K974812

JUN 1 1998

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: December 17, 1997

DEVICE TRADE NAME: COBE® CML Duo® With SMAR$_x$T™
Surface Modified Membrane Oxygenator

COMMON/USUAL NAME: Flat Sheet Membrane Oxygenator with Integral Heat Exchanger

CLASSIFICATION NAME: Cardiopulmonary Bypass Oxygenator with Heat Exchanger

PREDICATE DEVICE: COBE® CML Duo® Membrane Oxygenator

DEVICE DESCRIPTION:

The COBE® CML Duo® With SMAR$_x$T™ Surface Modified Membrane Oxygenator is a flat sheet membrane blood oxygenator with integral heat exchanger. A surface-modifying material is added to the primary blood contact surfaces of the oxygenator and integral heat exchanger to improve the blood compatibility of the device. The product is sterilized by ethylene oxide, is for single use only, and has a nonpyrogenic fluid pathway.

INDICATIONS FOR USE

The COBE® CML Duo® With SMAR$_x$T™ Surface Modified Membrane Oxygenator is intended for use in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® CML Duo® With SMAR$_x$T™ Surface Modified Membrane Oxygenator has the same intended use as the COBE® CML Duo® Membrane Oxygenator. The only differences between the Duo with SMAR$_x$T Oxygenator and the currently marketed Duo Oxygenator are 1) the Duo with SMAR$_x$T Oxygenator contains the surface-modifying material and the Duo Oxygenator does not; 2) a surfactant is used in the heat exchanger of the Duo Oxygenator but not in the heat exchanger of the Duo with SMAR$_x$T Oxygenator. Otherwise, all materials, components, and sterilization and manufacturing processes for the two devices are the same.

Biocompatibility testing, in-vitro testing, and ex-vivo testing were performed to demonstrate that the COBE® CML Duo® With SMAR$_x$T™ Surface Modified Membrane Oxygenator is substantially equivalent to the currently marketed COBE® CML Duo® Membrane Oxygenator.

In-vitro testing consisted of:

Stability testing, surface-modifying material
SEM Analysis
Blood pathway operating volume
Pressure drop
Gas pathway pressure drop
Gas transfer
Gas transfer duration
Blood pathway integrity
Unrecoverable blood volume
Blood cell damage
Heat exchanger performance
Surface-modifying material leaching
Surface-modifying material blood compatibility

Ex-vivo testing consisted of:

Perfusion and animal survivor experiments
Surface-modifying material blood compatibility

These data support that the COBE® CML Duo® With SMAR$_x$T™ Surface Modified Membrane Oxygenator is substantially equivalent to the currently marketed COBE® CML Duo® Membrane Oxygenator, and that the addition of the surface-modifying material does not significantly affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1998

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

Re: K974812
COBE® CML® Duo With SMAR$_x$T™
Regulatory Class: III (Three)
Product Code: DTZ
Dated: March 24, 1998
Received: March 25, 1998

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.

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/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

Indications For Use

510(k) Number (If known): K974812

Device Name: COBE® CML Duo® With SMAR$_x$T™ Surface Modified Membrane Oxygenator

Indications For Use:

The COBE® CML Duo® With SMAR$_x$T™ Surface Modified Membrane Oxygenator is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to six hours.

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 K974812

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