510(k) Summary of Safety and Effectiveness

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

The assigned 510(k) number is: K112317

Submitter

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Registration # 1066270

Official correspondent :

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Date Prepared:

December 12, 2011

Device name and classification:

- **Device Name:** FM-9000 Plus Fetal and Maternal Monitor

- **Classification Name:** 884.2740 Perinatal Monitoring System and Accessories

  Product code: HGM

- **Regulatory Class:** Class II

Predicate Device:

F9 Express Fetal and Maternal Monitor K100797 Manufacturer: EDAN Instruments

Device Description:

FM-9000 Plus Fetal and Maternal Monitor

The Fetal & Maternal Monitor provides the following primary features that can be available for the multiple configurations:

- Basic parameters: FHR, TOCO, Event Mark, AFM
- Dual FHR monitoring
- Internal parameters: UIP, DECG
- FHR limit alarm

Following facilities are also provided in addition to the above:

- Maternal ECG monitoring
- Maternal $SP0_2$ monitoring
- Maternal NIBP
- Maternal temperature monitoring

Intended Use:

The FM-9000 Plus Fetal and Maternal Monitor is intended for monitoring physiological parameters of pregnant women during antepartumn examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartumn examination rooms, labor and delivery rooms. The FM-9000 Plus Fetal and Maternal Monitor is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation. In addition, it provides a solution for maternal vital signs monitoring.

Effectiveness and Safety Contraindications:

Clinical Test

Clinical testing is not required

Non-clinical test:

The following quality assurance measures were applied to the development of the Fetal & Maternal Monitor:

- Software testing
- Hardware testing
- Safety testing
- Environment test
- Risk analysis
- Final validation

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use as the predicate device.

Substantially Equivalent Determination:

Verification and validation testing was done on the FM-9000 Plus Fetal and Maternal Monitor. This premarket notification submission demonstrates that FM-9000 Plus Fetal and Maternal Monitor is substantially equivalent to the predicate device.

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

Advanced Instrumentations, Inc.
% Jorge Millan, Ph.D.
Executive Director
Hialeah Technology Center, Inc.
601 West 20 Street
HIALEAH FL 33010

DEC 2 1 2011

Re: K112317
Trade/Device Name: FM-9000 Plus Fetal and Maternal Monitor
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: November 16, 2011
Received: November 17, 2011

Dear Dr. Millan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

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.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K112317

Indications for Use

510(k) Number (if known): K112317

Device Name:

FM-9000 Plus Fetal and Maternal Monitor

Indications for Use:

The FM-9000 Plus Fetal and Maternal Monitor is intended for monitoring physiological parameters of pregnant women during antepartumn examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartumn examination rooms, labor and delivery rooms. The FM-9000 Plus Fetal and Maternal Monitor is intended for providing Non-Stress testing or fetal monitoring for pregnant women from the 28th week of gestation. In addition, it provides a solution for maternal vital signs monitoring.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K112317

Diagnostic Ultrasonic Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Fetal and Maternal Monitor model F9000 Plus

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other* (Specify)
Ophthalmic										
Fetal				N						
Abdominal										
Intra-operative(Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheran Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (specify)										

N = new indication P=previously cleared by FDA: e=ADDED UNDER appendix E

Additional comments: The above is an ultrasound system for the fetal heart rate detection.

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Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112317

Diagnostic Ultrasonic Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

1 MHz PW fetal probe- model F9000 Plus

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other* (Specify)
Ophthalmic										
Fetal				P						
Abdominal										
Intra-operative(Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheran Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (specify)										

N = new indication P=previously cleared by FDA: e=ADDED UNDER appendix E

Additional comments: The above is a 1 mHz PW transducer for the fetal heart rate detection.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

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