



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 20 2004

em-tec GmbH  
c/o Mr. Stefan Preiss  
Responsible Third Party Official  
TUV Product Service  
1775 Old Highway 8  
New Brighton, MN 55112-1891

Re: K040909  
Trade Name: Sono TT Ultrasonic Flowcomputer  
Regulation Number: 21 CFR 870.2100  
Regulation Name: Cardiovascular Blood Flowmeter  
Regulatory Class: Class II (two)  
Product Code: DPW  
Dated: April 6, 2004  
Received: April 8, 2004

Dear Mr. Preiss:

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 Sono TT Ultrasonic Flowcomputer, as described in your premarket notification:

CT3/8x3/32"A

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>".

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If you have any questions regarding the content of this letter, please contact Kachi Enyinna at (301) 443-8262.

Sincerely yours,

*Bram D. Zuckerman*

*BZ* Bram D. Zuckerman, M.D.  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K040909

Device Name: Sono TT Ultrasonic Flowcomputer

Indications for Use:

The Sono TT Ultrasonic Flowcomputer in combination with an ultrasonic clamp-on Transducer is indicated for the contact less volumetric measurement of liquid flowing through tubing systems. The measurement principle is the ultrasound transit-time method.

The medical use of the device is appropriate in the following extracorporeal procedures:

- Cardio-pulmonary bypass, membrane-oxygenation, hemodialysis, hemofiltration, plasmapheresis
- Perfusion, infusion, transfusion
- Several shunt-applications

The Flowcomputer can be used in intensive care units and operating rooms. For the patient's safety the device is to be operated only by qualified medically-trained personnel.

**Contraindication:**

This device has been built and sold only for the intended purpose mentioned above. The supplied measured values serve only to monitor the flow rate of the device in use (e.g. oxygenator, blood pump). These values are not to be used either for an evaluation of a patient's status or for the basis of medical actions without the confirmation of another approved medical measurement procedure.

It is the operator's responsibility to use the device as described in the User's Manual and in any of its following revision releases. The use of clinical procedures and techniques lie in the physician's area of responsibility.

Prescription Use Yes AND/OR Over-The-Counter Use No  
 (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dana R. Kuchner  
 Division Sign-Off  
 Division of Cardiovascular Devices

510(k) Number K040909