K030449

CAPIOX® SX10 Hardshell Reservoir

MAR 0 5 2003

Submitter Information:
This Premarket Notification is submitted by:

Garry A. Courtney, MBA, RAC
Telephone: 1-800-283-7866, Ext. 7420

This Premarket Notification is submitted on behalf of:

Ashitaka Factory of Terumo Corporation
150 Maimaigi-cho
Fujinomiya city, Shizuoka Pref.
Japan 418-0015

Device Names:

Proprietary Name:	CAPIOX® SX10 Hardshell Reservoir
Common Name:	Blood Reservoir
Classification:	CPB Reservoirs are classified as Class II devices.

Predicate Device:
The CAPIOX® SX10 Hardshell Reservoir is substantially equivalent in intended use, materials, design, technology and principles of operation, and performance to the CAPIOX® SX 10 Hardshell Reservoir that was cleared for marketing under Premarket Notification K991973.

Intended Use:
The CAPIOX® SX10 Hardshell Reservoir is a hardshell reservoir used to store blood during extra-corporeal circulation from both the venous line and the cardiotomy line during cardiopulmonary bypass procedures lasting up to 6 hours. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The Hardshell Reservoir may also be used with vacuum-assisted venous return procedures during cardiopulmonary bypass procedures lasting up to 6 hours.

Principles of Operation and Technology:
The CAPIOX® SX Hardshell Reservoir is used as a blood storage device during cardiopulmonary bypass procedures. Venous blood enters the reservoir via gravity, or by way of external vacuum that may be applied to the reservoir.

Venous blood that is drawn from the patient enters the device through the venous blood inlet port. The blood passes through a defoamer to remove air from the blood and through a filter for removal of particulates.

Blood may also be suctioned into the reservoir from the cardiotomy field. This blood enters the device through the cardiotomy blood suction ports that are located on the lid assembly. As with the venous blood, the *cardiotomy* blood passes through a defoamer to facilitate air removal, and then through a filter for removal of particulates. Air is also removed from the blood due to its tendency to rise within a liquid medium.

Blood exits the device via gravity through the blood outlet port and is pumped through the remaining cardiopulmonary bypass circuit.

Design and Materials:

The *design* of the CAPIOX® SX10 Reservoir consists of a hard casing reservoir containing blood filters. It has a rotatable venous blood inlet port that permits minimizing tubing lengths, which could result in lower circuit priming volumes. The total capacity of the reservoir is 3000 mL.

The CAPIOX® SX10 Hardshell Reservoir contains a defoamer and a screen filter in the venous blood inlet section. The defoamer resides in the upper part of the reservoir, thus permitting blood to reside in the lower section of the reservoir.

The cardiotomy section of the SX10 Reservoir contains a defoamer and a "sock-like" filter to facilitate air removal and the removal of particulates from suctioned blood entering the reservoir.

The generic *materials* used in the CAPIOX® RX Hardshell Reservoir are polycarbonate, polypropylene, polyethylene terephthalate, silicone, polyvinyl chloride, polyurethane, nylon, stainless steel, ceramic, and polymer coating solutions.

Performance Evaluations:

The performance of the CAPIOX® SX10 Hardshell Reservoir is substantially equivalent to the performance of the predicate (unmodified) device. The following tests were conducted to demonstrate equivalence in performance:

- Filter Defoaming
- Pressure Drop
- Filtration Efficiency
- Effects Upon Cellular Blood Components
- Pressure Integrity Testing
- Fluid Breakthrough Time

Substantial Equivalence Comparison:
The CAPIOX® SX10 Hardshell Reservoir is substantially equivalent to the predicate SX10 Hardshell Reservoir device as follows:

Intended Use: The modified SX10 Hardshell Reservoir and the predicate (unmodified) SX10 Hardshell Reservoir share the same exact intended uses. Each is used to store blood during extra-corporeal circulation from both the venous line and the cardiotomy line during cardiopulmonary bypass procedures lasting up to 6 hours.

Each of the reservoirs (modified and unmodified) contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The (modified) SX10 Hardshell Reservoir and the (unmodified) SX10 Hardshell Reservoir each may also be used with vacuum-assisted venous return procedures during cardiopulmonary bypass procedures lasting up to 6 hours.

Principles of Operation and Technology: The (modified) SX10 Reservoir and the predicate SX Reservoirs each utilize gravity and/or vacuum to draw blood into the device, and each has filters and defoamers that facilitate the removal of particulate and air, respectively. Air is also removed from the circulating blood within both devices due to the tendency of air to rise within a liquid medium.

Design and Materials: The design and the materials of the (modified) SX10 Reservoir and the (unmodified) SX10 Reservoir are essentially the same. Differences include a "sock-like" cardiotomy filter in the modified device vs. a "pleated" filter design in the predicate device; and the addition of channeling groves at the base of the reservoir in the modified device that are not present in the unmodified predicate device.

The materials used in the two devices are identical except that the modified device contains Terumo's X-Coating polymer, which is not present on the unmodified SX10 Hardshell Reservoir. The X-Coating polymer has been applied to multiple Terumo products that have been reviewed and cleared for marketing by the United States Food and Drug Administration.

Performance: Comparison studies of the performance of the (modified) SX10 Hardshell Reservoir and the predicate SX10 Reservoir were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the devices.

Substantial Equivalence Summary:
In summary, the (modified) CAPIOX® SX10 Hardshell Reservoir and the predicate (unmodified) CAPIOX® SX10 Reservoir are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Biocompatibility studies were conducted as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- Terumo has conducted material characterization studies – including physico-chemical profiles of aged and non-aged devices to demonstrate stability of the materials, and found the materials to be stable over the expiry of the product.

- The polymer coating materials that are applied to the blood-contacting surfaces of the device were also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

Conclusion:

In summary, the CAPIOX® SX10 Hardshell Reservoir is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate (unmodified) CAPIOX® SX10 Hardshell Reservoir (K991973).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 5 2003

Terumo Medical Corporation
c/o Mr. Gary A. Courtney
125 Blue Ball Road
Elkton, MD 21921

Re: K030449
CAPIOX SX10 Hardshell Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: February 7, 2003
Received: February 11, 2003

Dear Mr. Courtney:

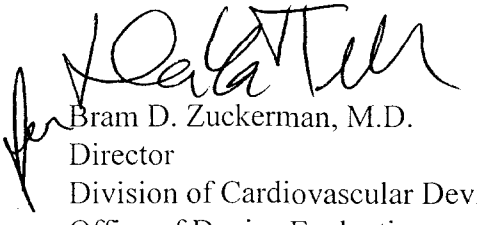
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21CFR 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,



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

Enclosure

510(k) Number (if known):

Device Name: **CAPIOX® SX10 Hardshell Reservoir**

Indications For Use:

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Garry A. Courtney 02/07/03

Garry A. Courtney, MBA, RAC
Sr. Regulatory Affairs Specialist
Terumo Cardiovascular Systems

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030449