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		1-832-285-9423
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-101EX 8M Vascular Doppler
Common Name:	Cardiovascular blood flowmeter
Classification Name:	Cardiovascular blood flowmeter
Manufactured by:	Hayashi Denki Co., Ltd., Japan

3. Predicate Device(s):

K915550, Mini-Doppler II ES-100V, Koven Technology, Inc.

4. Classifications Names & Citations:

Class II per 21 CFR 2100, Cardiovascular blood flowmeter.

5. Description:

The Echo Sounder ES-101EX 8M is a single-handed vascular Doppler system that utilizes the well understood principle of Doppler shift of an ultrasound signal to detect the flow of blood within arteries and display heart rate.

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 and displays blood velocity motion, peak velocity, mean velocity and heart rate.

7. Contra-indications:

None known at this time.

8. Comparison:

The Echo Sounder ES-101EX 8M Doppler has the same device basic characteristics as the predicate device.

9. Test Data:

The Echo Sounder ES-101EX 8M 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 8M 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 8M Doppler.

11. Conclusions:

The conclusion drawn from these tests is that the Echo Sounder ES-101EX 8M 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

FEB 1 3 2004

Koven Technology, Inc.
c/o Mr. J. Harvey Knauss
Adelphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K031931
Echo Sounder ES-101EX 8M Vascular Doppler
Regulation Number: 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW
Dated: June 22, 2003
Received: June 26, 2003

Dear Mr. Knauss:

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 Bi-Directional Doppler Volume Flowmeter, as described in your premarket notification:

Model ES-101EX

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 Kachi Enyinna at (301) 443-8262.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number K031931

Device Name: **Echo Sounder ES-101EX 8M Vascular Doppler**

Indications for use:

Evaluation of blood flow in patients with peripheral vascular disease, heart sounds and rates.

Prescription Device.

Federal Law (US) restricts this device to sale, distribution, and use by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use **YES** OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R. Kodimer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031931