



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 27 1998

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: K974085
COBE® Oxygenator Products
Regulatory Class: III (Three)
Product Code: 74 DTZ
Dated: October 24, 1997
Received: October 29, 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.

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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,

A handwritten signature in black ink, reading "Thomas J. Callahan". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

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): _____

Device Names: *Cobe® Hard Shell Venous Reservoirs, Unfiltered and Filtered*
Cobe® Venous Reservoir Bags
Cobe® Flat Sheet Membrane Oxygenators
Cobe® Hollow Fiber Membrane Oxygenators

Indications For Use:

COBE® HARD SHELL VENOUS RESERVOIRS, UNFILTERED AND FILTERED are intended for storage (and filtration, if filtered) of blood during surgical procedures on adults requiring extracorporeal circulation for periods up to six hours.

COBE® VENOUS RESERVOIR BAGS are intended for use as a blood reservoir during extracorporeal blood circulation.

COBE® FLAT SHEET MEMBRANE OXYGENATORS are intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to six hours (one model is a variable prime oxygenator intended to be used during cardiac surgical procedures on neonates, infants, pediatrics, and small adults requiring cardiopulmonary bypass).

COBE® HOLLOW FIBER MEMBRANE OXYGENATORS are 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)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____