DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 19, 2014

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

Re: K141194
Trade/Device Name: FM-3000 Fetal Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: Class II
Product Codes: HGM, HGS, HFN, HGP
Dated: August 19, 2014
Received: August 22, 2014

Dear Jorge 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

for
Benjamin Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141194

Device Name:

FM-3000 Fetal Monitor

Indications for Use:

The FM-3000 Fetal Monitor is intended for non-invasive and invasive monitoring of fetus during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

It provides Non-stress testing for pregnant women from the 28th week of gestation. It can externally monitor the fetal heart rate using ultrasound and uterine activity via a pressure sensing transducer. Alternatively, it can internally monitor one of the fetal heart rates with an electrocardiograph and uterine activity with an intrauterine pressure catheter.

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)

Diagnostic Ultrasound indications for Use Form

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

1MHz PW fetal probe

Intended use : Diagnostic ultrasound imaging or fluid flow 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										
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric										
Small Organ(specify)										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheraln Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

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

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE I FNEEDED

CONCURRENCE OF cdrh, Office of Device Evaluation (ODE)

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: K141194

Submitter

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Date Prepared:

November 10, 2014

Device name and classification:

- **Device Name:** FM-3000 Fetal Monitor
- **Classification Name:** System, Monitoring, Perinatal
- **Regulation Number:** 21 CFR 884.2740
- **Regulation Name:** Perinatal Monitoring System and Accessories
- **Product code:** HGM, HGS (catheter, intrauterine and introducer) HFN (transducer, pressure, intrauterine), HGP (electrode, circular (spiral), scalp and applicator)
- **Regulatory Class:** Class II

Predicate Device:

F3 Fetal Monitor K102140 Manufacturer: EDAN Instruments

Device Description:

FM-3000 Fetal Monitor

With non-invasive ultrasound Doppler, external pressure sensing transducer and direct fetal electrocardiograph technique, the FM-3000 Fetal Monitor provides Non-Stress testing for pregnant women from the **28th** week of gestation. It can externally monitor the fetal heart rate using ultrasound and uterine activity. Alternatively, it can internally monitor one of the fetal heart rate with direct fetal electrocardiograph technique and uterine activity with an Intrauterine Pressure Catheter.

The Fetal monitor can be connected with Central Monitoring System via a RJ45 interface. Also it can be connected to wireless network module via a DB9 interface, and the wireless network module will complete the data switch of the monitor and the Obstetrical Central Monitoring System.

The FM-300 is not intended for use in intensive care units, operating rooms or for home use.

Accessories

Accessory	**Part Number**
Ultrasound Transducer	12.01.109301
TOCO Transducer	12.01.31527
Remote Event Marker	12.01.31112
Belt	11.57.02264
Aquasonic Coupling Gel (0.25ltr bottle)	11.57.78001
Intrauterine Pressure Cable Connecting Wire	01.13.107796
Intrauterine Pressure Cable	11.13.104152
Disposable Intrauterine Pressure Catheter	11.57.104153

Direct ECG Cable	11.13.02148
Disposable Fetal Spiral Electrode	11.57.02145
Disposable Maternal Attachment Pad Electrode	11.57.02146

Patient Contact Materials

Parts		Nature	Biocompatibility analysis
ultrasonic transducer	shell	ABS plastic	The material for this ultrasound transducer is cleared under K 040903
	cable	FR-PVC	
TOCO Transducer	shell	ABS plastic	
	cable	FR-PVC	
Remote marker	shell	ABS plastic	
	cable	FR-PVC	
Aquasonic Coupling Gel		water soluble hypoallergenic	The biocompatibility analysis of these accessories is submitted in K 040903 which has been cleared.
Belt		Cotton	
Disposable Fetal Spiral Electrode			
Disposable Maternal Attachment Pad Electrode			The accessories manufactured by Tyco have been cleared under K 904745
DECG Cable			
Disposable Intrauterine Pressure Catheter			
Intrauterine Pressure Cable			The accessories manufactured by Tyco have been cleared under K 910742

Indications for Use:

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It provides Non-stress testing for pregnant women from the 28th week of gestation. It can externally monitor the fetal heart rate using ultrasound and uterine activity via a pressure sensing transducer. Alternatively, it can internally monitor one of the fetal heart rates with an electrocardiograph and uterine activity with an intrauterine pressure catheter.

Performance Data

The FM-3000 Fetal Monitor is identical to the predicate device in terms of design, materials, specifications, and manufacturing. Therefore, no new testing was needed to support substantial equivalence. The FM-3000 Fetal Monitor relied on the biocompatibility, electrical safety, electromagnetic compatibility, software, acoustic output, and bench testing from the predicate device to support substantial equivalence

Comparison to the predicate device:

The FM-3000 Fetal Monitor is identical the predicate device in terms of design, materials, specifications, and manufacturing. Therefore, there are no differences in technological characteristics between the two devices. The only difference between the predicate device and the FM-3000 Fetal Monitor is the device name and branding in the labeling

Substantially Equivalent Determination:

Since the FM-3000 Fetal Monitor was identical to the predicate device in terms of technological characteristics, including design, materials, specifications, and manufacturing, no new testing was needed. Therefore, descriptive characteristics were precise enough to determine that the FM-3000 Fetal Monitor performs comparably to the predicate device that is currently marketed for the same intended use.