OCT 2 7 2011

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K112529

Submitter

Advanced Instrumentations, Inc.
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Miami, Fl 33166
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Registration # 1066270

Official correspondent :

Jorge Millan, PhD
Email: jmillan@hiatec.org
601 West 20 St
Hialeah, FL 33010
Phone : (305) 925-1260

Date Prepared:

August 25, 2011

Device name and classification:

- **Device Name:** TD-5000 & TD-6000 Ultrasonic Tabletop Doppler
- **Classification Name:** 884.2660 Fetal ultrasonic monitor and accessories
  Product code: KNG
- **Regulatory Class:** II

Predicate Device:

SD5 & SD6Ultrasonic Tabletop Doppler. K092997 Manufacturer: EDAN Instruments

Device Description:

Ultrasonic Tabletop Doppler provides the following primary features:

- Basic parameters: FHR
- 240 seconds fetal heart sound record and playback
- Infrared communication (for TD-6000 only)
- Ni-MU1 battery for 20 hours continuous working of main unit
- Li-ion battery for *2.5* hours continuous working of TD-6000 probe
- Charge the TD-6000 probe battery by main unit
- Continuous wave Doppler transducer for FUR detection

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.

Effectiveness and Safety Contraindications:

Clinical Test

Clinical testing is not required

Non-clinical test:

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

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use, same design principle, same electrical classification, same measurement mode and same accuracy as the predicate device.

Substantially Equivalent Determination:

Verification and validation testing was done on the TD-5000 & TD-6000 Ultrasonic Tabletop Doppler. This premarket notification submission demonstrates that TD-5000 & TD-6000 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
Silver Spring, MD 20993

OCT 2 7 2011

Advanced Instrumentations, Inc.
% Jorge Millan, Ph.D.
Executive Director
Hialeah Technology Center, Inc.
601 West 20 St.
HIALEAH FL 33010

Re: K112529
Trade/Device Name: TD-5000 & TD6000 Ultrasonic Tabletop Doppler
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: August 26, 2011
Received: September 1, 2011

Dear Dr. Millan:

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 TD-5000 & TD6000 Ultrasonic Tabletop Doppler, as described in your premarket notification:

Transducer Model Number

2MHz CW wireless fetal probe-model: TD-6000
3MHz CW wireless fetal probe-model: TD-6000
2MHz CW fetal probe-model: TD-5000
3MHz CW fetal probe-model: TD-5000

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 895. 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 Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name:

TD-5000 & TD-6000 Ultrasonic Tabletop Doppler

Indications for 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.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
Office of Cardiovascular Device Evaluation and Safety

510(k) K112529

Diagnostic Ultrasonic Indications for Use Form

Fill out one form for each ultrasound system and each transducer

2MHz CW wireless fetal probe- model: TD-6000

Intended Use: Diagnostic Ultrasound imaging or fluid 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										
Intra-operative(Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheran 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 2MHz CW transducer for the fetal heart rate detection.

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112529

Diagnostic Ultrasonic Indications for Use Form

Fill out one form for each ultrasound system and each transducer

3MHz CW wireless fetal probe- model: TD-6000

Intended Use: Diagnostic Ultrasound imaging or fluid 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										
Intra-operative(Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheran 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 3MHz PW transducer for the fetal heart rate detection.

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112529

Diagnostic Ultrasonic Indications for Use Form

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

2 MHz CW fetal probe- model: TD-5000

Intended Use: Diagnostic Ultrasound imaging or fluid 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										
Intra-operative(Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheran Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (specify)										

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Additional comments: The above is a 2MHz CW transducer for the fetal heart rate detection.

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510K K112529

Diagnostic Ultrasonic Indications for Use Form

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

3MHz CW fetal probe- model: TD-5000

Intended Use: Diagnostic Ultrasound imaging or fluid 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										
Intra-operative(Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheran Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (specify)										

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Additional comments: The above is a 3MHz PW transducer for the fetal heart rate detection.

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