K99 3772

SUMMARY OF INFORMATION REGARDING SAFETY AND EFFECTIVENESS ISSUES FOR OXYGENATORS

Literature references were obtained through a search of the Medline database (1988 - October, 1999), and articles inhouse. Other sources were Medical Device Reports/Diogenese database (1985-October, 1999); consultation with Technical Support Department and internal complaint files (1988-October, 1999).

Note: A summary of the methods used to address these issues is presented on pp. 21-33.

TABLE 1

Item	Possible Cause	Reference[1]
Effect on Blood Components	Contact with foreign surfaces and air, turbulent blood flow/flow pattern, temperature, surgical procedures[2], excessive gas flow	1,2,3,4,5,6,7,8,9,10, 11,12,22, 29
Decrease/Poor Gas Exchange	Plasma leakage/plasma breakthrough, improper technique (failure to connect gas line, failure to increase O_2 during rewarming, etc.), device design, channeling, water condensation, thrombus in blood phase, improper storage	13,31 MDR database complaint file
Effects on coagulation system	Contact with foreign surfaces, inadequate anticoagulation	4, MDR database

[1]Numbers refer to references listed in the Bibliography following this Table.

[2]Effects upon leukocyte counts are also seen in other types of extracorporeal circulation such as hemodialysis, leukopheresis, and plasmapheresis.

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TABLE 1 (cont.)

Item	Possible Cause	Reference[3]
Biocompatibility	Contact with foreign surfaces, manner of oxygenation/vigourous bubbling, aggregation of immunoglobulins, protamine-heparin complex, protein denaturation at blood-polymer interface, constituents of priming solution/wetting agent, anesthesia, tissue damage	4,5,6,7,8,9,12,14,24, 25,26,27,28,30,32
Microemboli		15,16,17,18
Gaseous	Suction system, inadequate priming/debubbling, overocclusion of the pumphead setting, manner of oxygenation/vigorous bubbling,technique	
Blood component aggregates	Contained in cardiotomy/suction blood and in donor blood, activation of platelets and/or leukocytes due to contacting foreign surfaces,technique	
Debris, particulates	Manufacturing process, improper technique, other devices/equipment used in cardiopulmonary bypass, antifoam agents	
Absorption/uptake of medications	Absorption by some materials	19,20,21,23

[3]Numbers refer to references listed in the Bibliography following this Table.

TABLE 1 (cont.)

Item	Possible Cause	Reference[4]
Foaming/defoamer failure	Inadequate defoaming agent, using flow rates greater than maximum rated flow rate	MDR database, complaint file
Macro Air Bolus	Improper technique (e.g. clamping gas outlet line, loose connections) (See also microemboli above)	MDR database
Leaks: water, blood, gas, priming solution	Mishandling/damage during shipment, improper technique (e.g. overpressurizing), manufacturing defect	MDR database, complaint file
Broken/missing parts, packaging defects/sterility barrier broken	Damage during handling or shipping, manufacturing defect	MDR database, complaint file
Poor heat exchange	Heater/cooler malfunction, design	MDR database
Miscellaneous infrequent items: e.g. venous resistance, high pressure drop	Clotting, poor design	MDR database, complaint file
Contamination	Damage during shment, technique	observation
Failure of measuring temperature	Use of inappropriate thermistor	observation

[4]Numbers refer to references listed in the Bibliography following this Table.

SUMMARY OF INFORMATION REGARDING SAFETY AND EFFECTIVENESS ISSUES FOR DEFOAMERS

Literature references were obtained through a search of the Medline database (1988 – October, 1999), and articles inhouse. Other sources were Medical Device Reports/Diogenese database (1985-October, 1999); consultation with Technical Support Department and internal complaint files (1988-October, 1999).

Note: A summary of the methods used to address these issues is presented on pp. 34-36

TABLE 2

Item	Possible Cause	Reference[5]
Visible foaming	Poor performance, inadequate defoaming agent	MDR Database, complaint file
Structural defect	Manufacturing defect, damage during shipment or user handling	MDR Database, complaint file
Increase in pressure gradient, slow breakthrough	Inadequate patient anticoagulation, clots/blocking/poor performance	MDR Database

[5]Numbers refer to references listed in the Bibliography following this Table

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2000

Mr. Garry A. Courtney
Regulatory Affairs
Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K993772
Trade Name: X-Coated Capiox SX18 and SX25 Hollow Fiber Oxygenators with/without Detachable Hardshell Resevoirs.
Regulatory Class: III (Three)
Product Code: DTZ
Dated: March 4, 2000
Received: March 7, 2000

Dear Mr. Courtney:

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.

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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K993772/S1

Device Name: X-Coated CAPIOX® SX25 and SX18 Hollow Fiber Oxygenators with/without Detachable Hardshell Reservoirs.

Indications For Use:

Intended Use Described In The 510(k):

The X-Coated CAPIOX® SX25 and SX18 Hollow Fiber Oxygenators with/without Detachable Hardshell Reservoirs are used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery for periods up to 6 hours.

The integral heat exchanger is used to warm or cool blood or perfusion fluid as it flows through the device.

The (detachable) hardshell reservoir is used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal.

The X-Coat is a polymer coating that is applied to blood contacting surfaces of the oxygenator to reduce the adhesion of platelets to the surfaces of the device.

Garry A. Courtney
Regulatory Affairs
Terumo Medical Corporation

(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, Respiratory, and Neurological Devices
510(k) Number K993772

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)