K012898

SEP 1 7 2001

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: August 27, 2001

DEVICE TRADE NAME: CSC14 Blood Cardioplegia System

COMMON/USUAL NAME: Cardioplegia Heat Exchanger

CLASSIFICATION NAME: Cardiopulmonary Bypass Blood Heat Exchanger

PREDICATE DEVICE: SORIN BCD Vanguard Blood Cardioplegia System, #K934847

DEVICE DESCRIPTION:

The CSC14 Blood Cardioplegia System 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 a heat exchanger with integral bubble trap and various tubing configurations.

INDICATIONS FOR USE

The CSC14 Blood Cardioplegia System is intended to mix, cool, warm, and deliver oxygenated blood and cardioplegic solution for up to 6 hours. The device also allows monitoring of temperature and pressure, traps bubbles, and allows for air removal. Blood and cardioplegic solution are delivered to the patient by a 100% occlusive roller pump through the extension line and appropriate cannula.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The CSC14 Blood Cardioplegia System is identical to the SORIN BCD Vanguard Blood Cardioplegia System (K934847) in intended use, method of operation, and fundamental scientific technology. The two devices differ in the geometry and features of the integral bubble trap.

TESTING TO DETERMINE SUBSTANTIAL EQUIVALENCE

In-vitro tests were performed to demonstrate that the CSC14 Blood Cardioplegia System described in this submission is substantially equivalent to the SORIN CSC 14 Blood Cardioplegia System (K934847). In-vitro testing consisted of heat exchanger efficiency, pressure drop, priming volume, device integrity, connections integrity, sterile barrier integrity, and blood trauma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2001

Ms. Lynne Leonard
Sr. Regulatory Affairs Manager
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 8004-3599

Re: K012898
CSC14 Blood Cardioplegia System
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchangers
Regulatory Class: II
Product Code: DTR
Dated: August 28, 2001
Received: August 29, 2001

Dear Ms. Leonard:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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). 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (If known): K012898

Device Name: CSC14 Blood Cardioplegia System

Indications For Use:

The CSC14 Blood Cardioplegia System is intended to mix, cool, warm, and deliver oxygenated blood and cardioplegic solution for periods of up to six hours. The device also allows monitoring of temperature and pressure, traps bubbles, and allows for air removal. Blood and cardioplegic solution are delivered to the patient by a 100% occlusive roller pump through the extension line and appropriate cannula.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012898

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