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:
Name:	Koven Technology, Inc.
Address:	12125 Woodcrest Executive Dr. Suite 220 St. Louis, MO 63131
Telephone:	1-314-542-2101
Fax:	1-314-542-6020
Contact:	Heather Flotron President
Date:	

2. Device:

Proprietary Name: Smartdop 45 Bi-Directional Doppler

Common Name: Bi-Directional Doppler Volume Flowmeter and

Classification Name: Blood Flowmeter, Cardiovascular

3. Predicate Device:

Bidirectional Doppler W/Waveform Display, Smartdop 50
Koven Technology, Inc., K954397,
870-2100, DPW, Cardiovascular & Radiology

4. Classifications Names & Citations:

21 CFR 870.2100 Cardiovascular Blood Flowmeter, Class II,
DPW, Cardiovascular & Radiology

5. Description:

The Smartdop 45 is a hand held bi-directional Doppler is designed to obtain blood flow velocity wave and heart beats through Ultrasound. The ultrasound is transmitted from probe to patient body and moves straight through biophysical object and is reflected by the moving object (blood flow). The reflected ultrasound is received by the probe and is converted into electrical signals. The incoming Doppler-shifted signals are amplified and go through the Velocity Circuits to remove unnecessary signals and to provide a bi-directional readout. This phase-shifting technique, known as a McLeod circuit, is a standard method employed in direction seeking Doppler devices for several decades. It continues in wide use.

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

The LCD display can display combined bi-directional or directionally separated waveforms. The printer can print out patient information and waveform.

Integrated speaker provide Doppler sounds. A headset can be used, when is used it will mute the speaker.

The following probes may be utilized with the Smartdop 45 Doppler:

1. 2 MHz for fetal heart rate
2. 4 MHz detections of arterial and venous blood flow velocity
3. 5 MHz detections of arterial and venous blood flow velocity
4. 8 MHz detections of arterial and venous blood flow velocity
5. 10 MHz detections of arterial and venous blood flow velocity

The Smartdop 45 is intended for evaluation of the following:

- Fetal Heart rate
- ABI studies
- PEAK & MEAN blood velocity determinations
- Peripheral vascular procedures
- Blood pressure segmental studies
- Venous compressions
- Penile & digit systolic pressures
- Flow velocities in recovery room

6. Indications for use:

The Smartdop 45 detects arterial and venous blood flow in extremities as well as fetal heart sounds. The Smartdop 45 displays and prints bi-directional velocity waveform, numerical data and fetal heart rate with heart beat indicator. The Smartdop 45 probe selection is 2, 4, 5, 8 and 10 MHz.

7. Contra-indications:

None are known at this time.

8. Comparison:

The Smartdop 45 has the same device characteristics as the predicate device, except the predicate device does not have a 2 MHz fetal heart rate 2 MHz probe capability. The predicate device does not have computer interface capabilities.

9. Test Data:

The Smartdop 45 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 Smartdop 45 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 Smartdop 45.

11. **Conclusions**:

The conclusion drawn from these tests is that the Smartdop 45 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

APR 15 2005

Koven Technology, Inc.
% Mr. J. Harvey Knauss
Contract Consultant
Delphi Consulting Group
11874 South Evelyn Circle
HOUSTON TX 77071-3404

Re: K050601
Trade Name: Smartdop 45 Bi-Directional Blood Flow Meter with Waveform Display
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: DPW, IYN, and ITX
Dated: March 7, 2005
Received: March 16, 2005

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 Smartdop 45 Bi-Directional Blood Flow Meter with Waveform Display, as described in your premarket notification:

Transducer Model Number

BT2M20S8C (2 MHz)
BT4M05S8C (4 MHz)
BT5M05S8C (5 MHz)
BT8M05S8C (8 MHz)
BT10M05S8C (10 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon
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

Smartdop 45 Bi-Directional Blood Flow Meter Device

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of 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										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N- new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and Radiological **Devices**
510(k) Number K050601

Diagnostic Ultrasound Indications for Use Form

Fetal Heart Rate Probe BT2M20S8C 2 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of 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										
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: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and Radiological **Devices**
510(k) Number K050601

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Arterial and Venous Blood Flow Velocity Probe BT4M05S8C 4 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N- new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Maricya Brogdon

(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and Radiological **Devices**
510(k) Number K050601

Diagnostic Ultrasound Indications for Use Form

Arterial and Venous Blood Flow Velocity Probe BT5M05S8C 5 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N- new indication; P= previously cleared by FDA; E= added under Appendix E

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050601

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Arterial and Venous Blood Flow Velocity Probe BT8M05S8C 8 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N- new indication; P= previously cleared by FDA; E= added under Appendix E

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Larry C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050601

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Arterial and Venous Blood Flow Velocity Probe BT10M05S8C 10 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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Nancy C Brogdon

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050601

Prescription Use (Per 21 CFR 801.109)