K031504

JUL 18 2003

Summary

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

1. Company making the submission:

	Company making submission:	or	Correspondent (contract):
Name:	**Koven Technology, Inc.**		Delphi Consulting Group
Address:	12125 Woodcrest Executive Dr. Suite 220 St. Louis, MO 63141		11874 South Evelyn Circle Houston, Texas 770713404
Telephone:	1-314-542-2101		1-713-723-4080
Fax:	1-314-542-6020		1-775-429-9524
Contact:	Paul G. Koven President		J. Harvey Knauss Consultant
E-mail:	Koven@koven.com		harvey@delphiconsulting.com

2. Device:

Proprietary Name:	Echo Sounder ES-102EX Single-handed Fetal Doppler
Common Name:	Ultrasonic Fetal Monitor
Classification Name:	Fetal ultrasonic monitor and accessories
Manufactured by:	Hayashi Denki Co., Ltd., Japan

3. **Predicate Device(s):**

K023143, Echo Sounder, Model ES-102EX Fetal Doppler.

4. Classifications Names & Citations:

Class II per 21 CFR 2660, Fetal ultrasonic monitor and accessories.

5. **Description:**

The Echo Sounder ES-101EX Single-handed Fetal Doppler system utilizes the well understood principle of Doppler shift of an ultrasound signal to detect the flow of blood within the fetal heart wall motion and arteries.

The unit amplifies the high frequency oscillation output and then supplies this to the transmitter transducer. The high frequency voltage is converted to ultrasound by the transducer and is transmitted to external objects. The ultrasound transmitted by the transducer movers straight through biophysical object(s), and is reflected by the moving object (fetal heartbeat etc.). The reflected ultrasound is received by the receiving transducer and is converted into electronic signals again.

The converted electronic signals are amplified and then are detected. After removing unnecessary noise signals and improving S/N ratio at the filter circuit, the Doppler shift signals are amplified and are converted to audible sound pressure through a speaker or a headset. Simultaneously the signals are applied to the heart rate LCD display.

6. Indications for use:

Detection of fetal life, detection of multiple pregnancies, fetal screens from early gestation through delivery and general indication of fetal well being. Verify fetal heart viability following patient trauma.

7. Contra-indications:

None known at this time.

8. Comparison:

The Echo Sounder ES-101EX Single-handed Fetal Doppler has the same device characteristics as the predicate device.

9. Test Data:

The Echo Sounder ES-101X Single-handed Fetal Doppler device has been subjected to extensive safety, performance, and validations prior to release. Final testing for the system includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies with applicable industry and safety standards.

The Echo Sounder ES-101EX Single-handed Fetal Doppler device labeling includes instructions for safe and effective use. It includes Warning, Cautions, and guidance for use.

10. Literature Review:

A review of literature pertaining to the safety of Doppler Blood Flowmeters has been conducted. Appropriate safeguards have been incorporated in the design of the Echo Sounder ES-101EX Single-handed Fetal Doppler.

11. Conclusions:

The conclusion drawn from these tests is that the Echo Sounder ES-101EX Single-handed Fetal Doppler device is equivalent in safety and efficacy to its predicated device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2003

Mr. Paul Koven
President
Koven Technology, Inc.
12125 Woodcrest Executive Drive, Ste. 220
ST LOUIS MO 63141

Re: K031504
Trade Name: Echo Sounder, Single-handed ES-101EX
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: 85 KNG
Dated: May 12, 2003
Received: June 3, 2003

Dear Mr. Koven:

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 Echo Sounder, Single-handed ES-101EX, as described in your premarket notification:

Transducer Model Number

2.25 MHz

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Rodrigo C. Perez 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

Enclosure(s)

K031504

Transducer (Probe): 2.25 MHz Transducer

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
Ophthalmic										
Fetal					P					
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 2.25 MHz unfocused CW transducer for fetal heart rate detection. Released to market K915550.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031504

Prescription Use ✓

K031504

Echo sounder ES-101EX System

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
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 F

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031504

Prescription Use ✓