

510(k) Summary

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

CONTACT PERSON: Lynne Leonard
Phone: (303) 467-6586
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DATE PREPARED: January 21, 1999

DEVICE TRADE NAME: COBE® VVR 4000™ Filtered Hardshell Venous Reservoir

COMMON/USUAL NAME: Filtered Venous Reservoir with Integral Cardiotomy Filter

CLASSIFICATION NAMES: Cardiopulmonary Bypass Blood Reservoir with Defoamer and Cardiotomy Suction Line Blood Filter; Autotransfusion Apparatus

PREDICATE DEVICES: COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir
Baxter/Bentley BMR-4500G Filtered Venous Reservoir
Baxter/Bentley HSR-4000 Filtered Venous Reservoir

DEVICE DESCRIPTION:

The COBE® VVR 4000™ Filtered Hardshell Venous Reservoir, a sealed hardshell venous reservoir with defoamer and integral cardiotomy filter, is a sterile device with non-pyrogenic fluid pathways, for single use only, and is not to be resterilized by the user. It is designed for collection and return of postoperative chest drainage, and for storage and filtration of blood during adult surgical procedures requiring cardiopulmonary bypass for periods of up to six hours.

The maximum capacity of the COBE® VVR 4000™ Filtered Hardshell Venous Reservoir is approximately 4000 ml. The device operates at venous blood flow rates up to 8 liters/minute, cardiotomy flow rates up to 4 liters/minute, or at a combined maximum flow rate of 8 liters/minute.

During cardiopulmonary bypass, the device receives the patient's venous blood (under vacuum assisted or non-vacuum assisted venous return conditions) and also receives cardiotomy suction blood and filters it prior to returning it to the circulating blood volume. Entrained air is removed from both the venous blood and cardiotomy blood by the defoamer.

Following cardiopulmonary bypass, the device may be converted for use in postoperative chest drainage. Shed blood which has been stored in the reservoir less than six hours may be autotransfused for blood volume replacement.

The major components of the reservoir are the bucket, the ports, the defoamer, and the cardiotomy filter. The bucket serves both as a primary structural component of the device and as a transparent vessel to contain excess blood volume and to allow for the monitoring of changes in blood volume. The ports provide blood tubing connections between the reservoir and the patient, the defoamer serves to remove gross air from the incoming venous and cardiotomy suction blood, and the filter removes particles from cardiotomy suction blood.

INDICATIONS FOR USE

The COBE® VVR 4000™ Filtered Hardshell Venous Reservoir is intended to be used in adult surgical procedures requiring cardiopulmonary bypass for periods of up to six hours, and for postoperative chest drainage collection and autotransfusion.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® VVR 4000™ Filtered Hardshell Venous Reservoir is substantially equivalent to the currently marketed COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir (K984456). The two devices are identical except that the COBE® VVR 4000™ Filtered Hardshell Venous Reservoir has a gasketed lid joint, vent port, and pressure relief valve. Both the COBE® VVR 4000™ Filtered Hardshell Venous Reservoir and the COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir are intended to be used in adult surgical procedures requiring cardiopulmonary bypass for periods of up to six hours. The COBE® VVR 4000™ Filtered Hardshell Venous Reservoir has the added indication of postoperative chest drainage collection and autotransfusion of the collected blood.

The COBE® VVR 4000™ Filtered Hardshell Venous Reservoir is also substantially equivalent to the Baxter/Bentley BMR-4500G Filtered Venous Reservoir. Both devices are sealed hardshell venous reservoirs with a defoamer and integral cardiotomy filter, designed for storage and filtration of blood during adult surgical procedures requiring cardiopulmonary bypass. The COBE® VVR 4000™ Filtered Hardshell Venous Reservoir has the added indication of postoperative chest drainage collection and autotransfusion of the collected blood.

The COBE® VVR 4000™ Filtered Hardshell Venous Reservoir is also substantially equivalent to the Baxter/Bentley HSR-4000 Filtered Venous Reservoir. Both devices are sealed hardshell venous reservoirs with a defoamer and integral cardiotomy filter, designed for storage and filtration of blood during adult surgical procedures requiring cardiopulmonary bypass, and for postoperative chest drainage collection and autotransfusion of the collected blood.

Biocompatibility and in-vitro tests were performed to demonstrate that the COBE® VVR 4000™ Filtered Hardshell Venous Reservoir is substantially equivalent to the COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir, the Baxter/Bentley BMR-4500G Filtered Venous Reservoir, and the Baxter/Bentley HSR-4000 Filtered Venous Reservoir.

In-vitro testing consisted of:

- Filtration Efficiency
- Minimum Operating Volume
- Pressure Relief Valve Operation
- Reservoir Implosion Resistance
- Blood Cell Damage



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 1999

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

Re: K990239
COBE® VVR 4000™ Filtered Hardshell Venous Reservoir
Regulatory Class: III (Three)
Product Code: 74 DTP - DTN
Dated: January 22, 1999
Received: January 25, 1999

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.

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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): K990239

Device Name: COBE® VVR 4000™ Filtered Hardshell Venous Reservoir

Indications For Use:

The COBE® VVR 4000™ Filtered Hardshell Venous Reservoir is intended to be used in adult surgical procedures requiring cardiopulmonary bypass for periods of up to six hours, and for postoperative chest drainage collection and autotransfusion.

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 _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____