

K991973

SEP 3 1999

**SECTION II: SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
PERTAINING TO SUBSTANTIAL EQUIVALENCE**

Proprietary Device Name: CAPIOX® SX10 Hardshell Reservoir

Classification Name: Cardiopulmonary bypass blood reservoir, defoamer, cardiotomy suction line filter

Reason for Submission:

Addition of the use of vacuum-assisted venous drainage to the intended use of the hardshell reservoir.

Intended Use:

The CAPIOX® SX10 Hardshell Reservoir is a hardshell reservoir used to store blood during extracorporeal 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 is also used in the vacuum-assisted venous return technique during cardiopulmonary bypass procedures lasting up to 6 hours.

Description:

CAPIOX® SX10 Hardshell Reservoir has a rotatable venous blood inlet port to permit minimizing tubing lengths which could result in lower circuit priming volumes.

The 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 permitting blood to reside in the lower section of the reservoir while not in constant contact with the defoamer. The total capacity of the reservoir is 3000 mL.

The cardiotomy section of the hardshell reservoir contains a defoamer and a cardiotomy filter to facilitate gas bubble removal and the removal of particulates/emboli from suctioned blood entering the reservoir.

Substantial Equivalence:

The CAPIOX® SX10 Hardshell Reservoir is substantially equivalent to the CAPIOX® SX Hardshell Reservoir (K982223) as follows:

Section II. Summary of Safety and Effectiveness Information

Additional Safety Information:

- Pyrogen Testing
- Sterilization conditions have been validated to provide a Sterility Assurance Level (SAL) of 10 to the negative sixth.
- Ethylene Oxide residuals 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).
- Manufacturing control testing
- Blood contacting materials were tested in accordance with 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 contact duration).

Section II. Summary of Safety and Effectiveness Information

The Summary of Safety and Effectiveness Information Pertaining to Substantial Equivalence was prepared on May 13, 1999.

Prepared by: Garry A. Courtney
Regulatory Affairs Specialist

Prepared for: Terumo Medical Corporation
2101 Cottontail Lane
Somerset, NJ 08873



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 3 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gary A. Courtney
Regulatory Affairs Associate
Terumo Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
Elkton, MD 21921

Re: K991973
CAPIOX® SX10 HARDSHELL RESERVOIR
Regulatory Class: III (Three)
Product Code: 74 DPN, 74 DTN
Dated: June 6, 1999
Received: June 11, 1999

Dear Mr. Courtney:

We have reviewed your Section 510(k) 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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 and additionally 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991973

Device Name: CAPIOX® SX10 Hardshell Reservoir

Indications For Use:
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The Hardshell Reservoir is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass procedures lasting up to 6 hours

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991973

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)