K970463 MAY -6 1997

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

Proprietary Device Name: CAPIOX® E Hollow Fiber Oxygenator with integral heat exchanger and arterial reservoir.

Classification Name: Cardiopulmonary bypass oxygenator, heat exchanger, reservoir.

Reason for Submission:

Modification to existing device.

Intended Use:

The CAPIOX® E Hollow Fiber Oxygenator is used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery. The integral heat exchanger is used to warm or cool the blood or perfusion fluid flowing through the device. The reservoir is used to store blood and the defoamer facilitates air removal. The device is intended for use during extracorporeal circulation for up to 6 hours.

Description

CAPIOX® E Hollow Fiber Oxygenator contains an integrated heat exchanger. The CAPIOX E oxygenator is a membrane oxygenator consisting of microporous polypropylene hollow fibers. Blood flows external to the hollow fibers while gases flow inside the fibers. The heat exchanger consists of stainless steel pipes with blood flowing outside the pipes and water flowing inside the pipes. A thermistor probe is located near the blood ports of the oxygenator which can be connected to accessory temperature monitoring equipment if desired. The device also contains an arterial reservoir with a defoamer which facilitates removal of air.

Substantial Equivalence

The CAPIOX® E with integrated heat exchanger and arterial reservoir is substantially equivalent to the CAPIOX SX18 Hollow Fiber Oxygenator with integrated heat exchanger and venous reservoir (K961000) as follows:

Intended use: same

Design and Materials:

Gas exchange is accomplished through hollow polypropylene fibers in both devices. In both devices blood flows outside the fibers while gas flows on the inside of the fibers.

The CX*E and the SX18 oxygenators both have integrated heat exchangers. Both heat exchangers use straight stainless steel tubes. In the CX*E blood flows outside the tubes and water flows inside the tubes, and in the SX18 blood flows inside the tubes while water flows outside the tubes.

Both oxygenators housings are made of clear polycarbonate and the fibers of both oxygenators are the same polypropylene.

The reservoir of the CAPIOX E is positioned to receive the oxygenated blood from the oxygenator and the blood is then pumped to the arterial circulation. The reservoir of the CAPIOX SX18 is positioned to receive the blood from the venous circulation and from the cardiotomy field; this blood is pumped into the oxygenator and then into the arterial circulation. In both cases the reservoirs are employed to hold a reservoir of blood and to facilitate air removal with defoamers.

There are no significant differences in design and materials of these devices.

Technology and Principles of Operation

Both the CX*E and the SX18 devices use membrane hollow fiber technology. The CAPIOX E receives blood from the venous circulation by gravity; blood flows into the heat exchanger/oxygenator and into the arterial reservoir from which it is pumped into the arterial circulation. Blood flows into the SX18 reservoir by gravity (or by suction from the cardiotomy field). From the reservoir, some form of pumping mechanism is

utilized to transfer blood to the heat exchanger and from there to the oxygenator compartment and into the arterial circulation.

The technology and principles of operation for the CAPIOX E and the SX18 are substantially equivalent.

Table 1

Specifications

	CAPIOX E	CAPIOX SX18
Intended Use (Oxygenator)	Used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of patients during open heart surgery for up to 6 hours	Used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of patients during open heart surgery for up to 6 hours
Membrane technology	Hollow Fiber	Hollow Fiber
Membrane material	Polypropylene	Polypropylene
Blood flow relative to fiber	Outside	Outside
Effective surface area of oxygenator	3.0 m2	1.8 m2
Heat exchanger	Integrated	Integrated
Heat Exch. Material	Stainless steel tubes	Stainless steel tubes
Heat Exch. Max. water Pressure	42 PSI	42 PSI
Blood Flow relative to Heat Exchanger Pipes	Outside	Inside
Blood Flow	HE->Oxygenator->Reservoir->Pump->Patient	Reservoir->Pump->HE->Oxygenator->Patient
Blood Flow Rate	0.5-6.5 LPM	0.5-7 LPM
Static Priming Volume (Oxygenator and heat exchanger)	800 mL (with 300 mL of priming solution in arterial reservoir)	270 mL (oxygenator and heat exchanger)
Hardshell Reservoir	Integrated	Detachable
Maximum Gas Flow	20 LPM	20 LPM

Table 1 (continued)

	CAPIOX® E	CAPIOX® SX18
Ports -Blood port	Blood Inlet/Outlet port: 1/2"	Blood Inlet port: 3/8" Blood Outlet port: 3/8"
-Female luer port	---	1 port (air purge port)
-Gas port	Gas inlet and outlet ports: 1/4"	Gas inlet and outlet ports: 1/4"
-Water port	Water inlet and outlet ports: 1/2" (Hansen quick connect fittings)	Water inlet and outlet ports: 1/2" (Hansen quick connect fittings)
Cardiotomy port	3/8"	-----
Reservoir		
Intended Use	To temporarily store blood, facilitate air removal from venous return during cardiopulmonary bypass for up to 6 hours	To temporarily store blood, facilitate filtration of particulates and air removal from venous return and suctioned blood during cardiopulmonary bypass for up to 6 hours
Ports Venous blood inlet Suction Blood outlet Vertical port to filter Quick prime & vent port Female luer Auxiliary	 --- --- 3/8" --- 1/4" 2 to inside filter ---	 1/2" rotatable 1/4" X 6 3/8" 3/8" 1/4" 4 to inside filter 1 to outside filter 2 on venous blood inlet 3/8"
Reservoir volume Maximum Minimum	 3,500 mL 300 mL	 4,000 mL 200 mL
Maximum blood flow rate	6.5 LPM	Cardiotomy inlet: 5 LPM Venous flow: 7 LPM Combined: 7 LPM
Antifoam component	Polyurethane foam defoamer	Polyurethane foam defoamer
Thermistor probe	Luer thermistor on venous blood inlet and arterial blood outlet	Luer thermistor on venous blood inlet

These differences do not affect the substantial equivalence of the devices since both provide adequate gas exchange for clinical use.

Performance

Comparison of the CAPIOX E oxygenator with integrated heat exchanger and the CAPIOX SX18 oxygenator with integrated heat exchanger performance was conducted.

The test results indicated the CAPIOX E performs in a substantially equivalent manner to the CAPIOX SX18.

The CAPIOX E oxygenator with integrated heat exchanger and the CAPIOX SX18 oxygenator with integrated heat exchanger 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.

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 tests include 100% performance and leak 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).

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Prepared by: Sandi Hartka, M.A.S., R.A.C.
Manager Regulatory Affairs

for: Terumo Medical Corporation
2100 Cottontail Lane
Somerset, NJ 08873