

JUN 23 1999

K982467 page 1 of 5

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
PERTAINING TO SUBSTANTIAL EQUIVALENCE**

Proprietary Device Name: CAPIOX® Cardioplegia

Classification Name: Cardiovascular heat exchanger

Reason for Submission:

New device.

Intended Use:

The CAPIOX Cardioplegia is cardiopulmonary bypass heat exchanger consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device for periods up to 6 hours.

Description

CAPIOX® Cardioplegia consists of heat exchanger pipes, filter screen, casing, ports, screw ring, O-ring and potting material. A thermistor probe is located on the blood outlet port which can be connected to temperature monitoring equipment.

The water ports can be connected to 1/2" inner diameter water tube or coupler (e.g. Hansen-quick connect).

This device provides high heat exchanger performance and air trapping function.

Blood (or perfusion fluid) flows through the heat exchanger pipes and water flows outside the pipes. Blood (or perfusion fluid) flow is counter-current to the water flow.

Substantial Equivalence

The CAPIOX® Cardioplegia is substantially equivalent to Sorin BCD Vanguard and the Sarns Conducer. The discussion and table below compare the CAPIOX® Cardioplegia with the Sorin BCD Vanguard cleared under K934847 and the Sarns Conducer (K923311).

II - Summary and Certification
Summary of Safety and Effectiveness

Intended Use

All the devices are cardiopulmonary bypass heat exchangers consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device.

Design and Materials

All three devices are designed for blood/fluid flow into the lower portion of the device and exit at the top. The water flow enters the top and exits the bottom. The blood flow is counter current to the water flow.

The Sarns Conducer shares some generic blood contact materials with the CAPIOX Cardioplegia. The materials that are different are commonly present in devices used in the cardiopulmonary bypass circuit. (No information was available for the Sorin Vanguard materials).

The CAPIOX Cardioplegia is designed with straight stainless steel pipe blood conduits. The Sorin Vanguard uses pleated plate epoxy-coated stainless steel and the Sarns Conducer uses bellows.

Technology and Principles of Operation

All three devices receive blood/fluid which is pumped through tubing into the device. The water flow in counter current to the blood flow in all three devices. The water temperature is controlled separately from the cardioplegia device. The water either heats or cools the blood/fluid based upon the water temperature entering the device and the blood/fluid entering the device as shown in the following formula:

Heat exchanger performance factor: $\frac{T_{bo}-T_{bi}}{T_{wi}-T_{bi}}$

Twi : Water temperature (40°C)

Tbi: Inlet test solution temperature

Tbo: Outlet test solution temperature

II - Summary and Certification
 Summary of Safety and Effectiveness

Specifications

Table 1

	CAPIOX Cardioplegia	Sorin BCD Vanguard	Sarns Conducer
Intended Use	Used to cool or warm oxygenated blood, cardioplegic solution, or their mixture	Used to cool or warm oxygenated blood, cardioplegic solution, or their mixture	Used to cool or warm oxygenated blood, cardioplegic solution, or their mixture
Priming volume (mL)	52±5	335	15
Maximum blood flow rate (mL/min)	500	Adult: 500 Pediatric: 250	***
Maximum operating pressure (mmHg)	500	500**	600
Filter			
Filter material	Polyester	Polyester	Not available
Filter area (cm ²)	9.8±1.0	3.81	
Pore size (um)	96±10	105	
Heat Exchanger			
Type	Straight pipe	Pleated plate	Bellows
Material	Stainless steel*	Epoxy-coated Stainless steel	***
Surface area (cm ²)	640±60	500	***
Blood inlet port	1/4 inch	1/4 inch	1/4 inch
Blood outlet port	3/16 inch	3/16 inch	1/4 inch

*Stainless steel: SUS-304, 304L, 316, 316L specified in JIS G4305

**Maximum pressure is not defined, but labeled as 'Pressure relief valve opens at 500 mmHg or above.'

***Unknown

II - Summary and Certification
Summary of Safety and Effectiveness

Performance

Comparison of the CAPIOX® Cardioplegia and Sorin BCD Vanguard performance was conducted. A comparison of the Sarns Conducer was compared with the CAPIOX Cardioplegis for the water compartment pressure drop.

In summary, some differences in performance were observed between the CAPIOX Cardioplegia and the Sorin BCD Vanguard, however, these differences are not clinically significant nor do they raise new issues of safety or effectiveness.

Conclusion:

In summary, the CAPIOX Cardioplegia and the Sorin BCD Vanguard are substantially equivalent in intended use, design and materials, technology/principles of operation, specifications and performance. Differences as described above do not raise new issues of safety or effectiveness.

Terumo's statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Additional Safety Information

- Pyrogen Testing
- Sterilization conditions have been validated to provide a Sterility Assurance Level (SAL) of 10⁻⁶.
- 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).

II - Summary and Certification
Summary of Safety and Effectiveness

Date Prepared July 6, 1998

Prepared by: Sandi Hartka,
Manager Regulatory Affairs

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 23 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sandi Hartka
Manager, Regulatory Affairs
Terumo Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
Elkton, MD 21921

Re: K982467
CAPIOX® Cardioplegia
Regulatory Class: II (Two)
Product Code: DTR
Dated: March 24, 1999
Received: March 26, 1999

Dear Ms. Hartka:

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 (Premarket 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.

Page 2 - Ms. Sandi Hartka

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): K982467

Device Name: CAPIOX® Cardioplegia

Indications For Use:

The CAPIOX Cardioplegia is cardiopulmonary bypass heat exchanger consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device for periods up to 6 hours.

Beverly G. Campbell
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982467

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)