Attachment 6

510(K) SUMMARY

DEC 2 8 2007

CADENCE II

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:	86-755-26892220
Fax:	86-755-26882223
Contact Person:	Jiang Yucai
Official Correspondent:	William Stern
Date Summary Prepared:	Oct 17, 2007

B. Device Information

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

Description of Device

The CADENCE II Fetal Monitor can provide different configurations according to different user requirements, FHR1 (US1), FHR2 (US2), TOCO, FM (remote marker), AFM (automatic fetal movement mark), fetal stimulator (optional), DECG (direct fetal ECG, optional), and IUP

(Intra-uterine Pressure, optional). The user can select the monitors according to requirements.
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.

C. Predicate Device Information

Cadence [K040903] [09/02/2004]

D. Indications for Use/Intended Use

The CADENCE II fetal monitor is used to monitor fetal well being during the antepartum period what is commonly called the non stress test. It is to be used by trained medical personnel in hospitals, clinics, physicians offices and in the patients home by prescription or doctors orders.

E. Substantial Equivalence

1. Is the product a device?
YES-The CADENCE II is a device.

2. Does the new device have the same intended use?
YES-The intended use for the CADENCE II is equivalent to that for the Cadence and is as follows:

Intended Use: Cadence

The Cadence fetal monitor is used to monitor fetal well being during the antepartum period what is commonly called the non stress test. It is to be used by trained medical personnel in hospitals, clinics, physicians offices and in the patients home by prescription or doctors orders.

3. Does the device have technological characteristics the raise new types of safety or effectiveness questions?
NO- The technological characteristics of the CADENCE II 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 CADENCE II and demonstrates that it is substantially equivalent to the predicate device Cadence

F. Safety Summary

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2007

Edan Instruments, Inc.
% Mr. William Stern
Multigon Industries, Inc.
1 Odell Plaza
YONKERS NY 10701

Re: K073221
Trade/Device Name: CADENCE II
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: November 7, 2007
Received: December 5, 2007

Dear Mr. Stern:

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.

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 Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known) K073221

Device Name CADENCE II

Indications for Use The CADENCE II fetal monitor is used to monitor fetal well being during the antepartum period what is commonly called the non stress test. It is to be used by trained medical personnel in hospitals, clinics, physicians offices and in the patients home by prescription or doctors orders.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use YES OR Over-The-Counter Use NO
(Per 21 CFR 801 Subpart D)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073221