K082602

510（K）Summary of Safety and Effectiveness

NOV 26 2008

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

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Date of Preparation: Jul 17, 2008

Proprietary Name: Fetal & Maternal Monitor (Models F6 and F9)

Classification Name: 21 CFR 884.2740 Perinatal monitoring system and accessories

Product code: HGM

Predicate Devices:

Predicate devices	CADENCE II	Corometrics 120 series maternal/ fetal monitor
Manufacturer	Edan Instruments, Inc.	GE Healthcare
K #	K073221	K991739

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

- Basic parameters: FHR, TOCO, Event Mark, AFM
- Optional Dual FHR monitoring
- Optional Internal parameters: IUP/DECG

- 12 hours waveforms playback
- Optional Built-in wireless module
- Software for data transmission to PC
- Quick printing for stored waveform
- Lithium battery for 4 hours continuous working
- Probe rack and wall mounting rack
- Optional Fetal Stimulator
- FHR limit alarm
- Pulse wave Doppler waterproof transducer for FHR detection

Comparison with predicate device

Monitoring Mode	Fetal & Maternal Monitor	CADENCE II	Corometrics 120 series maternal/ fetal monitor
FHR/Dual FHR	yes	yes	yes
TOCO	yes	yes	yes
Fetal ECG, IUP	yes	yes	yes

Intended Use: The Fetal & Maternal 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.

Fetal & Maternal Monitor provides Non-Stress testing for pregnant women from the 28th week of gestation. It can externally monitor the FHRs using ultrasound and uterine activity via a TOCO transducer. Alternatively, it can internally monitor one of the FHRs with DECG and uterine activity with an IUPC.

Contraindications: It is not intended for use in intensive care units, operating rooms or for home use.

Test Summary: 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

Conclusion: Verification and validation testing was done on the Fetal & Maternal Monitor. This premarket notification submission demonstrates that Fetal & Maternal Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Edan Instruments, Inc.
c/o Mr. William Stern
Official Correspondent
Multigon Industries, Inc.
1 Odell Plaza
YONKERS NY 10701

NOV 2 6 2008

Re: K082602
Trade/Device Name: Fetal and Maternal Monitor (Models F6 and F9)
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: Class II
Product Code: HGM
Dated: November 4, 2008
Received: November 5, 2008

Dear Mr. Stern

We have reviewed your Section 510(k) premarket 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Fetal and Maternal Monitor (Models F6 and F9), as described in your premarket notification:

1 MHz PW fetal probe – model F6
1 MHz PW fetal probe – model F9

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Glenn Bell, Ph.D., at (240) 276-3666.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

Indication for Use

510(k) Number (if known): K082602

Device Name: Fetal & Maternal Monitor (Models F6 and F9)

The Fetal & Maternal 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.

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Prescription Use X And/Or Over the Counter Use ___.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082602

K082602

Diagnostic Ultrasound indications for Use Form

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

1 MHz PW fetal probe- model F9

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 1 mHz 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)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K082602

K082602

Diagnostic Ultrasound indications for Use Form

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

1 MHz PW fetal probe- model F6

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										
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Musculo-skeletal Conventional										
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