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

April 17, 2002

Transonic Systems Inc.
34 Dutch Mill Rd
Ithaca, NY

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

Contact: Mark S. Alsberge

Product Name: Transonic Flow-QC® Set

Classification name: Hemodialysis Accessories, Blood Circuit
Gastroenterology and Urology
Class II, 78KOC
21 CFR §876.5820

SUBSTANTIAL EQUIVALENCE[1] TO:

510 (k) Number	Name	Applicant
K002816	Transonic Hemodialysis Flow Reverser	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 Flow-QC® Sets which are Hemodialysis extension sets for connection into standard Hemodialysis circuits. These sets provide tubing segments of consistent material and wall thickness to which our HD01 Hemodialysis system can be calibrated. They also provide an injection port for making cardiac output measurements with the HD01 system.

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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 Transonic Flow-QC® Sets are made of materials which have been tested in accordance with the ISO Standard 10993 and therefore suitable for the intended use of this product.

Substantial equivalence:

The Transonic Flow-QC® Sets is similar in materials, form and intended use to the Transonic Hemodialysis Flow Reverser currently marketed by Transonic Systems Inc. and cleared under K002816. The minor difference between Flow-QC Sets and the Transonic Hemodialysis Flow Reverser are that the Flow-QC Sets do not have a Flow reversing valve present in the Flow Reverser. This difference does not raise any new issues of safety or effectiveness regarding the Transonic Flow-QC® Sets.

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 ANSI/AAMI standard "*American National Standard for Hemodialyzer Blood Tubing*" RD17- 1994 was followed for the design and will continue to be followed for the production and quality assurance testing of this device.

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

AUG 12 2002

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

Re: K021571
Trade/Device Name: Transonic Flow-QC® Sets
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 MQS
Dated: May 8, 2002
Received: May 14, 2002

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 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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____
Device Name: Transonic Flow-QC® Sets
Indications for Use:

The Transonic Flow-QC Set is indicated for use as part of an extracorporeal blood circuit for hemodialysis when the Transonic HD01 System will be use to make access flow, recirculation, and/or cardiac output measurements during the patient's hemodialysis treatment.

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

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021571

(Optional Format 3-10-98)

(Posted July 1, 1998)