K964043
Sept. 29, 1997

9. 510(k) Summary

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

CONTACT PERSON: Mary L. Armstrong
Phone: (303) 467-6521
Fax: (303) 467-6525

DATE PREPARED: October 7, 1996

DEVICE TRADE NAMES: COBE® Optima™ Hollow Fiber Membrane Oxygenator
COBE® CML Duo™ Flat Sheet Membrane Oxygenator

COMMON NAMES: Hollow Fiber Membrane Oxygenator with Heat Exchanger
Flat Sheet Membrane Oxygenator with Heat Exchanger

CLASSIFICATION NAME: Cardiopulmonary Bypass Oxygenator and Cardiopulmonary Bypass Heat Exchanger

PREDICATE DEVICES: COBE® Optima™ Hollow Fiber Membrane Oxygenator
COBE® CML Duo™ Flat Sheet Membrane Oxygenator

DEVICE DESCRIPTION:

The COBE Optima™ is a hollow fiber membrane oxygenator with integral heat exchanger. Used in conjunction with other ancillary equipment and disposable products, this device will satisfy the patient's gas exchange and body temperature regulation requirements.

The CML Duo™ is a flat sheet membrane oxygenator with integral heat exchanger. Used in conjunction with other ancillary equipment and disposable products, this device will satisfy the patient's gas exchange and body temperature regulation requirements.

The products are sterilized by ethylene oxide gas and have nonpyrogenic fluid pathways.

INDICATIONS FOR USE:

The COBE Optima™ and CML Duo™ are intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

TECHNOLOGICAL CHARACTERISTICS:

This 510(k) covers a modification to the COBE Optima™ end cap to core joint and a modification to the COBE Optima and CML Duo heat exchanger seals. These modifications will not result in any labeling changes for the devices and are not intended to change the specifications or performance of these

devices. There are no significant changes being made to the processes used to manufacture or sterilize the devices. The modifications to the COBE Optima and CML Duo seals are being made to improve the manufacturability of these devices.

NONCLINICAL TEST RESULTS:

Blood pathway pressure drop and blood pathway integrity for the COBE Optima oxygenator with modified seals were tested and did not significantly change from the predicate device. Blood pathway pressure drop and blood pathway integrity for the CML Duo oxygenator with modified seals were tested and did not significantly change from the predicate device.

Biocompatibility tests of the raw materials used for these modifications indicate that they are safe for use in the COBE Optima and the COBE CML Duo.

CLINICAL TEST RESULTS:

No clinical testing was performed. Safety and efficacy can be determined by *in vitro* testing.

CONCLUSION:

In vitro testing and biocompatibility testing show that the modified devices are safe and effective and not significantly different from the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

SEP 29 1997

Re: K964043
COBE® Optima™ and COBE® CML Duo™ Membrane Oxygenators
with Seal Modifications
Regulatory Class: III (Three)
Product Code: 74 DTZ
Dated: September 15, 1997
Received: September 16, 1997

Dear Ms. Leonard:

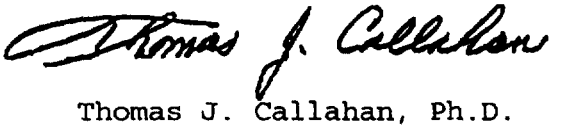
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

DTZ III - 870.4350 - CPB oxygenator

1. Indications For Use

510(k) Number (If known): K964043

Device Names: *COBE® Optima™ Hollow Fiber Membrane Oxygenator*
COBE® CML Duo™ Flat Sheet Membrane Oxygenator

Indications For Use:

The Optima™ and CML Duo™ are intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 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 K964043

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