

AUG 24 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: February 24, 1998

DEVICE TRADE NAME: COBE® Closed Venous Reservoir Bags With SMAR_xT™,
Model Numbers VRB® 1200™ and VRB® 1800™

COMMON/USUAL NAME: Venous Reservoir Bag

CLASSIFICATION NAME: Cardiopulmonary Bypass Blood Reservoir

PREDICATE DEVICE: COBE® VRB® 1200™ Closed Venous Reservoir Bag

DEVICE DESCRIPTION:

The COBE® Closed Venous Reservoir Bags With SMAR_xT™, Model Numbers VRB® 1200™ and VRB® 1800™ are sterile devices with non-pyrogenic fluid pathways, for single use only, and are not to be resterilized by the user. The devices accommodate both systemic venous and cardiotomy return blood. A surface-modifying material is added to the primary blood contact surfaces of the device to improve the blood compatibility of the materials.

The VRB® 1200™ with SMAR_xT consists of the bag with its basic ports (venous inlet, cardiotomy inlet, reservoir outlet, reservoir vent, venous sample port, and auxillary ports) along with several additional user features. The reservoir bag is attached directly to a rigid backing plate that contains a three stopcock blood sampling system, a reservoir vent line with a one-way valve, and a front plate that is designed to exert pressure on the bag, squeezing it between the front and back plates to assist in air removal. There is a volume indicator tape on the back plate which provides an indication of the amount of blood in the bag. There is also a level sensing magnet on the outside of the reservoir bag and a sensor in the bracket which allows the VRB® 1200™ with SMAR_xT to be used with the COBE® Air Emboli Protection System. The maximum volume of the reservoir bag is 1200 ml.

The VRB® 1800™ with SMAR_xT is a simplified version of the VRB® 1200™ with SMAR_xT. The VRB® 1800™ with SMAR_xT consists of only the bag with its basic ports (venous inlet, cardiotomy inlet, reservoir outlet, reservoir vent, venous sample port, and auxillary ports). It does not have the additional user features listed above for the VRB® 1200™ with SMAR_xT. The maximum volume of the reservoir bag is 1800 ml (the reservoir bag is identical to the VRB® 1200™ with SMAR_xT, but the maximum volume is greater in the VRB® 1800™ with SMAR_xT because it is not attached to the rigid back plate).

INDICATIONS FOR USE

The COBE® Closed Venous Reservoir Bags With SMAR_xT™ are closed, flexible reservoir bags intended to be used as blood reservoirs during adult cardiac surgical procedures requiring extracorporeal support for periods up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® Closed Venous Reservoir Bags With SMAR_xT™ have the same intended use as the COBE® VRB® 1200™ Closed Venous Reservoir Bag. The only differences between the COBE® Closed Venous Reservoir Bags With SMAR_xT™ and the currently marketed VRB® 1200™ are 1) the COBE® Closed Venous Reservoir Bags With SMAR_xT™ contain the surface-modifying material; 2) Model VRB® 1800™ with SMAR_xT is a simplified version of the VRB® 1200™, consisting only of the bag with its basic ports.

Biocompatibility testing, in-vitro testing, and ex-vivo testing were performed to demonstrate that the COBE® Closed Venous Reservoir Bags With SMAR_xT™ are substantially equivalent to the currently marketed COBE® VRB® 1200™ Closed Venous Reservoir Bag.

In-vitro testing consisted of:

- SEM Analysis
- Mechanical Integrity
- Air Challenge
- Bag Shutoff
- Collapse Volume
- Blood cell damage
- Surface-modifying material leaching
- Surface-modifying material blood compatibility

Ex-vivo testing consisted of:

- Surface-modifying material blood compatibility

These data support that the COBE® Closed Venous Reservoir Bags With SMAR_xT™ are substantially equivalent to the currently marketed COBE® VRB® 1200™ Closed Venous Reservoir Bag, and that the addition of the surface-modifying material does not affect safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 24 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: K980786
COBE® Closed Venous Reservoir Bags with SMAR_xT™
Regulatory Class: II (Two)
Product Code: DTN
Dated: June 10, 1998
Received: June 11, 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.

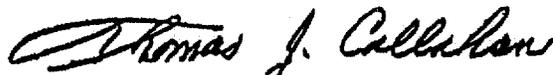
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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" (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): K980786

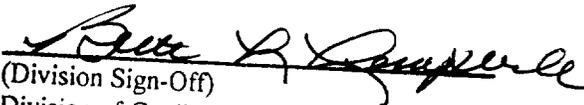
Device Names: COBE® Closed Venous Reservoir Bags With SMAR_xT™,
Model Numbers VRB® 1200™ and VRB® 1800™

Indications For Use:

The COBE® Closed Venous Reservoir Bags With SMAR_xT™ (Model Numbers VRB® 1200™ and VRB® 1800™) are intended to be used in adult surgical procedures requiring extracorporeal support 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 K980786

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use