K040023

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SECTION II
510(k) SUMMARY AND CERTIFICATION

CAPIOX® Flexible Venous Reservoir

Submitter Information:
This premarket notification is submitted by:

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Date of Preparation: December 23, 2003

Device Names:

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

Predicate Device:
The CAPIOX® Flexible Venous Reservoir is substantially equivalent in intended use, materials, design, technology and principles of operation, and performance to the Baxter/Bentley BMR1900G Venous Reservoir (w/ Duraflo Treatment).

Intended Use:
The CAPIOX Flexible Venous Reservoir is intended for use as a blood collection and storage device during cardiopulmonary bypass procedures. The device is intended for use in conjunction with blood-gas oxygenators in the extra-corporeal circuit.

The device may be used in procedures lasting up to six hours in duration.

Principles of Operation/Technology:
The CAPIOX® Flexible Venous Reservoir is used as a blood storage device during cardiopulmonary bypass procedures.

The reservoir bag is to be positioned at a level that is below patient level. When the bag is properly positioned, the blood that is drawn from the patient enters the reservoir via gravity into the blood inlet ports that are positioned at the base edge of the reservoir bag. As the patient's blood enters the device, it passes through a mesh filter that facilitates the removal of air from the blood. This removal of air via the mesh filter is accomplished when an air bolus makes contact with the mesh and is subsequently disintegrated.

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

Design and Materials:
The *design* of the CAPIOX® Flexible Venous Reservoir is one of a soft-shell casing that serves as a blood containment system within the bypass circuit.

The device is designed such that it contains a forked blood inlet port (Y-Connector) that will allow the entry of cardiotomy and venous blood. On the opposing side of the bag – along its base edge – is a blood outlet port, which allows for the blood's exit from the bag.

The top edge of the bag is characterized by a dual three-way stopcock assembly that is intended to facilitate the purging of air that could be contained within the stored blood. Additionally, the stopcock assembly may be used for the administration of drugs and/or necessary solutions used in bypass procedures.

A mesh filter is sealed to the inside of the bag, and is intended to facilitate the destruction of air bolus' that may be contained within the patient's blood.

The generic *materials* used in the CAPIOX® Flexible Venous Reservoir are polyvinyl chloride, polycarbonate, polyethylene, polyester, stainless steel, ABS, cyclohexanone and Terumo's *X-Coating*™ polymer solution.

Performance Evaluations:
The performance of the CAPIOX® Flexible Venous Reservoir is substantially equivalent to the performance of the predicate device – the Baxter/Bentley BMR1900G Venous Reservoir (w/ Duraflo Treatment). The following tests were conducted to demonstrate equivalence in performance:

- Effects Upon Cellular Blood Components
- Pressure Drop
- Air Handling Capability
- Prime Volume Evaluation
- Connector Pull Strength Evaluaton
- Mechanical Integrity

Substantial Equivalence Comparison:

The CAPIOX® Flexible Venous Reservoir is substantially equivalent to predicate Baxter/Bentley BMR1900G Venous Reservoir (w/ Duraflo Treatment), as indicated below:

Intended Use/Indications: The CAPIOX® Flexible Venous Reservoir and the predicate Baxter/Bentley BMR1900G Venous Reservoir (w/ Duraflo Treatment) share common intended uses.

Both devices are used as blood storage devices during cardiopulmonary bypass surgery. Each device is intended for use as a blood collection and storage device during cardiopulmonary bypass procedures. Furthermore, each device is intended for use in conjunction with blood-gas oxygenators in the extra-corporeal circuit.

A noted difference between the two devices with respect to *device indications* is that the predicate BMR1900G Reservoir is indicated for use in procedures when a heparin-treated blood path is desired. This noted difference is simply an attribute characteristic of the predicate device – and shall not be considered as safer and/or more effective than the proposed CAPIOX® Flexible Venous Reservoir.

Principles of Operation/Technology: The CAPIOX® Flexible Venous Reservoir and the predicate BMR1900G Reservoir utilize the exact same technology in their respective operations. With each device, the patient's blood enters the reservoir from the surgical field via gravity feed.

The blood enters each of the reservoirs via the blood inlet ports that are positioned along the base edge of the pliable bags. Upon entry into each of the bags, a patient's blood will pass through a screen mesh that will facilitate the removal of air from the blood. This process occurs when a bolus of air makes contact with the screen and is subsequently disintegrated.

Blood exits each of the devices via gravity through the blood outlet port and is subsequently pumped through the remainder of the cardiopulmonary bypass circuit.

Based upon the above-described *principals of operation*, it is concluded that the employed technology of the two devices is identical.

Design and Materials: The design of the CAPIOX® Flexible Venous Reservoir is equivalent to the predicate BMR1900G Reservoir. Both bags are soft-side venous reservoirs that can accommodate both venous and cardiotomy blood during a bypass procedure. Both bags contain a Y-Connector blood inlet port as well as a single-connector blood outlet port. Furthermore, both bags contain a screen mesh within the bag to facilitate air removal, as well as a dual stopcock air purging system at the upper edge of the bag. There are no significant or noted differences in design between the two bags.

The materials of construction of the two devices appear to be common with the noted exception of their respective blood-path coatings. Both bags are made of soft-sided plastics that allow for a pliable reservoir bag. Furthermore, both bags contain a polyester screen mesh and hard-plastic inlet and outlet ports for the blood. Generically, the materials appear to be the same between the two devices.

One notable difference in materials between the two devices is that the predicate BMR1900G Reservoir contains Baxter's (heparin-based) Duraflo treatment coating. The Terumo device does not contain a heparin-based coating, but rather, contains Terumo's X-Coating solution, which is intended to reduce the adhesion of platelets as blood circulates through the device.

It shall be noted that any differences between the materials of construction do not pose new issues of safety and effectiveness since the performance and biocompatibility studies aptly demonstrate acceptable performance and safety.

Performance: Terumo conducted exhaustive in-vitro studies to ascertain the performance of the CAPIOX® Flexible Venous Reservoir as compared to the predicate BMR1900G Reservoir. The comparative studies between the CAPIOX® Flexible Venous Reservoir and the predicate BMR1900G Reservoir include the following:

- Effects Upon Cellular Blood Components
- Pressure Drop
- Air Handling Capability
- Priming Volume
- Tubing Connection Strength
- Mechanical Integrity

In addition to the in-vitro comparative studies, Terumo conducted safety studies to demonstrate the safety of the device and the materials of device construction. Such studies include:

- Leaching/Extraction (of X-Coating)
- Biocompatibility
- Platelet Adhesion

Substantial Equivalence Summary:
In summary, the CAPIOX® Flexible Venous Reservoir and the predicate Baxter/Bentley BMR1900G Venous Reservoir (w/ Duraflo Treatment) are ***substantially equivalent*** in intended use, principles of operation/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 applicable guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Biocompatibility studies were conducted on the CAPIOX® Flexible Venous Reservoir. These 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 satisfy all biocompatibility test specifications.

Conclusion:

In summary, the CAPIOX® Flexible Venous Reservoir is substantially equivalent in intended use, principles of operation/technology, design and materials, and performance to the predicate Baxter/Bentley BMR1900G Venous Reservoir (w/ Duraflo Treatment).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

Terumo Cardiovascular Systems Corporation
c/o Mr. Garry A. Courtney
Sr. Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K040023
CAPIOX® Flexible Venous Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: January 5, 2004
Received: January 7, 2004

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), please contact the Office of Compliance at (301) 594-4646. 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) you may obtain. 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

Indications for Use

510(k) Number (if known): K040023

Device Name: Capiox® Flexible Venous Reservoir

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The device may be used in procedures lasting up to 6 hours in duration.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040023