

K963518

9. 510(k) Summary

DEC - 8 1997

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

CONTACT PERSON: Mary L. Armstrong  
 Phone: (303) 467-6521  
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DATE PREPARED: August 27, 1996

DEVICE TRADE NAME: COBE® Optima XP™ Hollow Fiber Membrane Oxygenator

COMMON NAME: Hollow Fiber Membrane Oxygenator with Heat Exchanger

CLASSIFICATION NAME: Cardiopulmonary Bypass Oxygenator and Cardiopulmonary Bypass Heat Exchanger

PREDICATE DEVICE: COBE® Optima™ Hollow Fiber Membrane Oxygenator

DEVICE DESCRIPTION:

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

The product is sterilized by ethylene oxide gas and has nonpyrogenic fluid pathways.

INDICATIONS FOR USE:

The Optima XP™ is 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:

The Optima XP™ is a new device created by modifying the existing Optima oxygenator by decreasing the fiber diameter and increasing the number of fibers. The result is an increase in membrane surface area in the Optima XP compared to the Optima.

The is no change in the intended use of the device.

There is no change to the heat exchanger. There are no significant changes to the processes or materials used to manufacture or sterilize the device.

*Optima XP™* and *Optima™* are trademarks of COBE Laboratories, Inc.

COBE® and COBE Cardiovascular® are registered trademarks of COBE Laboratories, Inc.

**NONCLINICAL TEST RESULTS:**

The oxygen transfer rate of the Optima XP is increased compared to the Optima. The new device also has a higher operating volume and gas side pressure drop. Carbon dioxide transfer rate, blood pathway pressure drop, unrecoverable volume, and blood trauma characteristics are not significantly different compared to the Optima.

The heat exchanger in both devices is identical in design, manufacture and installation, and therefore has not been evaluated for this 510(k).

**CLINICAL TEST RESULTS:**

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

**CONCLUSIONS:**

1. The increased membrane surface area of the Optima XP increases the oxygen transfer when compared to the Optima as intended.
2. Corresponding increases in priming volume and gas side pressure drop are acceptable.
3. No statistically significant differences were detected in other performance aspects of the Optima XP when compared to the Optima.
4. *In vitro* testing demonstrates the Optima XP is as safe and effective and performs as well as or better than the Optima.

*Optima XP*<sup>™</sup> and *Optima*<sup>™</sup> are trademarks of COBE Laboratories, Inc.

COBE<sup>®</sup> and COBE Cardiovascular<sup>®</sup> are registered trademarks of COBE Laboratories, Inc.



Rockville MD 20857

J. Dennis Bruner, Ph.D.  
Director of Quality  
COBE Cardiovascular, Inc.  
14401 W. 65<sup>th</sup> Way  
Arvada, Colorado 80004

DEC - 8 1997

Re: K963518  
COBE® Optima XP™ Hollow Fiber Membrane Oxygenator  
Regulatory Class: III (Three)  
Product Code: DTZ  
Dated: November 21, 1997  
Received: November 25, 1997

Dear Dr. Bruner:

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 (Pre-market 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 pre-market 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" (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

1. Indications For Use

510(k) Number (If known): K 963518

Device Name: COBE® Optima XP™ Hollow Fiber Membrane Oxygenator

Indications For Use:

The Optima XP™ is 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)

*Steve K. Rempke*  
(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K 963518

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use