K030462

IX. 510(k) SUMMARY

MAR 0 6 2003

SUBMITTER:	COBE Cardiovascular, Inc. 14401 West 65th Way Arvada, CO 80004 USA
CONTACT PERSON:	Charles Copperberg Senior Manager, Regulatory and Clinical Affairs Charlie.Copperberg@cobecv.com Phone: (303) 467-6521 Fax: (303) 467-6525
DATE PREPARED:	February 10, 2003
DEVICE TRADE NAME:	COBE Cardiovascular Revolution® Centrifugal Blood Pump with PC Coating
COMMON/USUAL NAME:	Centrifugal Blood Pump
CLASSIFICATION NAME:	Nonroller-type cardiopulmonary bypass blood pump
PREDICATE DEVICE:	COBE Cardiovascular Revolution Centrifugal Blood Pump K011835 Dideco Monolyth Mimesys Hollow Fiber Oxygenator K004001 Dideco Avant PH.I.S.I.O. Hollow Fiber Oxygenator K020351

DEVICE DESCRIPTION:

The Cobe Cardiovascular Revolution Pump with PC Coating is an extracorporeal blood pump that is provided sterile, single use only, with non-pyrogenic fluid pathways, and is not to be resterilized by the user. It may be sold as a stand-alone device or as a component of a customized heart/lung pack.

The Revolution Centrifugal Blood Pump with PC Coating utilizes a rotating, vaned impeller design to move blood by centrifugal force. Blood contact surfaces of the PC coated Revolution have been coated with phosphorylcholine to improve blood compatibility, resulting in reduced platelet adhesion on the coated surfaces.

SPECIAL 510(K) NOTIFICATION
Cobe Cardiovascular Inc.
Revolution® Centrifugal Blood Pump with PC Coating

INDICATIONS FOR USE:

The pump is intended for use only with Stöckert Instrumente Centrifugal Pump Consoles in cardiopulmonary bypass procedures for periods of up to six hours. Refer to the console operator's manual for console operating procedures.

The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON:

The Revolution Centrifugal Blood Pump with PC coating has the same intended use as the current Revolution Centrifugal Blood Pump. The two devices differ in that the blood contacting surfaces of the Revolution with PC coating have been treated with phosphorylcholine. Otherwise, materials, components, design, sterilization and manufacturing processes for the two devices are the same.

TESTING TO DETERMINE SUBSTANTIAL EQUIVALENCE:

In-Vitro laboratory tests were performed to demonstrate that the Revolution Centrifugal Blood Pump with PC Coating described in this submission is substantially equivalent to the Revolution Centrifugal Blood Pump (K011835).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 6 2003

COBE Cardiovascular, Inc.
c/o Mr. Charles Copperberg
Senior Manager, Regulatory and Clinical Affairs
14401 West 65th Way
Arvada, CO 80004

Re: K030462
Trade Name: COBE Cardiovascular Revolution® Centrifugal Blood Pump with PC Coating.
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type Cardiopulmonary Bypass Blood Pump
Regulatory Class: Class III (three)
Product Code: KFM
Dated: February 11, 2003
Received: February 12, 2003

Dear Mr. Copperberg:

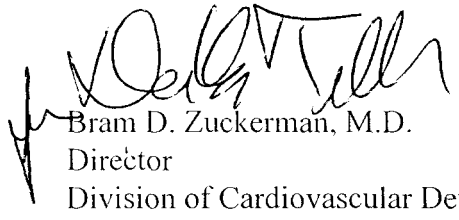
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K030462

Device Name: COBE Cardiovascular Revolution™ Centrifugal Blood Pump with PC Coating

Indications For Use:

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PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030462

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