2. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, by:

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On: March 10, 1998

2.1 Device Identification & Substantial Equivalency Claims

Table 2-1 summarizes the Device Identification and Substantial Equivalency Claims for the Transonic HD01-CO Cardiac Output Monitor.

Trade name →	TRANSONIC HD01-CO HEMODIALYSIS CARDIAC OUTPUT MONITOR
Common name →	Hemodialysis cardiac output monitor
Devices in this model family claimed →	Cardiac output monitor
Model Name →	HD01-CO
Legally marketed device to which SE is claimed →	American Edwards Lab's COC-1 Thermodilution Cardiac Output Computer.

Table 2-1: Device Identification and Substantial Equivalency Claims

2.2 Device Description.

The HD01 family of devices use transit-time ultrasound principles to measure blood flow and to register sound velocity indicator dilution curves. Standard Stewart-Hamilton equations are employed for the various calculations. Portions of these technologies are covered under Transonic Systems' USA and worldwide patents and pending patents.

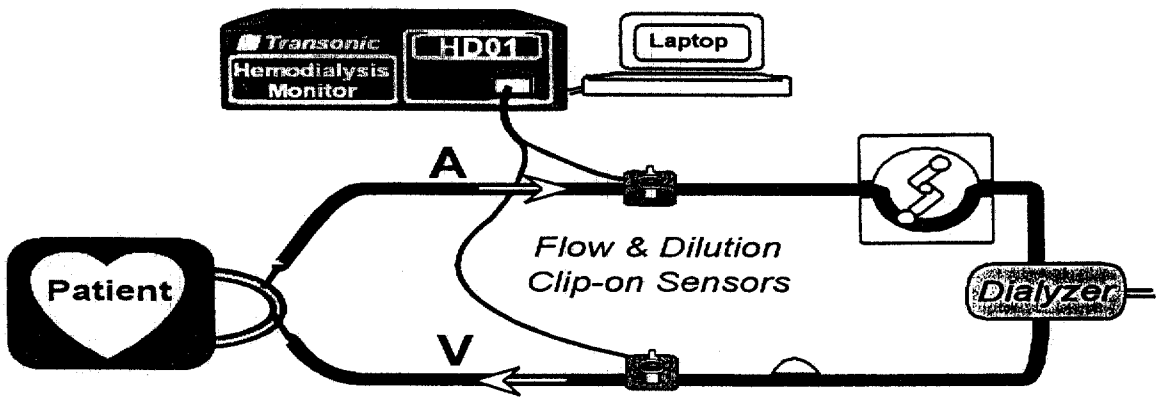

Figure 2-1: System block diagram of the HD01 flow/dilution meter.

All Transonic HD01-series hemodialysis monitor devices consist of the following components (see **Figure 2-1**):

- *HD01 Flow/Dilution meter (or HD01 meter)* - This is a bench-top, line-powered electronic measurement unit with a serial RS232 data output link, and connections for ultrasonic flow/dilution sensors. (See **Figure 1-1**, **Figure 1-3**, and **Figure 1-4** on pages 1-1 through 1-3.

- *Dual flow/dilution sensor* - these are two plastic-encased ultrasonic sensors connected to the HD01 unit (see **Figure 1-1** on page 1-1). One sensor is individually referred to as the "arterial sensor" and is clipped to the patient's arterial hemodialysis line, while the other (the "venous sensor") is clipped to the venous hemodialysis line.

- *Monitor software (also referred to as software)* - This is computer software installed on an IBM-PC compatible computer running Windows or Windows 95. The software receives signal data produced by the HD01 meter and performs the various device function calculations (QA, QB, R%, and CO - see **Table 1-1** on page **1-1**).

The various HD01 devices differ in their indications for use through the supplied software routines. The following section discusses the software routines for Cardiac Output measurement.

2.3 Cardiac Output (CO) Measurement Technique

The Cardiac Output (CO) measurement technique requires the following HD01 sensor configuration and injectable indicator solution:

- ultrasonic dilution sensors clipped to the venous and arterial dialysis lines
- venous and arterial blood lines are connected as normal (not reversed) to the dialysis needles
- Body temperature (37°C) 0.9% saline solution

The CO measurement starts by calibrating the venous indicator dilution sensor. This is done by injecting a 10 ml saline bolus into the venous bubble trap. Since all of the bolus volume passes through the venous sensor, the following equation determines that sensor's sensitivity to indicator dilution:

$$K = \frac{V_{cal}}{Q_b * S}$$

where:

V_{cal} = volume of calibration bolus injected (ml)
Q_b = mean dialysis blood flow (ml/min)
K = concentration scaling factor (ppm/millivolt)
S = area of ultrasonic dilution curve (volt - sec)

Like the calibration, the actual CO measurement requires a saline injection into the venous dialysis line. The difference is that the measurement bolus is larger (30 ml), and it is injected at a location close to the patient. This bolus circulates through the cardiopulmonary system, a fraction of it returns to the arterial sensor, and the arterial sensor records the indicator dilution.

Finally, the HD01-CO software integrates the indicator dilution curve and calculates Cardiac Output from the following formula:

$$Q_{CO} = \frac{V_{meas}}{KS}$$

where:

Q_{CO} = cardiac output (ml/min)
V_{meas} = volume of injected bolus (ml saline)
K = concentration scaling factor (ppm/mv)
S = area of dilution curve = 1 volt sec

2.4 Intended Uses of the HD01 Cardiac Output Monitor

The HD01-series monitors are intended for use by trained medical personnel, for assessment of a patient's hemodynamic condition through cardiac output determination while undergoing hemodialysis treatment

For use only by or on the order of a physician licensed by law to use or order the use of this device.

Contraindications:

- The H4D dual flow/dilution sensor is for clip-on use only onto the dialysis tubing specific to the flow sensor, and never on arteries or veins.
- Safe and effective use of these devices depend on correct application technique, adequate precaution and readiness for emergencies.
- Caution: Federal law restricts this device to use by or on the order of a physician.

2.5 Summary of Technological Comparison with Predicate Device.

The Transonic HD01-CO Cardiac Output Monitoring device uses ultrasonic velocity measurements to measure indicator dilution.

American Edwards Lab's COC-1 Thermodilution Cardiac Output Computer uses the same Stewart-Hamilton indicator dilution equations, but measures indicator dilution through blood temperature changes.

2.6 Safety

The HD01-series devices meet all requirements of:

- UL-544 & IEC 601-1
- The European Economic Council Directive 89/336/EEC (electromagnetic compatibility)
- Ultrasound intensity levels applied by the H4D clip-on flow/dilution sensors are 25 to 40 dB below FDA CDRH maximum pre-amendment levels for "Fetal Doppler and Other" applications, and have passed FDA review under 510(k) #K960817

All procedures required to execute these measurements (saline injection, change in blood line connections) are standard clinical procedures in which hemodialysis nurses are well trained.

The HD01 procedures introduce no extra components into the hemodialysis circuit, and at no time is patient sterility compromised.

2.7 Effectiveness.

Table 2-2 lists printed publications that document the effectiveness of the HD01-CO cardiac output measurements, while **Table 2-3** compares HD01-CO effectiveness with that of the predicate device. Appendix D contains copies of all these papers.

1. Krivitski, N.M., "Novel Method to Measure Access Flow During Hemodialysis by Ultrasound Dilution Technique," ASAIO Journal, Vol. 41, p. M741-M745, 1995.

2. Krivitski, N.M., "Cardiac Output Measurement in Extracorporeal Systems by Ultrasound Dilution," ASAIO Journal Abstracts, p. 82, 1994.

3. Nikiforov, U.V., Kisloukhine, V.V., Chaus, N.I., "Validation of a New Method to Measure Cardiac Output During Extracorporeal Detoxification," ASAIO Journal Vol. 42, No. 5, p. M903-M905, 1996.

4. Kisloukhine, V.V, Dean, D.A., "Validation of a Novel Ultrasound Dilution Method to Measure Cardiac Output During Hemodialysis," ASAIO Journal, Vol. 42, No. 5, p. M906-M907, 1996.

5. Sands, J.J., Glidden, D., Miranda, C., "Access Flow Measured during Hemodialysis," ASAIO Journal, Vol. 42, No. 5, p. M530-M532, 1996.

6. Depner, T.A., Eder, L.A., "Changes in Access Blood Flow and Appearance of Recirculation during Hemodialysis," XIIIth International Congress of Nephrology Abstracts, p. 570, 1995.

7. Chaus, N.I, Kislukhin, V.V., Dzemeshkevich, S.L., Zhidkov, I.L., "Comparison of Sound Velocity, Impedance, and Optical with Thermal Methods for Cardiac Output," FASEB Journal, Vol. 11, No. 3, Abstract #2872, 1997.

8. Depner, T.A. & Krivitski, N.M., "Influence of Access Blood Flow (AF) on Systemic Blood Flow in Hemodialysis Patients," JASN. Vol.8, p. 155A, 1997.

Table 2-2: Cardiac Output Theory, Validation & Application Reports (Appendix D contains copies of all these papers)

	American Edwards COC-1 Thermodilution Cardiac Output Computer with Swan Ganz catheter	**Transonic HD01-CO with H4D sensor**
Indications	For assessment of a patient's hemodynamic condition through cardiac output determination	For assessment of a patient's hemodynamic condition through cardiac output determination while undergoing hemodialysis
Contra-indications	Not for use on patients with recurring sepsis, patients with a hypercoagulable state, or (for some catheters) patients sensitive to heparin	Clip-on sensors for use only on patient-connected hemodialysis bloodlines, never on arteries or veins.
Safety		
Measurement Method	The medical community raises serious concerns on a possible higher co-morbidity when Swan-Ganz catheters are used.	Saline injection into HD venous line. No separate indwelling devices: measurement uses sensor clamped-on to hemodialysis line
Procedural Dangers to Patient	Inject saline directly into vena cava. Sterile indwelling catheter must be entered into a vein, passed through the heart (through two heart valves) and into the pulmonary artery	Measurement consists of procedures which are standard in hemodialysis administration
Electrical	Input leakage current < 50 μA Patient leakage current < 10 μA Patient isolation > 2500V 10 μA safety-trip electronics to protect against thermal sensor insulation failure	Input leakage current < 50 μA Patient leakage current < 10 μA Patient isolation > 2500V Double insulated sensor electronics, plus wall of sterile tubing.
Ultrasonic	Not applicable	Ultrasonic irradiation level is 320 times lower than CDRH permitted level for peripheral vessel use. (Already FDA-cleared under 510(K) #K960817)
Effectiveness		
Bench Accuracy	In vitro: ±3% (0-4°C), or ±4% (19-25°C) + thermistor-related sensing errors	From all sources: ± 5 %
Bench Repeatability	Computational variations: ± 3% Variations from all sources: Not Specified	Computational variations: Negligible Variations from all sources: ± 4%
In Vivo Accuracy	± 20% (inferred from literature)	±20%
Cardiac Output Measurement Range	0.1 to 20 L/min	1 to 20 L/min

Table 2-3: Comparisons between the HD01 devices and the predicate device

2.7 Summary of Safety and Effectiveness.

The bench and clinical tests cited above demonstrate that, like the predicate devices, the HD01-CO device is safe and effective for its intended use.

Cornelis J. Drost, President
Transonic Systems Inc.
34 Dutch Mill Road
Ithaca, NY 14850

March 10, 1998
Preparation date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1998

Mr. Cornelius J. Drost
President
Transonic Systems Inc.
34 Dutch Mill Road
Ithaca, New York 14850-9787

Re: K980906
Model HD01-CO Hemodialysis Monitor
for Cardiac Output
Dated: July 7, 1998
Received: July 8, 1998
Regulatory Class: II
21 CFR 876.5820/Procode: 78 MQS

Dear Mr. Drost:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Transonics Systems Inc. HD01-Series Hemodialysis Monitors, as described in your premarket notification:

Device Model	Transducer Model Number
HD01-CO	H4D FLOW/DILUTION SENSOR

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 for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 April 1995, "Format and Content of Diagnostic Ultrasound Special 510(k)." 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 "dsmo@fdadr.cdrh.fda.gov".

If you have any questions regarding the content of this letter, please contact Mr. Richard J. Williams at (301) 594-1220.

Sincerely yours,

for David A. Seymour

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

Enclosures

510 (k) NUMBER (IF KNOWN) : K980906

DEVICE NAME: Transonic Hemodialysis Monitor, Cardiac Output, Model HD01-CO

INDICATIONS FOR USE:

The HD01-CO monitor is intended for use by trained medical personnel, for assessment of a patient's hemodynamic condition through estimation of cardiac output while undergoing hemodialysis treatment in a non-critical care setting.

For use only by or on the order of a physician licensed by law to use or order the use of this device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980906