

510(k) SUMMARY

K 982986

MODEL HD-800 TUBING BLOOD FLOW METER

1. **COMPANY INFORMATION.** *Name:* Koven Technology Inc. *Address:* 300 Brookes Drive, Suite 105, Hazelwood, MO 63042. *Phone:* (314) 731-0008 *Contact:* Paul G. Koven, President
2. **DEVICE IDENTIFICATION.** *Trade Name:* Model HD-800 Tubing Blood Flow Meter. *Common Name:* Doppler Blood Flow Detector. *Classification Name:* Cardiovascular Blood Flowmeter, 74-DPW.
3. **PREDICATE DEVICE.** Transonic Systems Inc., Transonic Flowmeter--Models HT107, HT207, and 311--K872048, SE decision 6/21/88.
4. **DEVICE DESCRIPTION.** *General:* The subject device is a compact, continuous-wave Doppler ultrasound blood velocity detector equipped with four interchangeable clamp-on transducers for attachment to extracorporeal tubing. All transducers operate at a nominal frequency of 2.5 MHz and vary according to the internal diameter of the tubing in use and the volume flow range to be measured. *Operation:* The system provides an LCD display of mean volume blood flow through the insonated tubing in liters per minute or milliliters per minute averaged over the last three seconds and updated every 0.6 second. Volume flow is calculated by deriving flow velocity from the Doppler shift frequency using the standard formula and then multiplying the velocity by the diameter of the tubing in use. Audible and LED alarms are provided for disconnection of the transducer, excessive bubbles, flow exceeding measurement limits, cessation of flow exceeding 1 second or insufficient flow to permit measurement, and low battery power. *Power:* 15 volts DC. By AC adaptor or ten 1.5V AA batteries, as preferred.
5. **INTENDED USES.** The Model MD-800 is intended for the measurement of volume blood flow through extracorporeal tubing during the performance of hemodialysis and cardiopulmonary bypass procedures.
6. **COMPARISON WITH PREDICATE DEVICE.** Both devices are Doppler ultrasound systems designed to measure volume blood flow. The only significant differences are that the predicate device is supplied with a more extensive variety of ultrasound transducers and is recommended for intraoperative use as well as extracorporeal volume blood flow measurement. Also, the predicate device is AC rather than DC powered.
7. **PERFORMANCE DATA.** Measurement accuracy was evaluated by means of simultaneous comparison of values obtained with the subject device and an electromagnetic flowmeter using a flow phantom in which pig blood is pumped through vinyl chloride tubing at known flow rates. The maximum variance was 0.06 liters per minute. Doppler sensitivity was evaluated by determining the signal-to-noise ratio at minimum flow rates. Bubble detection capability was also determined using a flow phantom. Acoustic output was measured according to established standards and guidelines and reported following Track 1.



NOV 24 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paul G. Koven
President
Koven Technology Incorporated
300 Brookes Drive
Suite 105
Hazelwood, MO 60342-2746

Re: K982986
Model HD-800 Tubing Blood Flow Meter
Regulatory Class: II/21 CFR 870.2100/21 CFR 870.2120
Product Code: 74 DPW/74 DPT
Dated: August 17, 1998
Received: August 26, 1998

Dear Mr. Koven:

We have reviewed your Section 510(k) 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 Model HD-800 Tubing Blood Flow Meter, as described in your premarket notification:

Transducer Model Number

T-0110-1/4
T-0110-3/8
T-0110-1/2
T-0110-1/4 TO

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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:

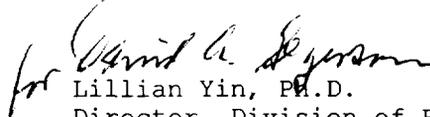
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982986

Device Name: Model HD-800 Tubing Blood Flow Meter

Indications For Use: The Model HD-800 Tubing Blood Flow Meter is indicated for the measurement of volume blood flow through extracorporeal tubing during the performance of hemodialysis and cardiopulmonary bypass procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982986

Prescription Use x
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

510(k) Number (if known) K982986

Device Name: HD-800 Tubing Blood Flow Meter

Transducer : 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 (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| 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: * Extracorporeal Use Only

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K982986

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

510(k) Number (if known) K982986

Device Name: HD-800 Tubing Blood Flow Meter

Transducer : T-0110-1/4

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 (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| 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) | | | | | | | | | | |

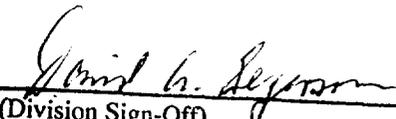
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT and Radiological Devices
 510(k) Number K982986

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

510(k) Number (if known) K982986

Device Name: HD-800 Tubing Blood Flow Meter

Transducer : T-0110-3/8

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

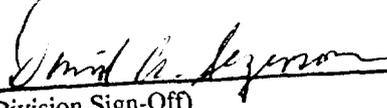
| Clinical Application | Mode of Operation | | | | | | | | | |
|-------------------------------|-------------------|---|---|-----|-----|---------------|-------------------|------------------------|--------------------|-----------------|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| 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: * Extracorporeal Use Only

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Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K982986

Prescription Use (Per 21 CFR 801.109)

00027

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

510(k) Number (if known) K982986

Device Name: HD-800 Tubing Blood Flow Meter

Transducer : T-0110-1/2

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 (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| 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) | | | | | | | | | | |

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Additional Comments: * Extracorporeal Use Only

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Legman
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT, **00029**
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K982986

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

510(k) Number (if known) K982986

Device Name: HD-800 Tubing Blood Flow Meter

Transducer : T-0110-1/4T0 (Medisys)

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 (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| 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: * Extracorporeal Use Only

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K98298600028