K993001

DEC -3 1999

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: September 2, 1999

DEVICE TRADE NAMES: COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoir, Filtered

COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoir, Nonfiltered

COMMON/USUAL NAMES: Hardshell Venous Reservoir with Integral Cardiotomy Filter
Hardshell Venous Reservoir, Nonfiltered

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

PREDICATE DEVICE: COBE® HVR® 4000™ Filtered Hardshell Venous Reservoir

DEVICE DESCRIPTION:

The COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs are sterile devices with non-pyrogenic fluid pathways, for single use only, and are not to be resterilized by the user. The devices are open, hardshell, venous blood reservoirs intended to be used during adult cardiac surgical procedures requiring extracorporeal support for periods of up to six hours. Two configurations are available, one with an integral cardiotomy filter and one without the filter.

The filtered version of the COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Venous Reservoir, in addition to receiving and storing the patient's venous blood and acting as blood volume buffer, is designed for receiving raw cardiotomy suction blood and filtering 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 nonfiltered version of the COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Venous Reservoir is designed for receiving and storage of the patient's venous blood and acting as blood volume buffer during cardiopulmonary bypass. The defoamer removes air entrained in the venous blood.

The major components of the filtered and nonfiltered COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs are the bucket, the porting, the defoamer, and in the filtered version, 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® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs are intended to be used in adult surgical procedures requiring cardiopulmonary bypass for periods of up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs have the same intended use as the predicate device, the COBE® HVR® 4000™ Filtered Hardshell Venous Reservoir. The primary difference between the COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs and the currently marketed COBE® HVR® 4000™ is the COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs contain a surface-modifying material which improves the blood compatibility of the device, resulting in reduced platelet adhesion on the treated surfaces.

Biocompatibility and performance tests demonstrate that the COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs are substantially equivalent to the currently marketed COBE® HVR® 4000™ Filtered Hardshell Venous Reservoir.

Performance testing consisted of:

1. Defoaming Capability
2. Minimum Operating Volume
3. Maximum Operating Volume
4. Filtration Efficiency
5. Blood trauma: platelet reduction, white blood cell reduction, and plasma free hemoglobin generation

In-vitro testing was performed to demonstrate improved blood compatibility of the materials containing the surface modifying additive and leach testing was conducted to show that the surface modifying additive does not leach from the device.

These data support that the COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs are substantially equivalent to the currently marketed COBE® HVR® 4000™ Filtered Hardshell Venous Reservoir.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC -3 1999

Ms. Lynne Leonard
Manager, Regulatory Submissions
Cobe Cardiovascular, Inc.
14401 West 65th Way
Aravada, CO 80004

Re: K993001
COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous
Regulatory Class:III(3)
Product Code: DTN
Dated: September 3,1999
Received: September 7,1999

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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications For Use

510(k) Number (If known): K993001

Device Names:

COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoir, Filtered
COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoir, Nonfiltered

Indications For Use:

The COBE® SMAR$_x$T™ HVR® 4000™ Surface Modified Hardshell Venous Reservoirs are intended to be used in adult surgical procedures requiring cardiopulmonary bypass 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 K993001

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____