K994008 1/4

SEP 2 9 2000

510K SUMMARY

1.0 Manufacturer's Name and Address:

BiOSYS Co., Ltd.
Medison Venture Tower, 997-4, Daechi-dong,
Kangnam-ku, Seoul 135-280, Republic of Korea

Corresponding Official:

Gary J. Allsebrook
C/o Regulatory Management Services
16303 Panoramic Way
San Leandro CA 94578-1116
Tel: (510) 276-2648 Fax: (510) 275-3559

2.0 Initial Distributor (if manufacturer is overseas):

M. T. Kwon, CEO/President, Medison America Inc.
6616 Owens Drive, Pleasanton, CA 94588
Telephone: (510) 463-2646

3.0 Date of Submission:

November 18, 1999

4.0 Device Name:

IFM-500, Ultrasound Fetal Monitor

5.0 Common Name:

Perinatal monitor

6.0 Classification:

Regulatory Class: II
Review Category: Tier II
Device Classification Panel: Obstetrics and Gynecology

	FR Number	Product Code
Monitor, Ultrasonic, Fetal	884.2740	85HGM

7.0 Establishment Registration Number:

Application in Process

8.0 514 Performance Standards:

There are no performance standards established under Section 514 for this device. However, the IFM-500 Ultrasound Fetal Monitor system tested in accordance with

European Standard EN / IEC 60601-1. EMC requirement was also tested in accordance with EN / IEC 60601-1-2.

8.0 Special Controls:
510(k) Special Report will be supplied prior to first customer shipment.

9.0 Prescription Status:
Prescription Device.

10.0 Manufacturing Location:
BiOSYS Co., LTd.
687-3, Sangoan-Ri
Hongchun-Kun, Kangwon-Do,
Republic of Korea

11.0 Sterilization Sites:
None

12.0 Reason for Submission:
BiOSYS proposes to introduce into interstate commerce for commercial distribution a new device referred to in this document as IFM-500 Ultrasound Fetal Monitor.

13.0 Identification of the TRACK being followed for the submission:
Track 1

14.0 Device Description and Intended Use:
The IFM-500 is an Perinatal 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 or twin fetal heart rates may be measured by means of Pulsed Doppler Ultrasound. Uterine Contraction (UC) is measured with an external TOCO transducer.

15.0 Software:
BiOSYS Company Ltd. certifies that the IFM-500 Fetal Monitor is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

16.0 Hazard Analysis
Hazard analysis on this product has been performed throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes, and their effects;

- Development of methodologies to control the occurrence of hazards and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of the predicate device. These are primarily related to failure of system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is "Minor".

17.0 Substantial Equivalence:

The following is a summary of the safety and effectiveness data on which the substantial equivalence determination is based:

Predicate Device Comparison Chart

Feature	IFM-500	Model 118 (K934959)
Indication for Use	- Fetal (perinatal fetal monitor)	- Fetal (perinatal fetal monitor) - Maternal monitor
Modes of Operation:	- Ultrasound mode - Uterine Contraction mode	- Ultrasound mode - Uterine Activity mode - ECG mode - Blood Pressure mode - Pulse Oximetry mode-
System Characteristics:	- Portable - LED display & Control Panel - Strip chart recorder - AC only 100 -240V, 50/60 Hz, 0.5 – 0.25 A	- Portable - LCD display & Control Panel - Strip chart recorder - AC only 100/120/220/230/240 V, 48-62 Hz, 100 W
FHR/UC Monitoring	Yes	Yes
Maternal Heart/Pulse Rate, NBP, SpO_2 Monitoring	No	Yes
Transducer Type:	- Circular Array (7 elements) - Tocotransducer	- Circular Array (9 elements) - Tocotransducer
Ultrasound Frequency	2.0 MHz	1.151 MHz
FHR Detection method	Pulsed-wave Doppler	Pulsed-wave Doppler

Feature	IFM-500	Model 118 (K934959)
FHR Range	50 – 240 BPM	50 – 210 BPM
UC Range	00 – 99 relative units 00 – 99 mmHg	0 – 100 relative units 0 – 100 mmHg
UC Detection method	Strain gauge strength	Strain gauge strength
Detection of fetal movement via ultrasound transducer	No	Yes
Alarm	Yes (Audible)	Yes (Audible & Visible)
Printer(Recorder) Type	Thermal array (dots/mm)	Thermal array (dots/mm)
Acoustic Output Display & FDA Limits:	Less than Track 1 maximum acoustic values	Less than Track 1 maximum acoustic values
Product Safety Certification	- IEC 60601-1	- IEC 601-1 - UL 544
EMC Compliance	- IEC 60601-1-2	
Patient Contact Materials	Plastic, ABS AF-302 (intact skin)	Plastic (intact skin)

Accessories or Kits

Feature	IFM-500	Model 118 (K934959)
Accessories	- Event marker - Strip chart (paper)	- Event marker - Strip chart (paper) - ECG electrode - SpO_2 sensor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2000

BiOSYS Co., Ltd.
c/o Mr. Gary J. Allsebrook
Official Correspondent
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116

Re: K994008
BiOSYS IFM-500 Intelligent Fetal Monitor
Dated: June 14, 2000
Received: July 3, 2000
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) 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.

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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):

Device Name: BiOSYS, IFM-500 Perinatal Fetal Monitor

Indications For Use:

The IFM-500 is an Perinatal 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 or twin fetal heart rates may be measured by means of Pulsed Doppler Ultrasound. Uterine Activity is measured with an external TOCO transducer.

(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 901.109)

(Optional Format 1-2-96)

David A. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994408