K960974

JUL 14 1997

510(k) SUMMARY

SUBMITTER:	COBE Cardiovascular, Inc. 14401 W. 65th Way Arvada, CO 80004
CONTACT PERSON: Phone: Fax:	Mary L. Armstrong (303) 467-6521 (303) 467-6525
DATE PREPARED:	March 31, 1997
DEVICE TRADE NAME:	COBE® *Century*™ Perfusion Pump
COMMON NAME:	Peristaltic perfusion blood pump
CLASSIFICATION NAME:	Roller-type cardiopulmonary bypass blood pump and Cardiopulmonary bypass heart-lung machine console
PREDICATE DEVICE:	COBE Precision Blood Pump

DEVICE DESCRIPTION:

The COBE *Century* Perfusion Pump is the principal component of the COBE *Century* Perfusion System. It is a peristaltic-type roller pump that functions by tube-occluding rollers that move along a piece of tubing. As the pump head rotates, the rollers draw fluid through the tubing. Pumped fluids are contained within the tubing and have no contact with the pump. The pump has positive displacement over a wide range of flow rates and delivery pressures.

The COBE *Century* Perfusion Pump consists of:

- a front panel containing displays and operational switches
- a pump head with the roller pump mechanism and shields
- a chassis containing control cards, a power supply, and connectors for external devices

COBE® is a registered name of COBE Laboratories, Inc.
Century™ is a trademark of COBE Laboratories, Inc.

INDICATIONS FOR USE:

The COBE *Century* Perfusion Pump is intended for use in cardiopulmonary surgical procedures requiring pumping of fluids in an extracorporeal circuit for periods up to 6 hours.

TECHNOLOGICAL CHARACTERISTICS:

The COBE *Century* Perfusion Pump is a modification of its predicate, the COBE Precision Blood Pump. As such, it retains most of the technological characteristics of its predicate.

Through software and hardware modifications, the pump has an improved user interface and an improved overspeed protection circuit. Updating of the user interface involved replacing most of the rotary switches with membrane switches, replacing the front panel that holds the switches, and providing additional displays. Improving the overspeed protection circuit involved increasing overspeed sensitivity at low speeds, adding a fixed, maximum speed limit, and implementing a safety function which detects a component failure in the speed set-point circuitry.

The COBE *Century* Perfusion Pump and its predicate are equipped with universal tubing clamps, which allow the pumps to accommodate a wide range of tubing sizes and types with a minimum of hardware changes. For non-continuous pumping applications only, polyvinylchloride (PVC) tubing of 1/8 inch to 1/4 inch inside diameter (ID) by 1/16 inch wall minimum can be accommodated. For continuous pumping, PVC tubing of 1/4 inch (ID) by 3/32 inch wall to 5/8 inch ID by 1/8 inch wall can be accommodated. For continuous and non-continuous pumping, silicone rubber tubing with 3/16 inch ID by 1/16 inch wall to 5/8 inch ID by 1/8 inch wall can be accommodated.

Flow rate (Liters Per Minute) through the pumps is based on pump speed (Revolutions Per Minute) and tubing ID. Flow rates can range from .01 LPM (3/16 inch ID and 1 RPM) to over 10 LPM (for larger sizes of tubing and higher speeds). For some sizes of tubing, two segments of tubing can be placed in the pump head at the same time.

The COBE *Century* Perfusion Pump is *not*—nor is it intended to be—interchangeable with its predecessor, the COBE Precision Blood Pump. However, the COBE *Century* Perfusion Pump and its predicate device are each compatible with certain other devices: 1) The COBE *Century* Perfusion Pump can be run in master/slave mode with another COBE *Century* Perfusion Pump. Similarly, the COBE Precision Blood Pump can be run in master/slave mode with another COBE Precision Blood Pump. 2) The COBE *Century* Perfusion Pump can be operated in conjunction with the COBE Computerized Perfusion Controller (CPC). Similarly, the COBE Precision Blood Pump can be operated in conjunction with the COBE Computerized Perfusion Controller (CPC). The CPC can be used to pressure-limit either pump, volumetrically control either pump, and/or pulse either pump. 3) The COBE *Century*

Perfusion Pump can be used with the COBE Air Emboli Protection System (AEPS). Similarly, the COBE Precision Blood Pump can be used with the COBE Air Emboli Protection System (AEPS). The AEPS is designed to provide protection against air embolism during cardiopulmonary bypass surgery by stopping the pump if specific conditions are sensed.

NONCLINICAL TEST RESULTS:

The COBE *Century* Perfusion Pump was tested to assure that it met its functional specifications and its user interface specification. It successfully met all specifications at the system test level, where every system requirement was addressed by a corresponding test or tests.

CLINICAL TEST RESULTS:

No clinical testing was performed.

CONCLUSIONS:

The COBE *Century* Perfusion Pump is a modification of the COBE Precision Blood Pump. Through hardware and software modifications, the *Century* Perfusion Pump has an improved user interface and an improved overspeed protection circuit. The COBE *Century* Perfusion Pump is substantially equivalent to the COBE Precision Blood Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 14 1997

Re: K960974
COBE® Century™ Perfusion Pump
Regulatory Class: II (Two)
Product Code: 74 DWB
Dated: April 11, 1997
Received: April 14, 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.

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

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

Enclosure

2. *Indications For Use*

510(k) Number (If known): K960974

Device Name: COBE® *Century*™ Precision Blood Pump

Indications For Use:

The COBE *Century*™ Precision Blood Pump is intended for use in cardiopulmonary surgical procedures requiring pumping of fluids in an extracorporeal circuit for periods up to 6 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 K960974

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