

OCT 7 1999

510(k) Summary

SUBMITTER: COBE Cardiovascular®, Inc.
14401 W. 65th Way
Arvada, CO 80004

CONTACT PERSON: Lynne Leonard
Phone: (303) 467-6586
Fax: (303) 467-6429

DATE PREPARED: April 20, 1999

DEVICE TRADE NAME: COBE® Optimin™ Hollow Fiber Membrane Oxygenator

COMMON/USUAL NAME: Hollow Fiber Membrane Blood Oxygenator with Integral Heat Exchanger

CLASSIFICATION NAME: Cardiopulmonary Bypass Oxygenator with Heat Exchanger

PREDICATE DEVICES: COBE® Optima XP™ Hollow Fiber Membrane Oxygenator
TERUMO® Capiox® SX 10 Hollow Fiber Membrane Oxygenator.

DEVICE DESCRIPTION:

The COBE® Optimin™ Hollow Fiber Membrane Oxygenator is a sterile device with non-pyrogenic fluid pathways, for single use only, and is not to be resterilized by the user. The device is a blood oxygenator with integral heat exchanger. Microporous polypropylene, hollow fiber membrane material separates the blood and gas pathways inside the oxygenator, with the blood pathway outside and the gas pathway inside the hollow fiber membrane. Blood is pumped into the device through the blood inlet port. The blood inlet and blood outlet ports are 3/8" and include a locking mechanism which accepts a 1/4" reducing connector if the user desires to utilize 1/4" ID rather than 3/8" ID circuit tubing. The blood is channeled into the blood pathway of the heat exchanger, where the blood temperature is varied by controlling the water temperature in the water pathway of the heat exchanger. As the blood exits the heat exchanger it passes around a stainless steel temperature probe well, where the temperature of the blood may be monitored as it enters the oxygenator. Blood from the heat exchanger enters the oxygenator through the inlet manifold, and then flows around the outside of the fibers. The fibers are oriented horizontally in the oxygenator case, with flow entering the top of the fiber bundle and exiting the bottom to facilitate priming and debubbling. Gas exchange takes place as the blood makes its way into the bottom outlet manifold where it is directed out of the oxygenator through the blood outlet port and back to the patient. Sweep gas is introduced into the fibers through the gas inlet port on the inlet cap. The gas flows through the lumen of the hollow fibers. Gas exchange between the blood and gas pathways takes place through the micropores in the hollow fiber wall. Sweep gas flowing through the fibers collects in the outlet cap, where it may be scavenged.

INDICATIONS FOR USE

The COBE® Optimin™ Hollow Fiber Membrane Oxygenator is intended to be used in surgical procedures requiring extracorporeal gas exchange support and blood temperature control. It is intended to be used in procedures requiring a maximum blood flow rate of 5 liters/min and lasting up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® Optimin™ Hollow Fiber Membrane Oxygenator is substantially equivalent to the currently marketed COBE® Optima XP™ Hollow Fiber Membrane Oxygenator (K963518). The COBE® Optimin™ Oxygenator has a lower priming volume and is rated for lower blood and gas flow rates than the COBE® Optima XP™ Oxygenator, thus the COBE® Optimin™ Oxygenator is for smaller adult and pediatric patients, whereas the COBE® Optima XP™ Oxygenator is for adult patients.

The COBE® Optimin™ Oxygenator is substantially equivalent to the currently marketed Terumo® Capiiox® SX 10 Hollow Fiber Oxygenator (K960074). Specifications for the two devices are comparable and they are substantially equivalent in features and intended use.

Substantial equivalence was based on in-vitro testing of the COBE® Optimin™ Hollow Fiber Membrane Oxygenator. In-vitro testing consisted of:

1. Blood pathway operating volume
2. Blood pathway pressure drop
3. Gas pathway pressure drop
4. Oxygen transfer rate
5. Carbon dioxide transfer rate
6. Oxygen transfer duration, minimum/maximum flow rates
7. Carbon dioxide transfer duration, minimum/maximum flow rates
8. Blood pathway integrity
9. Water pathway integrity
10. Unrecoverable blood volume
11. Blood trauma (platelet reduction, white blood cell reduction, and plasma free hemoglobin generation)
12. Heat exchanger efficiency

These data support substantial equivalence of the COBE® Optimin™ Hollow Fiber Membrane Oxygenator to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynne Leonard
Manager, Regulatory Submissions
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K991452
COBE® Optimin™ Hollow Fiber Membrane Oxygenator
Regulatory Class: III (Three)
Product Code: 74 DTZ
Dated: August 9, 1999
Received: August 10, 1999

Dear Ms. Leonard:

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.

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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, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (If known): K991452/S'

Device Name: COBE® Optimin™ Hollow Fiber Membrane Oxygenator

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Q. Rempel
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991452

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