K961734

July 7, 1997

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

Proprietary Device Name: CAPIOX® 308 Hollow Fiber Oxygenator with integral heat exchanger

Classification Name: Cardiopulmonary bypass oxygenator, heat exchanger.

Reason for Submission:

New device.

Intended Use:

The CAPIOX® 308 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 device is intended for use during extracorporeal circulation for up to 6 hours.

Description

CAPIOX® 308 Hollow Fiber Oxygenator (CAPIOX 308) contains an integrated heat exchanger. The CAPIOX 308 oxygenator is a membrane oxygenator consisting of microporous polypropylene hollow fibers. Blood flows internal to the hollow fibers while gases flow outside the fibers. The heat exchanger consists of stainless steel pipes with blood flowing inside the pipes and water flowing outside the pipes. A thermistor probe is located near the outlet port of the oxygenator which can be connected to accessory temperature monitoring equipment if desired.

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Substantial Equivalence

The CAPIOX® 308 Oxygenator with integrated heat exchanger is substantially equivalent to the Avecor 0800 2A Oxygenator and Omnitherm Heat Exchanger as follows:

Intended use: same

Design and Materials:

The CAPIOX 308 has an integrated heat exchanger while the Avecor 0800 2A oxygenator is designed to operate with the separate Avecor Omnitherm Heat Exchanger.

Gas exchange is accomplished through hollow polypropylene fibers in the CAPIOX 308. Blood flows through the fibers while gas flows on the outside the fibers.

The Avecor 0800 2A has a flat reinforced silicone rubber membrane envelope wound in a spiral coil around a polycarbonate spool. The entire unit is encased by a tight-fitting silicone rubber sleever. The interior of the envelope is the gas compartment containing a spacer screen permitting gas flow.

The heat exchanger of the CAPIOX 308 uses straight stainless steel tubes as blood conduits with water flowing on the outside of the tubes.

The Avecor Omnitherm Heat Exchanger is a tube-in-shell design, and consists of thin-walled aluminum tubes containing aluminum rod inserts shaped in a "staircase" pattern to promote gentle mixing of the blood and to conduct heat from the tube walls into the bloodstream. The water and blood paths are separated at each end of the device by a pair of manifolds, between which is an air space which is open to the atmosphere through a hole in the shell of the heat exchanger. Water flows on the outside of the tubes.

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 CAPIOX 308 uses hollow fibers while the Avecor 0800 2A uses a membrane plate. Some form of pumping mechanism is utilized to transfer blood from the reservoir to the heat exchanger (separate for Avecor, integral for CAPIOX 308) and from there to the oxygenator component.

The technology and principles of operation for the CAPIOX 308 and the Avecor 0800 2A are substantially equivalent.

Specifications

Table 1

Effective surface area of oxygenator	0.8 m^2	0.8 m^2
Heat Exch. Max. water Pressure	42 PSI	45 PSI
Blood Flow Rate	0-0.8 LPM	0-1.2 LPM
Static Priming Volume (Oxygenator and heat exchanger)	95 mL	148 mL
Dimension	Height: 24.0 cm Width: 10.5 cm Weight: 400 g	Oxygenator Height: 38.5 cm Width: 8.0 cm Weight: 530 g Heat Exchanger Height: 47.5 cm Width: 6.5 cm Weight: 230 g

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

II - Summary and Certification
Summary of Safety and Effectiveness

Performance

Comparison of the CAPIOX 308 with integrated heat exchanger and the Avecor 0800 2A and Omnitherm Heat Exchanger performance was conducted.

The test results indicated the CAPIOX 308 performs in a substantially equivalent manner to the Avecor 0800 2A and Omnitherm Heat Exchanger.

The CAPIOX 308 with integrated heat exchanger and the Avecor 0800 2A and Omnitherm 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.

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 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).

II - Summary and Certification
Summary of Safety and Effectiveness

Date Prepared April 12, 1996

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

for: Terumo Medical Corporation
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Somerset, NJ 08873

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 1997

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

Re: K961734
CAPIOX® 308 Oxygenator Hollow Fiber Oxygenator with Integrated Heat Exchanger
Regulatory Class: III (Three)
Product Code: DTZ
Dated: April 6, 1997
Received: April 9, 1997

Dear Ms. Hartka:

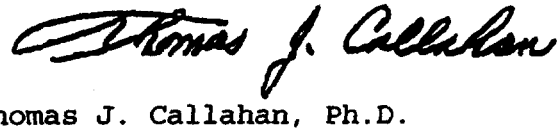
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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.

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" (21 CFR 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/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

870.4350 Oxygenator

510 K # K961734

Device Name: CAPIOX^{R} 308 Hollow Fiber Oxygenator with integral heat exchanger

Indications For Use:

The CAPIOX 308 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. This device is for use during extracoporeal circulation for up to 6 hours. This device is for use with neonatal and pediatric patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thanh Nguyen for Beth Lemperle

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K961734

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

(Optional Format 1-2-96)
Revised