OCT 7 1998

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:	July 9, 1998
DEVICE TRADE NAME:	COBE® Vacuum Relief Check Valve
COMMON/USUAL NAME:	Vacuum/Pressure Safety Valve
CLASSIFICATION NAME:	Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting (21 CFR 870.4290)
PREDICATE DEVICES:	C.R. Bard, Inc. William Harvey® #H-130 Overpressure Safety Valve (K820297) American Omni Medical, Inc. #RLV-2100 Non-adjustable Suction Control Valve (K861428)

INDICATIONS FOR USE

The COBE® Vacuum Relief Check Valve is indicated for use during cardiopulmonary bypass surgery to help prevent the buildup of excessive vacuum pressure when suctioning either from the heart or the surgical field, and to help prevent inadvertent flow of air into the heart.

DEVICE DESCRIPTION

The COBE® Vacuum Relief Check Valve is a sterile device with a non-pyrogenic fluid pathway. It is for single use only and is not to be resterilized by the user. The device consists of a housing with a 1/4" inlet port and a combination 1/4" and 3/8" outlet port (to accommodate either 1/4" or 3/8" ID tubing on the outlet side). It contains a unidirectional valve which prevents retrograde flow and an umbrella valve that opens under excessive vacuum, allowing air in to relieve the excessive vacuum pressure in the line. In addition, the device contains an over-pressure relief band which opens under excess positive pressure, allowing blood to escape. Arrows molded into the housing indicate the direction of flow through the device.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® Vacuum Relief Check Valve is substantially equivalent in intended use, performance, method of operation, and design features to the C.R. Bard, Inc. William Harvey® #H-130 Overpressure Safety Valve (K820297), and the American Omni Medical, Inc. #RLV-2100 Non-adjustable Suction Control Valve (K861428).

The primary differences in the three devices are:

1. The unidirectional duckbill valve and the vacuum umbrella valve in the COBE® Vacuum Relief Check Valve are of a one piece design. Both the C.R. Bard, Inc. William Harvey® #H-130 and the American Omni Medical, Inc. #RLV-2100 have a separate unidirectional duckbill valve and vacuum umbrella valve.
2. The COBE® Vacuum Relief Check Valve and the American Omni Medical, Inc. #RLV-2100 contain an over-pressure relief band. The C.R. Bard, Inc. William Harvey® #H-130 uses a second umbrella valve to relieve excessive positive pressure.
3. The American Omni Medical, Inc. #RLV-2100 and the C.R. Bard, Inc. William Harvey® #H-130 have 1/4" inlet and outlet ports. The COBE® Vacuum Relief Check Valve has a 1/4" inlet port and a combination 1/4" and 3/8" outlet port to accept either tubing size on the outlet side.

Performance testing was conducted to demonstrate substantial equivalence of the COBE® Vacuum Relief Check Valve to the predicate devices. Performance testing consisted of:

1. Vacuum Pressure Relief
2. Positive Pressure Relief
3. Retrograde Flow Prevention
4. Hemolysis
5. Leak Testing
6. Connection Bond Strength

Data from these tests support that the COBE® Vacuum Relief Check Valve is substantially equivalent to the C.R. Bard, Inc. William Harvey® #H-130 Overpressure Safety Valve (K820297), and the American Omni Medical, Inc. #RLV-2100 Non-adjustable Suction Control Valve (K861428).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1998

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

Re: K982406
COBE™ Vacuum Relief Check Valve
Regulatory Class: II (Two)
Product Code: MJJ
Dated: July 9, 1998
Received: July 10, 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): K992406

Device Name: COBE® Vacuum Relief Check Valve

Indications For Use:

The COBE® Vacuum Relief Check Valve is intended to be used during cardiopulmonary bypass surgery to help prevent the buildup of excessive vacuum pressure when suctioning either from the heart or the surgical field, and to help prevent inadvertent flow of air into the heart.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...vision Sign-Off)
...ivision of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982406

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