K101960

510(k) Summary of Safety and Effectiveness

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

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AUG 1 0 2010

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Date of Preparation: 2010-6-21

Proprietary Name: Sonotrax Series Ultrasonic Pocket Doppler

(Models:Sonotrax Lite, Sonotrax Basic, Sonotrax BasicA, Sonotrax Pro, Sonotrax II , Sonotrax II Pro, Sonotrax Vascular)

Classification Name: 21 CFR 884.2660 Fetal ultrasonic monitor and accessories

21 CFR 884.2660 Ultrasonic Blood Flow Monitor

Product code: KNG

HEP

Predicate Devices:

Predicate devices	SONOTRAX ULTRASONIC POCKET DOPPLER
Manufacturer	Edan Instruments, Inc
K #	K080087

Device Description: The Sonotrax series Ultrasonic Pocket Doppler is a hand-held device for non-invasive measurement and display of fetal heart rate and blood flow velocity utilizing the principle of Doppler shift of an ultrasound. The ultrasound is transmitted from the probe to patient

body (maternal abdominal wall), and moves through biophysical objects. The acoustic ultrasound is reflected by blood and moving objects such as the fetal heart. The reflected ultrasound is received by the probe and is converted into electric signals.

The waveform data are applied to the CPU for all the digital processing on LCD Display, operation keys. The audio signal is taken off for the routing to the speaker to generate the analogue signals before digital processing.

The following probes are supplied with the Ultrasonic Pocket Doppler:

1. 2MHz for fetal heart rate.
2. 3MHz for fetal heart rate
3. 4MHz for detections of arterial and venous blood flow velocity.
4. 5MHz for detections of arterial and venous blood flow velocity.
5. 8MHz for detections of arterial and venous blood flow velocity.

Comparison with predicate device

The Sonotrax Series Ultrasonic Pocket Doppler models in item 2.above including Sonotrax Lite, Sonotrax Basic, Sonotrax BasicA, Sonotrax Pro, Sonotrax II , Sonotrax II Pro, Sonotrax Vascular, have the same device characteristics as all the predicate approved devices in item 3. above. All of these above models use the same technology and circuitry as the already approved Sonotrax Doppler cleared under K080087. In this modification application, we have added a 5MHz vascular probe for vascular use. Hence the Sonotrax Series Ultrasonic Pocket Doppler models above are substantially equivalent to the predicate devices cited.

Intended Use:

The Sonotrax series of Ultrasonic Pocket Doppler are intended for use by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physicians assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The 2 MHz and/ or 3 MHz obstetrical 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.

The 4 MHz, 5 MHz and/or 8 MHz vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

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 Sonotrax series of Ultrasonic Pocket Doppler

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

Conclusion: Verification and validation testing was done on the Sonotrax series of Ultrasonic Pocket Doppler. This premarket notification submission demonstrates that Sonotrax series of Ultrasonic Pocket 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 – WO66-G609
Silver Spring, MD 20993-0002

Mr. Yue Qiuhong (Tracy)
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AUG 10 2010

Re: K101960
Trade/Device Name: Sonotrax Series Pocket Doppler
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG and HEP
Dated: July 8, 2010
Received: July 12, 2010

Dear Mr. Yue Qiuhong:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

AUG 1 0 2010

510(k) Number (if known):

Device Name: Sonotrax Series Ultrasonic Pocket Doppler
(Models: Sonotrax Lite, Sonotrax Basic, Sonotrax BasicA, Sonotrax Pro, Sonotrax II, Sonotrax II Pro, Sonotrax Vascular)

The Sonotrax Series Ultrasonic Pocket 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.

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Prescription Use ___X___ (21 CFR Part 801 Subpart D)

And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIUD

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

510K K101960