20 are

equivalent to the Bistos Co.,Ltd. Model BT-300, and BiOSYS Co.,Ltd, Model IFM-500.

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 FM20 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.

End of Section

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

NOV - 8 2011

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

Re: K110612
Trade/Device Name: FM20 Fetal Monitor
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: October 7, 2011
Received: October 24, 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): K110612

Device Name: FM20 Fetal Monitor

Indications for Use:

The FM20 is a Fetal Monitor for measuring and recording maternal contraction and fetal heart rate. Data is displayed on a front panel LCD(7") Display, recorded on a strip chart recorder and may be transmitted over RS232 port to a remote data receiver. Single/Twin fetal heart rates may be measured by means of Doppler Ultrasound. Uterine Activity is measured with an external TOCO transducer.

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110612

FM20 Fetal Monitor
510(k) Submission

Appendix F

Diagnostic Ultrasound Indications For Use Form

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

1MHz PW DOPPLER FETAL PROBE – MODEL : FM20
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				P						
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(Part 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110612