Attachment 3

510(k) Summary

NOV 10 2010

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

Date prepared: September 20, 2010

1. **Applicant:**
   Edan Instruments, Inc.
   3/F - B, Nanshan Medical Equipments Park,
   Nanhai Rd 1019#, shekou,
   Nanshan Shenzhen, 518067 P.R. China
   Contact person: Randy Jiang

2. **Manufacturer:**
   Edan Instruments, Inc.
   3/F - B, Nanshan Medical Equipments Park,
   Nanhai Rd 1019#, shekou,
   Nanshan Shenzhen, 518067 P.R. China

3. **Submitter:**
   Mr. Jigar Shah
   Official Correspondent for
   Edan Instruments, Inc.
   mdi Consultants, Inc.
   55 Northern Blvd., Suite 200
   Great Neck, New York 11021
   Tel: 516-482-9001
   Fax: 516-482-0186
   Jigar@mdiconsultants.com

4. **Trade/proprietary Name:**
   Fetal & Maternal Monitor (Models F9 Express and F6 Express)

5. **Classification name:**
   21 CFR 884.2740 Perinatal monitoring system and accessories.

6. **Product Code:**
   HGM

7. **Predicate Devices:**
   - Edan Instruments F9/F6 Maternal/Fetal Monitor K082602
   - GE Healthcare GE129 Maternal/Fetal Monitor K991739

8. **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
- Dual FHR monitoring
- Internal parameters: IUP, DECG
- FHR limit alarm

Following facilities are also provided in addition to the above:

- Maternal ECG monitoring
- Maternal SpO_2 monitoring
- Maternal NIBP
- Maternal temperature monitoring

9. Intended Use:

The F9 Express and F6 Express fetal & maternal monitor is intended for monitoring physiological parameters of pregnant women 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.

F9 Express and F6 Express fetal & 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.

10. Contraindications:

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

11. Substantial Equivalence Discussion:

Monitoring mode	F6 & F9 Express New Device	F6 & F9 K082602	COROMETRICS 120 SERIES (129 configuration)K991739
FHR/ Dual FHR	Yes	Yes	Yes
TOCO	Yes	Yes	Yes
Fetal ECG, IUP	Yes	Yes	Yes
MECG	Yes		Yes
SpO2	Yes		Yes
NIBP	Yes		Yes

12. Summary of Testing:

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

13. 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Edan Instruments, Inc.
c/o Mr. Jigar Shah
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

NOV 10 2010

Re: K100797
Trade/Device Name: Fetal and Maternal Monitor (Models F6 Express and F9 Express)
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: Class II
Product Code: HGM
Dated: November 5, 2010
Received: November 8, 2010

Dear Mr. Shah:

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.

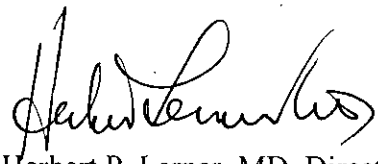
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Kathy Daws-Kopp, at (301) 796-6535.

Sincerely yours,



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

Enclosures

Indication for Use

NOV 1 0 2010

510(k) Number (if known): K100797

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

F6 Express and F9 Express fetal & maternal monitor is intended for monitoring physiological parameters of pregnant women during ante-partum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in ante-partum examination rooms, labor and delivery rooms.

F6 Express and F9 Express fetal & 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 ___
(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, Gastro-Renal, and Urological Devices
510(k) Number K100797

Diagnostic Ultrasound indications for Use Form

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

1 MHz PW fetal probe- model F6 Express

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				P						
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, Gastro-Renal, and Urological Devices
510(k) Number K100797

Diagnostic Ultrasound indications for Use Form

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

1 MHz PW fetal probe- model F9 Express

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				P						
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										

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CONCURRENCE OF cdrh, Office of Device Evaluation (ODE)

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