510(k) Summary

MAY 13 2011

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

Date: Dec. 1, 2009

1. Company and Correspondent making the submission:

Name – Bistos Co., Ltd.
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448, Gasan-dong, Geumcheon-gu, Seoul, 153-772, Rep. of KOREA
Telephone – +82-2-2108-4626
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Contact – Mr. Hyung-Ju Oh
E-mail : duckcy@bistos.co.kr
Internet – http://www.bistos.co.kr

2. Device :

Trade/proprietary name	: BT-350 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)

4. Classifications Names & Citations :

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

5. Description :

- BT-350 is the fetal monitor that measures the fetal heart rate(FHR) and uterine contraction. Using these parameters, the medical team can monitor fetal status and check uterine contraction degree. BT-350 irradiates ultrasound wave to the abdomen of a pregnant woman, and detects the Doppler frequency signal reflected from the heart of the fetus. BT-350 analyzes this signal and displays the heart rate by LCD or LED(7-

Segment). Also, BT-350 provides the sound from the heart of fetus.

BT-350 measures the uterine contraction of a pregnant woman by pressure sensors and displays the numerical values.

And BT-350 prints the heart rate of the fetus and the values of uterine contraction.

- BT-350 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-350 is capable of Twin Monitoring with two pulsed Ultrasound Transducers.
- BT-350 has a free voltage(100 – 240VAC input) power adaptor.

6. Indication for use :

- The BT-350 is a Prenatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and on a strip chart recorder. This data is intended to aid in assessing the well being of the fetus during the antepatum periods(Non-Stress Test). Therefore the BT-350 is not used in delivery room. This device is for use only by trained medical personnel located in hospitals, clinics, doctor's offices and in the patient's home.

7. Comparison with predicate device :

Bistos Co., Ltd., believes that the BT-350 Fetal Monitor are substantially equivalent to the IFM-500 of Biosys Co., Ltd.

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-350 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bistos Co., Ltd.
c/o Mr. Steve Kohn
Healthcheck Systems, Inc.
4802 Glenwood Road
BROOKLYN NY 11234

MAY 13 2011

Re: K103545
Trade Name: Model BT-350 Fetal Monitor
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM and HGL
Dated: May 6, 2011
Received: May 6, 2011

Dear Mr. Kohn:

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-350 Fetal Monitor, as described in your premarket notification:

Transducer Model Number

1MHz PW Doppler Fetal Probe – Model BT-350

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.

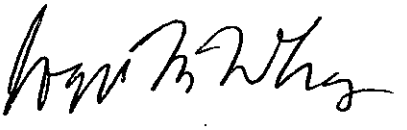
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Kathryn Daws-Kopp at (301) 796-6535.

Sincerely yours,



Herbert P. Lerner, MD, Director (Acting)
Division of Reproductive, Gastro-Renal, and
Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number(if known) : K103545

Device Name : BT-350 Fetal Monitor

Indications for Use :

The BT-350 is a Prenatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and on a strip chart recorder. This data is intended to aid in assessing the well being of the fetus during the antepatum periods(Non-Stress Test.) Therefore the Bt-350 is not used in delivery room. This device is for use only by trained medical personnel located in hospitals, clinics, doctor's offices and in the patient's home.

Prescription Use ___V___ AND/OR Over-The-Counter Use_____

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

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103545

Diagnostic Ultrasound Indications For Use Form

System: Model BT-350 Fetal Monitor
Transducer: 1MHz PW Doppler Fetal Probe – Model BT-350

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			P				
	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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number: K103545