K 040903

SEP - 2 2004

- CADENCE 510k SUBMISSION

Cadence Fetal Monitor
Edan Instruments, Inc.

SUMMARY

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

1. Submitters name, address, phone number, contact person and preparation date:

Name: Edan Instruments, Inc.
4/F, New Energy Building
2009 Nanyou Road
Nanshan, Shenzhen, Guangdong
5188054 China
Phone: 86 755 26062059
Fax: 86 755 26062022
Responsible person: Xie Xicheng

Official Correspondent:

William Stern
Multigon Industries, Inc.
1 Odell Plaza
Yonkers, N.Y. 10701
Phone: 914 376 5200 X27
Fax: 914 376 5565

Date of Preparation: 4/2/04

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2. Device:

Proprietary Name: Cadence Ante partum Fetal Monitor model 2001 (Singleton) and model 2002 (Twins)

Common Name: Fetal Monitor
Classification Name: 21 CFR 884.2740 System, Monitoring, Perinatal
Product Code: HGM
Manufactured By: Edan instruments, Inc. China

2. Predicate Devices:
Comparison of the Cadence Fetal monitor to the Predicate Devices

DEVICE	CADENCE 2001,2002	SONICAID 820	COROMETRICS 171 AND 172
ATTRIBUTE			
510k Number	k040903	k002150	k991905
Singleton (model 2001)	yes	yes	yes
Twins (model 2002)	yes	yes	yes
Fetal Heart Detection: Pulsed Doppler With Auto-Correlation	yes	yes	yes
Fetal Heart Rate Display Units	1 BPM	1 BPM	1 BPM
Fetal Heart Rate Range	50-210 BPM	30-240 BPM	50-210 BPM
Ultrasound Frequency	2 MHz	1.5 MHz and 2.0 MHz	1.15 MHz
Ultrasound Power (mw/sq.cm)	6.972 ISPTA	less than 100 ISPTA	5 ISATA

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Fetal Heart Rate Alarms	yes	yes	yes
DEVICE	CADENCE	SONICAID 820	COROMETRICS 171/172
ATTRIBUTE			
Toco Transducer Type	strain gauge	strain gauge	strain gauge
Toco Range (relative units)	0-100	0-100	0-100
Toco Resolution (relative units)	1	1	1
Chart Recorder	yes	yes	yes
Numeric Display Of Results	yes	yes	yes

Conclusion: The Cadence model 2001 singleton and 2002 twin monitors are Similar and equivalent to the two predicate devices , the Sonicaid 820 and the Corometrics 171/172 in principles of operation, specifications, and performance.

3. Classification Names:

Class II as per 21 CFR 884.2740 System., Monitoring,Perinatal

5. Description

The Cadence Fetal monitor is a perinatal monitoring system for non-invasively measuring, displaying and printing out in graphic form on a strip chart recorder maternal

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abdominal contractions and fetal heart rate for either a singleton fetus or twin fetuses during the last trimester. A manual hand held pushbutton marker for patient identification of contractions is also part of the monitor. The Cadence Fetal monitor uses one or two ultrasound transducers for monitoring the fetal heart rate (FHR) depending on whether there is a singleton or twin pregnancy. The multi crystal , broad band ultrasound transducer operates at a frequency of 2 mHz. The ultrasound transducer or transducers are placed on the maternal abdomen by means of one or two belts and transmits the ultrasound signal to the fetal heart(s). The transducer(s) also receive the echo from the fetal heart(s) and processes the echoes determining the fetal heart rate(s) The TOCO transducer is also placed on the maternal abdomen with a belt and it detects the forward displacement of the maternal abdominal muscles during a contraction. The TOCO transducer is a tocotonometer which operates on the strain gauge principle to measure displacement. The central section of the TOCO transducer is depressed by the forward displacement of the abdominal muscles during a contraction. It is used for assessing frequency and duration of uterine contractions. It gives an indication of contractions pressure.

The fetal heart rate(s) and TOCO percent contractions pressure are displayed on numerical readouts and printed out on a strip chart recorder in graphic form.

A fetal event marker pushbutton is also available for the patient to identify contractions manually by pushing the button on the fetal event marker.

6. Indications for Use.

The Cadence Fetal Monitor, model 2001 for singletons and model 2002 for twins, is a fetal monitor for monitoring fetal well being during the antepartum period. It performs what is commonly called the non –stress test.

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The Cadence Fetal Monitor 2001/2002 is to be used by trained medical personnel in hospitals, clinics, physicians offices and in the patients home by prescription or doctors orders.-

7. Contra-Indications.

None known at this time

8. Comparison to Predicate Devices.

The Cadence Fetal Monitor has the same device characteristics of all of the approved predicate devices listed in item 3 above with the commonality of ultrasound transducer(s) principles of operation, TOCO transducer principle of operation, ultrasound fetal heart detection and display, contraction detection and display and fetal event marker and display, and graphic recording and display available.

9. Test Data:

The Cadence Fetal monitor device has been subjected to Extensive safety, performance testing, and validation before release. Final testing of the Cadence Fetal monitor included various performance tests designed to ensure that the device met all of its functional requirements and performance specifications. Safety tests have been performed to ensure the device complies with applicable industry and safety standards.

The Cadence fetal monitor device labeling includes instructions for safe and effective use, warnings, cautions, and guidance for use. It has been shown there fore to be safe and effective.

10. Literature Review:

A review of the literature pertaining to the safety of the Cadence Fetal monitor has been conducted and appropriate safeguards have been incorporated in the design of the Cadence Fetal monitor.

11. Conclusions:

The conclusion drawn from these tests is that the Cadence

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Fetal monitor is equivalent in safety and efficacy to the predicate devices listed in # 3. above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2004

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

Re: K040903
Trade/Device Name: Cadence Antepartum Fetal Monitor; Model 2001 – Cadence (singleton) and Model 2002 – Cadence Dual (twin)
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: August 4, 2004
Received: August 10, 2004

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 Antepartum Fetal Monitor as described in your premarket notification:

Transducer Model Number

2 MHz PW Doppler 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 (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Slade Stratton at (301) 594-1212.

Sincerely yours,

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

Enclosures

Diagnostic Ultrasound Indications for Use Form

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

2 mHz PW DOPPLER FETAL PROBE- MODEL:CADENCE

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of 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										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The above is a 2 mHz Pulsed Wave Transducer for fetal heart rate detection

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguren

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040903

Prescription Use (Per 21 CFR 801.109)

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Indications for Use

510(k) Number (if known): K040903

Device Name: Cadence Fetal Monitor 2001/2002

Indications For Use:

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The Cadence Fetal Monitor 2001/2002 is to be used by trained medical personnel in hospitals clinics, physicians offices, and in the patients home by prescription or doctors orders.

Prescription Use YES (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use ~~NO~~ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040903