K080116

SEP 0 8 2008

510(k) Summary of Safety and Effectiveness in Accordance with SMDA'90

May 17, 2008

Transonic Systems Inc.
34 Dutch Mill Rd
Ithaca, NY

Telephone: (607) 257-5300
Fax: (607) 257-7256

Contact: Mark S. Alsberge

Product Name: Transonic COstatus System

Classification name: Single-Function, Preprogrammable Diagnostic Computer
Circulatory System Devices Panel
Class II, 74 DXG
21 CFR §870.1435

SUBSTANTIAL EQUIVALENCE[1] TO:

510 (k) Number	Name	Applicant
K023960	LiDCOplus Hemodynamic Monitor	LiDCO Limited
K980906	Transonic Hemodialysis Monitor, Cardiac Output (Measurement)	Transonic Systems Inc.

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 COstatus System which is an apparatus using an indicator dilution technique for the measurement fluid volumes. The system is a variation of the HD01 system which can measure CO during a Hemodialysis treatment. The COstatus system uses a peristaltic pump to draw a small volume of blood passed the sensors rather than using a Hemodialysis circuit. The system can thereby be used on any patient with arterial and venous access lines.

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[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA - regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

Material:

The components of the Transonic COstatus System are made of materials, which have been tested in accordance with the ISO Standard 10993 appropriate to their patient contact and therefore suitable for the intended use of this product.

This COstatus system consists of the following components;

HCM101 Cardiac output meter
HC2T Sensors
ADT2005D AV-Loop tubing set
ADT2005E AV-Loop tubing set
HCS3002 Sensor Tubing Adaptor
HCP01 AV-Loop Pump
HFW1000 Fluid Warmer
HCR01 Printer
HCMD01 Data Transfer Module

Substantial equivalence:

The Transonic COstatus System is similar in materials, form and intended use to the Transonic Hemodialysis Monitor, Cardiac Output HD01 system which can measure CO during a Hemodialysis treatment currently marketed by Transonic Systems Inc. cleared by the under K980906 and the LiDCOplus Hemodynamic Monitor cleared by K023960. The difference between COstatus system and the HD01 is that the COstatus system uses a peristaltic pump to draw a small volume of blood passed the sensors rather than using a Hemodialysis circuit. The system can thereby be used on any patient with arterial and venous access lines. The system can be used on patients in other clinical settings such as an ICU. The LiDCOplus Hemodynamic Monitor also uses a small peristaltic pump, but uses lithium chloride as an indicator whereas the COstatus uses saline. The LiDCOplus Hemodynamic Monitor does not return withdrawn blood to the patient, but the COstatus runs as a closed loop returning all drawn blood. These differences do not raise any new issues of safety or effectiveness regarding the Transonic COstatus System.

Safety and Effectiveness:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, 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 products 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 8 2008

Transonic Systems, Inc.
c/o Mr. Mark S. Alsberge
VP Medical and Regulatory Affairs
34 Dutch Mill Road
Ithaca, NY 14850-9787

Re: K080116
Trade/Device Name: Transonic COStatus System
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: September 4, 2008
Received: September 4, 2008

Dear Mr. Alsberge:

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.

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 letter will allow you to begin marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): _K080116_____
Device Name: ___Transonic COSTATUS System _____
Indications for Use:

The Transonic COSTATUS System is indicated for use in patients greater than or equal to 2 years old (child, adolescent, adult) with arterial and venous lines in the diagnostic assessment of cardiovascular status including cardiac output and associated hemodynamic parameters.

Prescription Use ____Yes_____ AND/OR Over-The –Counter Use ____NO___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurence of CDRH, Office of Device Evaulation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080116