MAR 27 2000

K994389

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: December 27, 1999

DEVICE TRADE NAME: COBE® HVR® 2200 Hardshell Venous Reservoir, Filtered

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

CLASSIFICATION NAMES: Cardiopulmonary Bypass Blood Reservoir
Cardiopulmonary Bypass Defoamer
Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter

PREDICATE DEVICE: Medtronic Minimax Filtered Hardshell Venous Reservoir

DEVICE DESCRIPTION:

The COBE® HVR® 2200 Hardshell Venous Reservoir is a sterile device with non-pyrogenic fluid pathways. It is designed for single use only, and is not to be resterilized by the user. The device is an open, hardshell venous blood reservoir intended to be used during cardiac surgical procedures requiring extracorporeal support for periods of up to six hours. The COBE HVR 2200 is a smaller version of the COBE® HVR® 4000 Hardshell Venous Reservoir (K971669, K984456). The COBE® HVR® 4000 Hardshell Venous Reservoir has a maximum volume of 4000 ml, while the COBE® HVR® 2200 Hardshell Venous Reservoir has a maximum volume of 2200 ml. The smaller volume of the reservoir makes the COBE HVR 2200 more suited for smaller adult and pediatric patients, while the COBE HVR 4000 is for adult patients.

The COBE HVR 2200 is used during cardiopulmonary bypass surgery to receive and store the patient's venous blood and to act as blood volume buffer, as well as to receive raw cardiotomy suction blood and filter it prior to returning it to the circulating blood volume. Entrained air is removed from both the venous blood and cardiotomy suction blood by the defoamer. The major components of the device are the bucket, the porting, 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 porting provides blood tubing connections between the reservoir and the patient, the defoamer serves to remove gross air from incoming venous and cardiotomy suction blood, and the filter removes particles from the cardiotomy suction return blood.

INDICATIONS FOR USE

The COBE® HVR® 2200 Hardshell Venous Reservoir is intended to be used in surgical procedures requiring cardiopulmonary bypass for periods of up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® HVR® 2200 Filtered Hardshell Venous Reservoir is substantially equivalent to the predicate device, the Medtronic Minimax Filtered Hardshell Venous Reservoir in intended use, operating principle and overall design and features. The devices have minor differences in performance specifications such as blood and cardiotomy flow rates, minimum operating volume, and maximum volume capacity.

Biocompatibility and performance tests demonstrate substantial equivalence of the two devices. Performance testing consisted of:

1. Defoaming Capability
2. Minimum Operating Volume
3. Maximum Operating Volume
4. Filtration Efficiency
5. Blood Pathway Integrity
6. Port Integrity
7. Blood trauma

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2000

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

Re: K994389
COBE® HVR® 2200 Filtered Hardshell Venous Reservoir
Regulatory Class: II (two) and III (Three)
Product Code: DTN and DTP
Dated: December 27, 1999
Received: December 28, 1999

Dear Ms. Leonard:

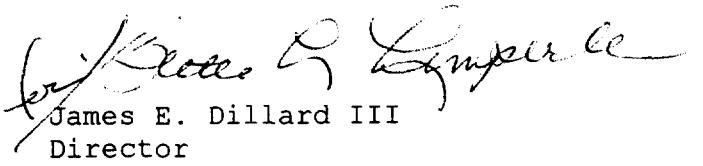
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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,



James E. Dillard III
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): K 994389

Device Name:

COBE® HVR® 2200 Filtered Hardshell Venous Reservoir

Indication For Use:

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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 K994389

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____