JAN 1 1 1999

K984456

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 14, 1998

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

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

CLASSIFICATION NAME: Cardiopulmonary Bypass Blood Reservoir with Defoamer and Cardiotomy Suction Line Blood Filter

PREDICATE DEVICE: COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir (K971669)

DEVICE DESCRIPTION:

The COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir is a sterile device with non-pyrogenic fluid pathways, for single use only, and is not to be resterilized by the user. The device is an open venous blood reservoir with integral cardiotomy filter.

INDICATIONS FOR USE

The COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir is intended to be used in adult cardiac surgical procedures requiring cardiopulmonary bypass for periods up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The modified COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir described in this submission is substantially equivalent to the original, unmodified COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir (K971669). The modified COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir is identical to the original, unmodified COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir (K971669) in intended use, specifications, features, method of operation, and fundamental scientific technology. The two devices differ in the materials used in the defoamer and cardiotomy filter.

TESTING TO DETERMINE SUBSTANTIAL EQUIVALENCE

In-vitro tests were performed to demonstrate that the modified COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir described in this submission is substantially equivalent to the original, unmodified COBE® HVR™ 4000 Filtered Hardshell Venous Reservoir (K971669). In-vitro testing consisted of venous blood flow, defoaming capacity, filtration efficiency, operating volume, breakthrough volume, unrecoverable volume, filter loading, blood trauma, and minimum/maximum operating volumes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 1999

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

Re: K984456
COBE® HVR® 4000 Filtered Hardshell Venous Reservoir
Regulatory Class: II (Two) and III (Three)
Product Code: DTN/DTP
Dated: December 14, 1998
Received: December 15, 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 (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'(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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications For Use

510(k) Number (If known): K 98 4456

Device Names: COBE® HVR® 4000 Filtered Hardshell Venous Reservoir

Indications For Use:

The COBE® HVR® 4000 Filtered Hardshell Venous Reservoir is 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 K 984456

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)