K092997

510(k) Summary of Safety and Effectiveness

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

Submitter:

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NOV 1 0 2009

Official correspondent:

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Date of Preparation: 2009-9-23

Proprietary Name: Ultrasonic TableTop Doppler (Models SD5, SD6)

Classification Name: 21 CFR 884.2660 Fetal ultrasonic monitor and accessories

Product code: KNG

Predicate Devices:

Predicate devices	IMEXDOP CT+	Sonotrax series pocket doppler
Manufacturer	Imex Medical Systems, Inc	Edan Instruments, Inc
K #	K942441	K080087

Device Description: Ultrasonic TableTop Doppler provides the following primary features:

- Basic parameters: FHR
- 240 seconds fetal heart sound record and playback
- Infrared communication(for SD6 only)
- Ni-MH battery for 20 hours continuous working of main unit
- Li-ion battery for 2.5 hours continuous working of SD6 probe
- Charge the SD6 probe battery by main unit
- Continuous wave Doppler transducer for FHR detection

Comparison with predicate device

The Ultrasonic TableTop Doppler models including SD5 and SD6

have the same device characteristics as the predicate devices mentioned above, the 2MHz, 3MHz probes for heart rate detection uses the same technology and circuitry as the cleared Sonotrax series pocket Doppler under K080087. The Ultrasonic TableTop Doppler is also similar and comparable to the IMEXDOP CT+ cleared under K024197. Hence Ultrasonic TableTop Doppler above is substantially equivalent to the predicate devices cited.

Intended Use: The Ultrasonic TableTop Doppler is intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The 2 MHz and/or 3 MHz probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. They can also be used to verify fetal heart viability following patient trauma.

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 Ultrasonic Doppler

- Software testing
- Hardware testing
- Safety testing
- Environment test
- Risk analysis
- Final validation

Conclusion: Verification and validation testing was done on the Ultrasonic TableTop Doppler. This premarket notification submission demonstrates that Ultrasonic TableTop Doppler 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.
% Mr. William Stern
Official Correspondent
Multigon Industries, Inc.
1 Odell Plaza
YONKERS NY 10701

NOV 1 0 2009

Re: K092997
Trade/Device Name: Ultrasonic TableTop Doppler (Models SD5 and SD6)
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: September 25, 2009
Received: September 28, 2009

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 Ultrasonic TableTop Doppler (Models SD5 and SD6) as described in your premarket notification:

Transducer Model Number

2MHz CW fetal probe – model: SD5
3MHz CW fetal probe – SD5
2MHz CW wireless fetal probe – model: SD6
3MHz CW wireless fetal probe – model: SD6

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound indications for Use Form

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

2MHz CW fetal probe- model: SD5

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 2MHz CW 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 K092997

Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound indications for Use Form

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

3MHz CW fetal probe- model: SD5

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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Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound indications for Use Form

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

2MHz CW wireless fetal probe- model: SD6

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										

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Diagnostic Ultrasound indications for Use Form

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

3MHz CW wireless fetal probe- model: SD6

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										
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