K023082

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: BIONET Co., LTD

2-Address: #501, KICOX Venture Center, 188-5,
Guro-Dong, Guro-Gu
Seoul, South Korea

MAR 0 3 2003

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4-Fax: +82 2 6300 6425

5-Contact Person: Dong-Joo Kang, CEO

6-Date summary prepared: September 10th, 2002

7- Official Correspondent: Mansour Consulting LLC

8- Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA

9- Phone: (678) 908-8180

10- Fax: (425) 795-9341

11- Contact person: Jay Mansour, president

12-Device Trade or Proprietary Name: BABYCARE

13-Device Common or usual name: HEP

14-Device Classification Name: MONITOR, BLOOD-FLOW, ULTRASONIC

15-Substantial Equivalency is claimed against the following device:
IMEX's Pocket, 510k #k910462 (refer to Appendix 2 for FDA website printout). This notification for BABYCARE is of the ABBREVIATED type

16-Description of the Device:

BABYCARE is a fetal ultrasonic monitor designed to transmit and receive ultrasonic energy into and from the pregnant woman by means of continuous wave (doppler) echoscopy.

BABYCARE is a compact pocket Doppler, and it is intended for use to display the measured Fetal Heart Rate on LCD and to allow the user to hear a crystal clear Fetal Heart Beat Sound.

Being operated with battery, it allows babies to be checked anywhere, at any time. Using high sensitive and harmless ultrasound sensor, it detects and displays the accurate FHR on the LCD. BABYCARE is especially suitable for routine use in OB/GYN.

Features:

- *Accurate FHR detection & display*
- *Clear sound offered from separate speaker*
- *Cap-shaped speaker for probe protection*
- *Compact size and battery operated*
- *Harmless ultrasound sensor*
- *Easy to use*

Technical Specifications:

- *Display: 3-digit segment*
- *FHR Measuring Range: 50-240 bpm*
- *Measurement Resolution: ± 3bpm*
- *Speaker output power: 1 W*
- *Ultrasound frequency: 2.0 Mhz*
- *Power: 9V battery*
- *Sensitivity: 12 Weeks Fetus*
- *Weight: 290g (without battery)*
- *Standard Accessory: Gel, 9V battery*

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17-Intended use of the device: *(Indications for use typed on a separate FDA form)*
BABYCARE is a fetal ultrasonic monitor designed to transmit and receive ultrasonic energy into and from the pregnant woman by means of continuous wave (doppler) echoscopy.
BABYCARE is a compact pocket Doppler, and it is intended for use to display the measured Fetal Heart Rate on LCD and to allow the user to hear a crystal clear Fetal Heart Beat Sound.

18-Safety and effectiveness of the device:
This device is safe and effective as the predicate device.
This is better expressed in the tabulated comparison (Paragraph 19 below)

19-Summary comparing technological characteristics with other predicate device:
Please find below a tabulated comparison supporting that **BABYCARE** is substantially equivalent to other medical devices in commercial distribution.
Also, Equivalency detailed chart path is attached.

FDA file reference number	510k # K910462
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	*Comparison result*
Indications for use	Identical: Refer to indications for use details within submission
Target population	Identical: Predicate device and our device are used by obstetrician, gynecologist, nurse, midwife.
Design	Similar: Predicate is designed for separable sensor BabyCare is designed for separable speaker
Materials	Similar: Predicate is made of ABS materials. BabyCare is made of ABS and ULTEM(PolyEtherImid) materials.
Performance	Identical: Both predicate and BabyCare, it is possible to measure fetal heart rate after the 12 weeks of pregnancy. output≤ 100mW/cm2 FHR: 50bpm~240bpm
Sterility	Not applicable
Biocompatibility	Not Applicable
Mechanical safety	Similar: A coarse surface and a sharp corner of a device which has cause of patient damage of predicate device and our device are removed and covered. Further technical details: BabyCare is designed to protect weak sensor, so it has separable speaker which can protect sensor.
Chemical safety	Not applicable
Anatomical sites	Not applicable

Human factors	Not applicable
Energy used and/or delivered	Similar: Predicate- NiCad rechargeable battery BabyCare-9V alkaline battery
Compatibility with environment and other devices	Identical: Predicate and BabyCare are suitable for EMI and EMC test.
Where used	Identical: maternity hospital
Standards met	Identical:
Electrical safety	Identical
Thermal safety	Identical
Radiation safety	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 3 2003

Bionet Co., Ltd.
% Mr. Jay Mansour
President
Mansour Consulting, LLC
1308 Morningside Park Drive
ALPHARETTA GA 30022

Re: K023082
Trade/Device Name: BabyCare
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: 85 HEP
Dated: January 7, 2003
Received: January 10, 2003

Dear Mr. Mansour:

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 (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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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

K023082

510(k) Number (if known): K023082

Device Name: BABYCARE

Indications for Use:

BABYCARE is a fetal ultrasonic monitor designed to transmit and receive ultrasonic energy into and from the pregnant woman by means of continuous wave (doppler) echoscopy.

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Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023082

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

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)