

K971669

**510(k) Summary**

JUL 23 1997

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

**CONTACT PERSON:** Mary L. Armstrong  
Phone: (303) 467-6521  
Fax: (303) 467-6429

**DATE PREPARED:** 5/5/97

**DEVICE TRADE NAME:** COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir  
COBE® HVR™ 4000 Nonfiltered Hardshell Venous Reservoir

**COMMON NAME:** Hardshell venous reservoir with integral cardiotomy filter  
Hardshell venous reservoir

**CLASSIFICATION NAME:** Cardiopulmonary bypass blood reservoir with defoamer and cardiotomy suction filter  
Cardiopulmonary bypass blood reservoir with defoamer

**PREDICATE DEVICE:** Maxima Hardshell Venous Reservoir - Top Entry, Model MHR-T

**DEVICE DESCRIPTION:** The HVR™ 4000 Filtered Hardshell Venous Reservoir is an open cardiopulmonary bypass blood reservoir with defoamer and cardiotomy suction filter. Used in conjunction with other ancillary equipment and disposable products, this device will satisfy an adult patient's blood storage and cardiotomy filtration requirements during surgical procedures.

The HVR™ 4000 Nonfiltered Hardshell Venous Reservoir is an open cardiopulmonary bypass blood reservoir with defoamer. Used in conjunction with other ancillary equipment and disposable products, this device will satisfy an adult patient's blood storage requirements during surgical procedures

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

**INDICATIONS FOR USE:** The HVR 4000 Filtered is intended for storage and filtration of blood during surgical procedures on adults requiring extracorporeal circulation for periods of up to six hours.

The HVR 4000 Nonfiltered is intended for storage of blood during surgical procedures on adults requiring extracorporeal circulation for periods of up to six hours.

**TECHNOLOGICAL CHARACTERISTICS:** Comparing the HVR™ 4000 Filtered Hardshell Venous Reservoir and the HVR™ 4000 Nonfiltered Hardshell Venous Reservoir with the Maxima Hardshell Venous Reservoir, some similarities and differences are noted in the design and technology employed to accomplish their intended uses.

All three devices use a knitted polyester fabric as the outer defoamer covering. In the filtered devices (i.e., the HVR 4000 Filtered and the Maxima Hardshell Venous Reservoir), filtration is accomplished through use of polyurethane foam for gross filtration and polyester depth media for fine filtration.

All three devices include the same functional types of porting in essentially the same numbers and sizes. For venting, the Maxima Hardshell Venous Reservoir uses a port on its cover where the COBE HVR 4000 Hardshell Venous Reservoirs use an open cover design. Both COBE devices use a one-piece, molded venous inlet port, whereas the Maxima device uses a two-piece inlet comprised of a rigid, injection molded port joined to a flexible, polyvinylchloride tube.

**NONCLINICAL TEST RESULTS:** The blood trauma characteristics of the HVR 4000 Filtered and the HVR 4000 Nonfiltered are not significantly different compared to the Maxima Hardshell Venous Reservoir. Filtration efficiency of the HVR 4000 Filtered meets specification. Volume capacity of both COBE devices meet specification. Material biocompatibility, sterilization and packaging of both COBE devices meet requirements. All labeling claims have been substantiated. The COBE HVR 4000 Hardshell Venous Reservoirs will be labeled with a one year expiration period.

**CLINICAL TEST RESULTS:** No clinical testing was performed. Safety and efficacy were determined by *in vitro* testing.

**CONCLUSIONS:**

1. The COBE devices' blood trauma characteristics are comparable to those of the predicate device.
2. The COBE devices' maximum operating volumes meet claims
3. The COBE devices' minimum operating volumes meet claims
4. The COBE devices' filtration efficiency meets claims
5. Material biocompatibility, sterilization and packaging for the COBE devices meet requirements
6. All labeling claims for the COBE devices have been substantiated

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

HVR™ is a trademark of COBE Laboratories, Inc.



JUL 23 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Ms. Mary L. Armstrong  
Regulatory Affairs Manager  
COBE Cardiovascular, Inc.  
14401 W. 65th Way  
Arvada, Colorado . 80004-3599

Re: K971669  
COBE® HVR™ 4000 Reservoirs  
Regulatory Class: II (Two)  
Product Code: 74 DTN  
Dated: May 5, 1997  
Received: May 6, 1997

Dear Ms. Armstrong:

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 requirement, 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.

Page 2 - Ms. Mary L. Armstrong

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

Indications For Use

510(k) Number (If known): K971669

Device Name: COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir  
COBE® HVR™ 4000 Nonfiltered Hardshell-Venous Reservoir

Indications For Use:

The HVR 4000 Filtered is intended for storage and filtration of blood during surgical procedures on adults requiring extracorporeal circulation for periods of up to six hours.

The HVR 4000 Nonfiltered is intended for storage of blood during surgical procedures on adults requiring extracorporeal circulation 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)

[Signature]

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K971669

Prescription Use x  
(Per 21 CFR 801.109)

OR

Over-The -Counter Use \_\_\_\_\_