Attachment H

NOV - 7 2008

510(K) SUMMARY

A. Submitter's Information

Name:	Edan Instruments, Inc
Address:	3/F - B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, shekou, Nanshan Shenzhen, 518067 P.R. China
Phone:	0086-755-26892220
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Contact Person:	Jiang Yucai
Official Correspondent:	William Stern
Date Summary Prepared:	Jul 13, 2008

B. Device Information

Trade/Device Name:	Fetal Monitor
Regulation Number:	884.2740
Classification Name:	System, Monitoring, Perinatal
Regulation Class:	Class II
Product Code:	HGM
Classification Panel:	Obstetrics/Gynecology

Description of Device

There are four models included in Cadence series Fetal monitor: Cadence, Cadence Dual, Cadence Pro and Cadence II.

The Fetal Monitor can provide different configurations according to different user requirements, FHR1 (Fetal Heart Rate 1), FHR2 (Fetal Heart Rate 2), TOCO, FM (remote marker), AFM (automatic fetal movement mark), FS (fetal stimulator, optional). The user can select the monitors according to requirements.

The Fetal monitor can be connected with Central Monitoring System via 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.
Cadence II adopts 5.7"LCD, and the collected data, trends, and monitoring parameters are displayed at the same screen. A built-in thermal recorder is used to record the monitoring information.
The data collected and stored by Fetal Monitor can be real-time transferred to PC or Obstetrical Central Monitoring System and can be managed and printed by the Insight software.

C. Predicate Device Information

Cadence [K040903] [09/02/2004]
Cadence II [K073221] [12/28/2007]

D. Indications for Use/Intended Use

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

E. Substantial Equivalence

1. Is the product a device?
YES-The Fetal Monitor is a device.

2. Does the new device have the same intended use?
YES-The intended use for the Fetal Monitor is equivalent to that for the predicate device.

3. Does the device have technological characteristics the raise new types of safety or effectiveness questions?
NO- The technological characteristics of the Fetal Monitor raise no new types of safety or effectiveness questions.

4. Does descriptive or performance information demonstrate equivalence?
YES- Edan Instruments, Inc. believes that the information provided in this submission clearly describes the Fetal Monitor and demonstrates that it is substantially equivalent to the predicate device.

F. Safety Summary

Edan Instruments, Inc. made several modifications to the Cadence cleared under K040903 and Cadence II cleared under K073221. All design control activities including safety risk analysis and the verification and validation activities conducted as related to the risks proved that the modified Fetal Monitor is substantially equivalent in intended use, design, principle of operations, performance, and contains the same fundamental scientific technology as the predicate device listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2008

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

Re: K082369
Trade/Device Name: Fetal Monitors, Models: Cadence, Cadence Dual, Cadence Pro and Cadence II
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Codes: HGM and HEL
Dated: October 10, 2008
Received: October 10, 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 Cadence Series Fetal Monitors, as described in your premarket notification:

Transducer Model Number

1 MHz PW waterproof fetal probe

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.

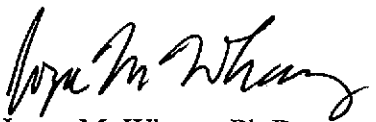
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Attachment C

Indications for Use Statement

Device Name Fetal Monitor

Indications for Use Cadence series Fetal 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. It is not intended for use in intensive care units, operating rooms or for home use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _YES_ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082369

Attachment D

Diagnostic Ultrasound indications for Use Form

Fill out one form for each ultrasound system and each transducer.
1 MHz PW waterproof fetal probe- model: Cadence, Cadence Dual, Cadence Pro, Cadence II

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.

CONCURRENCE OF cdrh, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082369