510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: July 2, 2003

510(k) number: K032068

Applicant Information:

CardioVention, Inc.
3045 Stender Way
Santa Clara, CA 95054

Contact Person: Tessa Yamut, Director of RA/QA
Phone Number: (408) 844-5130
Fax Number: (408) 988-2309

Device Information:

Classification: Class III

Trade Name: CardioVention CORx IOS-200 System

Classification Name: The CORx IOS-200 System is a cardiopulmonary bypass system consisting of an oxygenator (870.4350), a non-roller-type cardiopulmonary bypass blood pump (870.4360), a heat exchanger (870.4240) and a blood circuit defoamer (870.4230)

Equivalent Device:

The subject device is substantially equivalent in intended use and/or method of operation to the CardioVention CORx System [K012325].

Intended Use:

The CardioVention CORx System is intended to be used in surgical procedures requiring extracorporeal hemodynamic and gas-exchange support. The device contains a thermal regulating system. The device is indicated for use in procedures requiring a maximum blood flow rate of six liters/minute and lasting for up to six hours. The CORx System is intended for use with the Medtronic Bio-Medicus Bio-Console and the CardioVention PowerBase Console.

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Test Results:

Results of in-vitro testing demonstrate that the CardioVention CORx IOS-200 System is safe and effective for its intended function.

Summary:

Based on the intended use and product performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed and unmodified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2003

Cardiovention, Inc.
c/o Ms. Tessa Yamut
Director, RA/QA
3045 Stender Way
Santa Clara, CA 95054

Re: K032068
CardioVention CORx IOS-200 System
Regulation Number: 21 CFR 870.4240, 870.4350, 870, 4360, 870.4230
Regulation Name: Cardiopulmonary bypass (CPB) heat exchanger, CPB oxygenator, non-roller type CPB blood pump, CPB defoamer
Regulatory Class: Class II (two)
Product Code: DTR, DTZ, DTP, KFM
Dated: July 2, 2003
Received: July 3, 2003

Dear Ms. Yamut:

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. 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 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,

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

Enclosure

Indication for Use Statement

510(k) Number (if known): K032068

Device Name: CardioVention CORx IOS-200 System

Indications for Use:

The CardioVention CORx System is intended to be used in surgical procedures requiring extracorporeal hemodynamic and gas-exchange support. The device contains a thermal regulating system. The device is indicated for use in procedures requiring a maximum blood flow rate of six liters/minute and lasting for up to six hours. The CORx System is intended for use with the Medtronic Bio-Medicus Bio-Console and the CardioVention PowerBase Console.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032068