OCT 4 - 2005 K052190

510(k) Summary

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

Date: Jun 10, 2005

1. Company and Correspondent making the submission:

Name – Bistos Co., Ltd.
Address – 201, 2F, 239-15, Gasan-Dong, Geumcheon-Gu, Seoul, 153-801, Korea
Telephone – +82-2-862-0642
Fax – +82-2-862-0644
Contact – Mr. Seong Soo Hong
Internet – http://www.bistos.co.kr

2. Device :

Trade/proprietary name	: BT-300, BT-200 Fetal Monitor
Common Name	: Fetal Monitor
Classification Name	: System, monitoring, perinatal

3. Predicate Devices :

Manufacturer	: BiOSYS Co., Ltd.
Device	: IFM-500 Ultrasound Fetal Monitor
510(k) Number	: K994008(Decision Date - Sep. 29. 2000)
Manufacturer	: Edan Instruments, Inc.
Device	: Sonotrax Ultrasonic Pocket Doppler
510(k) Number	: K040480(Decision Date - May. 25. 2004)

4. Classifications Names & Citations :

21CFR 884.2740, HGM, System, Monitoring, Perinatal, Class2

5. Description :

- BT-300 is the fetal monitor that measures the fetal heart rate(FHR) which may be evaluated to predict fetal status and uterine contraction. BT-300 irradiates ultrasound

wave to the abdomen of a pregnant woman, and detects the Doppler frequency signal reflected from the heart of the fetus. BT-300 analyzes this signal and displays the heart rate by LED. Also, BT-300 provides the sound from the heart of fetus.

BT-300 measures the uterine contraction of a pregnant woman by pressure sensors and displays the numerical values.

And BT-300 prints the heart rate of the fetus and the values of uterine contraction.

- BT-300 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.
- BT-300 is capable of Twin Monitoring with two pulsed Ultrasound Transducers.
- BT-300 has a free voltage(100 – 240VAC input) power adaptor.

- BT-200 is a pocket-size fetal Monitor 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. BT-200 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.

6. Indication for use :

- The BT-300 is an Fetal Monitor for measuring and recording maternal contraction and fetal heart rate. Data is displayed on a front panel 7-segment LED Display, recorded on a strip chart recorder and may be transmitted over telephone lines 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.

- The BT200 is a Fetal Monitor for measuring fetal heart rate. Data is displayed on a front panel LCD Display. Fetal heart rate may be measured by means of Doppler Ultrasound.

7. Comparison with predicate device :

Bistos Co., Ltd., believes that the BT-300 and the BT-200 Fetal Monitor are substantially equivalent to the IFM-500 of BiOSYS Co., Ltd. And Sonotrax of Edan Instruments, Inc..

8. 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.

9. 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 Bistos Co., Ltd. concludes that BT-300 and BT-200 are safe and effective and substantially equivalent to predicate devices as described herein.

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

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2005

Bistos Co., Ltd.
% Mr. Marc M. Mouser
Officer Coordinator
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K052190
Trade Name: BT-300, BT-200 Fetal Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Product Code: HGM
Regulation Number: 21 CFR 884.2960
Regulation Name: Obstetric Ultrasonic Transducer
Product Code: HGL
Regulatory Class: II
Dated: September 16, 2005
Received: September 19, 2005

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 BT-300, BT-200 Fetal Monitor, as described in your premarket notification:

Transducer Model Number

BT-300
BT-200

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 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); 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 contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Colin Pollard at (301) 594-1180.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

Indications for Use

510(k) Number(~~if known~~): K052190

Device Name: BT-300, BT-200 Fetal Monitor

Indications for Use:

The BT-300 Fetal Monitor for measuring and recording maternal contraction and fetal heart rate. Data is displayed on a front panel 7-segment LED Display, recorded on a strip chart recorder and may be transmitted over telephone lines 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.

The BT200 is a Fetal Monitor for measuring fetal heart rate. Data is displayed on a front panel LCD Display. Fetal heart rate may be measured by means of Doppler Ultrasound.

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____

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

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

David G. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052190

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 : BT-200
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)

David A. Legan

(Division Sogn-Off)
Division of Reproductive, Abdominal,
And Radiological Devices
510(k) Number K052190

Prescription Use(Per 21 CFR 801.109)

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 : BT-300
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 :

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Prescription Use(Per 21 CFR 801.109)