DEC 16 2005

K043597

510(k) Summary

(As required by 21 CFR 807.92(c))

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CONTACT PERSON	(NAME)	Hyun-Joo Kwon
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US AGENT	(NAME)	Mr. Steven Minn
	(ADDRESS)	BIONET AMERICA, INC.
		3345 Wilshire Blvd., Suite 811
		Los Angeles, CA 90010
	(PHONE)	888-292-6060
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DATE OF SUMMARY	December 24, 2004	
DEVICE NAME	(Proprietary Name)	FC-700
	(Common Name)	FC-700
	(Classification Name)	Perinatal monitoring system and accessories
	(Regulation Number)	21 CFR §884.2740
	(Regulatory Class)	II
	(Product Code)	HGM
PREDICATE DEVICES	(510(k) Number)	K991905
	(Device Name)	COROMETRICS MODEL 171 AND 172 FETAL MONITOR
	(Submitter by)	GENERAL ELECTRIC MEDICAL SYSTEMS INFORMATION

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DEVICE DESCRIPTION

FC-700 is the fetal monitor that measures the fetal heart rate and uterine contraction.
FC-700 irradiates ultrasound wave to the abdomen of a pregnant woman and detects the Doppler frequency signal reflected from the heart of the fetus. FC-700 analyzes detected signal and displays the numerical values of the fetal heart rate by LED.
FC-700 measures the uterine contraction values of a pregnant woman by pressure sensors, analyzes measured value and displays the numerical values of the uterine contraction by LED.
FC-700 provides the sound from the heart of fetus.
And FC-700 prints graphically the heart rate of the fetus and the values of uterine contraction.

INTENDED USE

FC-700 is the fetal monitor that measures, displays numerical value of measured results by LED, prints graphically the fetal heart rate and uterine contraction of a pregnant woman, and also provides the sound from the heart of fetus. It is intended to aid comprehensive assessment for the well being of single fetus.
It intended to be used by trained healthcare personnel. It is not intended for home use.

COMPARISION OF TECHNOLOGICAL CHARACTERISTICS

Comparison Areas	FC-700	Predicate Device
Indications for use	FC-700 is the fetal monitor that measures, displays numerical value of measured results by LED, prints graphically the fetal heart rate and uterine contraction of a pregnant woman, and also provides fetal movement detection and fetal heart sound. It is intended to aid comprehensive assessment for the well being of single fetus.	Identical
Where used	Used by trained healthcare personnel. It is not intended for home use.	Identical
Performance	Fetal Heart Rate (FHR) Uterine Contraction (UC) Fetal Movement Detection High/Low Heart Rate Alarm Printing Monitoring Results Interface through RS232	Similar
Standard met	-Electrical safety: IEC60601-1 -EMC: IEC60601-1-2) so on. -Biocompatibility: ISO10993	Similar

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NONCLINICAL TESTS	It has tested for electrical safety according to IEC60601-1, electromagnetic compatibility according to IEC60601-1-2 and biocompatibility in accordance with the guidelines of International Organization for Standardization: Biological Evaluation of Medical Devices.
CONCLUSION	FC-700 is substantial equivalent to predicated device COROMETRICS MODEL 171 AND 172 FETAL MONITOR(K991905) of GENERAL ELECTRIC MEDICAL SYSTEMS INFORMATION.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

BioNet/BioNet America, Inc.
% Mr. Sun-Young Jeong
Regulatory Affairs Engineer
Research Institute for Medical Instruments
Medical Industry Techno Tower
R205, 1272 Maeji Heungup
Wonju, Kwangwon-Do
Republic of Korea

Re: K043597
Trade/Device Name: FC 700 Fetal Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: November 22, 2005
Received: November 22, 2005

Dear Mr. Jeong:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT BIONET CO., LTD.

510(k) NUMBER K043597

DEVICE NAME FC-700

INDICATIONS FOR USE

FC-700 is the fetal monitor that measures, displays numerical value of measured results by LED, prints graphically the fetal heart rate and uterine contraction of a pregnant woman, and also provides the sound from the heart of fetus. It is intended to aid comprehensive assessment for the well being of single fetus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)

K043597