SEP 20 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

COMPANY NAME AND CONTACT PERSON

June 28, 1999

Jostra Medizintechnik AG
Hechinger Straße 38
72145 Hirrlingen
Germany

Kathy Johnson, Product Manager
tel. (610)932-7365
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DEVICE NAME

Hollow Fibre Membrane Oxygenator Quadrox HMO 1010

COMMON NAME

Oxygenator

CLASSIFICATION NAME

Cardiopulmonary bypass oxygenator (21 CFR – 870.4350)

PREDICATE DEVICE OR LEGALLY MARKETED DEVICE

Avecor Cardiovascular, Inc. - Affinity Hollow Fiber Oxygenator (K 932252)

DEVICE DESCRIPTION

The Hollow Fibre Membrane Oxygenator Quadrox HMO 1010 is a blood gas exchanger with integrated heat exchanger. In open heart surgery it is used in an extracorporeal perfusion circuit first to oxygenate blood and remove carbondioxide second to regulate the blood temperature during short duration cardiopulmonary bypass procedures lasting 6 hours or less.
The oxygenation system is principally based on microporous polypropylene hollow fiber membranes. The heat exchanger is made of thight polyethylene fibers. The QUADROX consists of two membrane compartments. In the first chamber of the oxygenator, sheets of heat exchanger fibers and sheets of microporous oxygenation fibers are arranged crosswise. In the second chamber only sheets of the oxygenation fibers are arranged.

Blood enters the housing via the inlet connector and is distributed into a pre-chamber. Then the blood streams through the membrane package. In the first section it is tempered and oxygenated. In the second part only oxygenation and removal of carbondioxide takes place.
Positioned and integrated at the top of the oxygenator is a de-airing membrane. This membrane is a hydrophobic membrane allowing only gaseous substances to pass through the membrane but fluids are held back. The de-airing membrane allows easier priming, de-airing and elimination of air throughout the whole procedure. To prime the oxygenator the Luer cap has to be removed. It should be kept open during perfusion to eliminate air continuously.

INTENDED USE

The Hollow Fibre Membrane Oxygenator HMO 1010 is intended for use in an extracorporeal perfusion circuit to oxygenate blood and remove carbon dioxide and to temper blood during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS

Name of the Product	**Hollow Fibre Membrane Oxygenator HMO 1010 (Jostra)**	**Affinity Hollow Fiber Oxygenator (Avecor)**
Parameter		
510(k) number	not assigned	K932252
Specifications:		
Membrane Type	Microporous Polypropylene Hollow Fibre	Microporous Polypropylene Hollow Fibers
Membrane Structure	Hollow fibre woven mats	unknown
Membrane surface area	1.8 m^2	2.5 m^2
Static priming volume	250 ml	270 ml
Blood flow path	Around the fibres	Around the fibres
Recommended blood flow rate	0.5-7 liters/minute	1-7 liters/minute
Maximal recommended gas flow rate	15 liters/minute	unknown
Maximum water side pressure	14 psi	30 psi
Material of heatexchanger	Polyethylene	Stainless steel
Surface area of the heat exchanger	0.60 m^2	unknown
Arterial outlet port	3/8"	3/8"
Venous inlet port	3/8"	3/8"
Arterial sample port	Luer-Port	Female Luer Port
Recirculation port	¼"	¼"
Gas inlet port	¼"	¼"
Gas outlet port	¼"	3/8" non-barbed
Water ports	½" Quick-Connect Fittings (Hansen)	½" quick disconnects
Method of sterilization	Ethylene Oxide	unknown
Storage temperature	+15°C - +30°C (+59° -+86°F)	unknown
Use	Single-use device	Single-use device
Weight	0.7 kg	unknown

SUMMARY OF PERFORMANCE DATA

In-vitro Bench Testing:

In-vitro bench testing demonstrated that when compared to the predicate device (Affinity Hollow Fiber Oxygenator), the Hollow Fibre Membrane Oxygenator Quadrox HMO 1010 does not significantly affect safety and effectiveness and is substantially equivalent to the Affinity Hollow Fiber Oxygenator. The in-vitro bench testing included analysis of:

- Performance Tests
- Heat Exchanger Performance Factor
- Integrity testing of the product

In-vivo Testing:

- Animal Testing has been performed

Clinical Studies:

- Clinical comparative studies

Biocompatibility and Blood Cell Damage:

Biocompatibility testing of the Hollow Fibre Membrane Oxygenator Quadrox HMO 1010 was performed in accordance with the FDA Blue Book Memorandum - #G95-1 and Biological Evaluation of Medical Devices Guidance – International Standard ISO 10993-1, and in accordance with United States Pharmacopeia – XXIII.

Based on the results of the biocompatibility testing performed, the Hollow Fibre Membrane Oxygenator Quadrox HMO 1010 was determined to be biocompatible and nontoxic and, therefore, safe for its intended use.

Blood cell damage testing of the Quadrox HMO 1010 was performed.

Sterility:

Sterilization of the Hollow Fibre Membrane Oxygenator HMO 1010 has been validated to assure a sterility assurance level (SAL) of 10^{-6}.

EtO sterilized Hollow Fibre Membrane Oxygenator Quadrox HMO 1010 are according to Federal Register , Vol. 43, No. 122 – Friday, June 23, 1978.

EtO Residuals:

Hollow Fibre Membrane Oxygenator Quadrox HMO 1010 meets the limits for residual concentrations of ethylene oxide (<25 ppm), ethylene chlorohydrin (<25 ppm), and ethylene glycol (< 250 ppm) as published in Federal Register , Vol. 43, No. 122 – Friday, June 23, 1978.

Pyrogens:

Routine Pyrogen Testing is performed using the Limulus Amebocyte Lysate (LAL) method. Product testing and release criteria (less than 20 EU/ml) is in accordance to the December 1987 Guideline issued by the Food and Drug Administration, office of Compliance („Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices").

Conclusion

Performance, function, and biocompatibility testing demonstrated that the Hollow Fibre Membrane Oxygenator Quadrox HMO 1010 is substantially equivalent to the Affinity Hollow Fiber Membrane Oxygenator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 1999

Ms. Kathy Johnson
Product Manager
Jostra Inc.
2035 Sunset Lake Road
Newark, DE 19702

Re: K992559
Hollow Fiber Membrane Oygenator Quadrox HMO 1010
Regulatory Class: III (three)
Product Code: DTZ
Dated: July 29, 1999
Received: July 30, 1999

Dear Ms. Johnson:

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,

Thomas J. Callahan

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: K992559 ~~not yet known~~

Device Name: Hollow Fibre Membrane Oxygenator HMO 1010

Indications for Use Hollow Fibre Membrane Oxygenator HMO 1010
The Hollow Fibre Membrane Oxygenator HMO 1010 is intended for use in an extracorporeal perfusion circuit to oxygenate blood and remove carbondioxide during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rae B Gemperle . (Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
a Neurological Devices
5 (K) Number K992559

X Prescription Use