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SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
PERTAINING TO SUBSTANTIAL EQUIVALENCE

Proprietary Device Name: CAPIOX® SX18 Hollow Fiber Oxygenator with detachable Hardshell Reservoir

Classification Name: Cardiopulmonary bypass oxygenator, heat exchanger, reservoir, defoamer, blood filter and manifold.

Reason for Submission:

To extend the minimum flow rate specification.

Intended Use:

The CAPIOX® SX18 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 CAPIOX SX18 Hardshell Reservoir (detachable) is used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

Description

CAPIOX® SX18 Hollow Fiber Oxygenator contains an integrated heat exchanger and a detachable Hardshell Reservoir. This design permits an integrated system for ease of use as well as independent use of the oxygenator and of the Hardshell reservoir to accommodate a variety of circuit configurations.

The SX18 oxygenator is a membrane oxygenator consisting of microporous hollow fibers with an integrated heat exchanger, consisting of stainless steel tubes.

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The detachable Hardshell reservoir has a rotatable connection with the oxygenator which permits optimum positioning for connections in the circuit. The venous blood inlet port is also rotatable 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 total capacity of the reservoir is 4,000 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.

A detachable sampling system is positioned at the top of the hardshell reservoir which contains 3 three-way stopcocks. These stopcocks can be used for sampling. The sampling system contains a one-way valve permitting withdrawal of liquid samples but prohibiting entry of air into the blood exiting the oxygenator.

Substantial Equivalence

The CAPIOX® SX18 Oxygenator and Hardshell Reservoir are substantially equivalent to the Cobe CML Excel as follows:

Intended use: same

Design and Materials:

Both the CAPIOX SX18 and the Cobe CML Excel have integrated heat exchangers. The SX18 heat exchanger is coupled with the oxygenator, while the CML Excel heat exchanger is coupled with the reservoir. This design causes blood in the SX18 to flow from the reservoir to the pump and then to the heat exchanger/oxygenator, while the blood flows from the reservoir/heat exchanger to the pump and into the oxygenator in the CML Excel.

The hardshell reservoir for the SX18 is detachable while it is not detachable for the CML Excel.

The heat exchanger of the SX18 uses straight stainless steel tubes as blood conduits while the CML Excel uses coiled stainless steel tubes.

Gas exchange is accomplished through hollow polypropylene fibers in the SX18 and via a polypropylene plate membrane in the CML Excel.

Both devices incorporate hardshell reservoirs (open systems) which collect blood from the venous and cardiotomy returns. They both incorporate filters and defoamers/air separators to facilitate air and particulate removal.

Although some design dissimilarities exist, the performance testing results demonstrate that these differences do not present significant differences in the function and intended uses of the devices.

Technology and Principles of Operation

Both devices use membrane technology. The SX18 uses hollow fibers while the CML Excel uses a membrane plate. Both devices utilize gravity and/or external vacuum (cardiotomy) for blood collection into the reservoir. Air removal is facilitated by defoamers and the tendency of air to rise through liquid. Particulate removal is facilitated by the blood flow pathway through filters contained in the reservoirs. Some form of pumping mechanism is utilized to transfer blood from the reservoir component to the oxygenator component.

The technology and principles of operation for the SX18 and the CML Excel are substantially equivalent.

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Specifications

The priming volume for the SX18 is lower than that for the CML Excel (470 versus 850 mL, respectively). The membrane surface area for the SX18 is 1.8 m^2 and 3.0 m^2 for the Cobe CML Excel.

The maximum blood flow range for the SX18 is 7 LPM and for the Excel is 8 LPM (minimum is 0.5 LPM).

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

Performance

Comparison of the SX18 and CML Excel performance was conducted relative to the extended acceptable blood flow rate specification to include 0.5 - 2 LPM. The following tests were performed:

- Gas Transfer
- Pressure Drop of Heat Exchanger and Oxygenator

In summary, some differences in performance were observed between the SX18 and the CML Excel, however, these differences do not present clinically significant differences.

The SX18 and the CML Excel 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.

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Additional Safety Information

•Gas Transfer relative to time
•Heat Exchanger Performance Factor

•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.
Submissions Supervisor
Regulatory Affairs

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