DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 29, 2015

Transonic Systems Inc.
Naveen Thuramalla
VP, Engineering & Clinical Studies
34 Dutch Mill Road
Ithaca, NY 14850

Re: K134051
Trade/Device Name: Transonic ELSA System
Regulation Number: 21 CFR 870.1435
Regulation Name: Computer, Diagnostic, Pre-programmed, Single-function
Regulatory Class: II
Product Code: DXG
Dated: December 26, 2014
Received: December 29, 2014

Dear Naveen Thuramalla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K134051

Device Name
ELSA (Extracorporeal Life Support Assurance) System

Indications for Use *(Describe)*

The intended use of the ELSA system is to provide clinically relevant data to healthcare providers treating neonatal, pediatric, adult patients with arterial and venous lines for routine monitoring of diagnostic parameters: Delivered Flow; Recirculation; Oxygenator Blood Volume and other associated hemodynamic parameters.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Submitter's Name & Address: Transonic Systems Inc
34 Dutch Mill Road,
Ithaca, NY 14850

Contact Person & Telephone: Naveen Thuramalla
607-257-5300 (*326)

Date Summary Prepared: January 28, 2015

Device Name: Classification Name: Computer, Diagnostic, Pre-programmed, Single-function, 21 CFR 870.1435.
Product Class and Code: DXG and Class II
Classification Panel: Cardiovascular
Common/Usual Name: Extracorporeal, Diagnostic monitor
Proprietary Name: Transonic ELSA System

Predicate Devices: K960817: HD01-SERIES
TRANSONIC HEMODIALYSIS MONITOR

K113821: TRANSONIC COstatus Cardiac Output System

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Transonic Systems Inc. intends to introduce into interstate commerce the Transonic ELSA system, which is an apparatus based on transit time ultrasound indicator dilution techniques that provides clinically relevant data to healthcare providers treating patients undergoing Extracorporeal Life Support Procedures. The clinically relevant data (such as delivered flow, recirculation, oxygenator blood volume and other related hemodynamic parameters), shall indicate the efficacy of such procedures and quantify the patient's hemodynamic status. These patients could be in the intensive care units (ICU), operating room (OR) or other such environments.

Components:

ELSA system consists of the following components:

Model/Part #	Description
HCE101	ELSA monitor/meter
HnFX	- Sensor pair configuration (H6FX; H7FX; H9FX. Other sizes such as H5FX are possible depending on the size of the tubing used by clinicians with extracorporeal circuits). - Single head sensor configuration could also be used with ELSA system.
HFW1000	Fluid Bag Warmer
HCED01	Data Transfer Module

Substantial Equivalence:

The Transonic ELSA System for use with patients undergoing extracorporeal life support procedures is similar to the HD01- Series Transonic Hemodialysis Monitor (K960817) which is used in the diagnostic assessment of delivered blood flow, and recirculation. Both systems use clamp-on sensors placed on standard extracorporeal circuits to obtain diagnostic measurements.

Oxygenator blood volume (OXBV) measurement by ELSA system is similar to Central blood volume (CBV) measurement by Transonic COstatus Cardiac Output System (K113821). Both represent the volume between point of injection and point of detection of the indicator. The two systems are also similar in terms of touch screen device, on-screen user instructions, and measurement trend plots on the screen.

Both HD01 and COstatus devices are manufactured and marketed by Transonic Systems Inc. All three systems (ELSA, HD01 and COstatus) are based on transit time ultrasound dilution principles.

The difference between COstatus system and the proposed ELSA system is that the ELSA system would allow use of the system with patients being treated on extracorporeal life support procedures while COstatus system could be used with patients with in-situ arterial and venous catheters. COstatus measured CBV is the volume between injection site and recording site and includes the volume of blood in the heart, lungs and large vessels. Whereas, ELSA measured OXBV is the volume between injection site and recording site and includes the volume of blood in the oxygenator and any tubing in between the sensors.

The difference between ELSA system and the HD01 is that the ELSA system would be used with patients undergoing extracorporeal life support procedures while HD01 would be used with patients undergoing dialysis procedures.

These differences do not raise any new issues of safety or effectiveness regarding the use of Transonic ELSA System.

Bench Testing:

The ELSA system (HCE101) is deemed to be safe and effective based on the safety testing conducted in accordance with the IEC 60601-1 standard and the electromagnetic compatibility test report.

In addition, bench testing was conducted by Transonic Systems Inc. and the validation report can be found in Section 18 of this 510(k) submission. Prior to shipment, the finished product will be tested and must meet all required release specifications before distribution. The array of testing required for release includes, but are not limited to; physical testing and visual examination (in-process and finished product). The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures that ensure the product's performance parameters conform to the product design specifications. The testing instruction records for each of the individually required procedures are approved, released, distributed, and revised in accordance with document control cGMP's.

Conclusion:

Based on the information provided above, we conclude that the Transonic ELSA system is substantially equivalent to the predicate devices.