CardioVention CORx System

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 808.87 and 807.92.

Date Prepared: June 16, 2001

510(k) number: _____

I. 510(k) Submitter Information

Name:	Tessa Yamut
Title:	Director of Quality Assurance / Regulatory Affairs
Address:	3045 Stender Way Santa Clara, CA 95054
Contact Person:	Same as above
Preparation Date of the 510(k) Summary:	June 16, 2001

II. Device Information

Device Name:	CardioVention CORx System
Trade Name:	CardioVention CORx System
Common / Usual Name:	Oxygenator Centrifugal Blood Pump Venous Defoamer
Classification Name:	Cardiopulmonary Bypass Oxygenator Blood Pump, Non-roller type, Cardiopulmonary Bypass Cardiopulmonary Bypass Defoamer
Device Classification:	Class III Preamendments device for which FDA has not yet called for premarket approval applications.

III. Device Description

The CardioVention CORx System is an extracorporeal hemodynamic and gas exchange support system for extracorporeal perfusion. The CardioVention CORx System consists of an active venous air removal device (defoamer), a centrifugal blood pump, a membrane oxygenator, an AirVac Controller and a pump adapter. The AirVac Controller powers the detection and facilitates removal of entrained air in the air handling system (defoamer) of the disposable unit. The pump adapter, which is magnetic, allows the use of the Medtronic Biomedicus Bio-Console (k941921) with the CORx System. The Medtronic's Biomedicus Bio-Console drives the CORx System's centrifugal pump.

The following components of the CORx System disposable are provided sterile, for single use only:

Device	Description
Defoamer (Air Removal)	A device that replaces the air removal function of venous reservoirs by centralizing venous line air and actively removing the air
Centrifugal Blood Pump	An eight-vaned impeller (centrifugal) pump
Oxygenator	A hollow fiber gas transfer device utilizing polypropylene, double-mat, commercially available fiber

IV. Predicate Devices

The CardioVention CORx System, which consists of an active venous air removal device (defoamer), a centrifugal blood pump, a membrane oxygenator, an AirVac Controller and a pump adapter, is substantially equivalent to a combination of three predicate devices.

The Predicate Device for the CardioVention CORx System Oxygenator is:

Name:	Optimin Hollow Fiber Oxygenator
Manufacturer:	Cobe
Status:	Post-enactment

The Predicate Device for the CardioVention CORx System Centrifugal Pump, with the pump adaptor for use with Medtronic's Biomedicus Bio-Console is:

Name:	Sarns Delphin Centrifugal Blood Pump
Manufacturer:	Terumo Sarns
Status:	Post-enactment

The predicate device for the CardioVention CORx System Defoamer, with the AirVac Controller, is:

Name:	HVR2200 Hard Shell Venous Reservoir (defoamer)
Manufacturer:	Cobe
Status:	Post-enactment

V. Indications for Use

The CardioVention CORx System is intended to be used in surgical procedures requiring extracorporeal gas exchange support. This device can be used with a legally marketed thermal regulating system. The device is indicated for use in procedures requiring a maximum blood flow rate of six liters/minute and lasting up to six hours.

The CORx System is intended for use with Medtronic's Bio-medicus Bio-Console.

Comparison to Predicate Devices

The CardioVention CORx System is used for patient support and duplicates the functionality of three separate disposable predicate devices. A summary comparison of the intended uses and generic specifications between the CORx System and the predicate systems is provided on the following page. For many of the plastic components, the CardioVention CORx System utilizes the same materials as the predicate devices.

The largest surface area component of the CORx System, the microporous membrane material, is the identical material as the predicate membrane oxygenator. Both the predicate and CORx System membrane oxygenators are blood outside the fiber, hollow fiber designs. The predicate oxygenator contains an integral heat exchanger while the CORx System is designed to work with ancillary heating / cooling products.

Both the predicate centrifugal blood pump and the centrifugal blood pump component of the CORx System are of the "impeller" type and incorporate similar materials.

VI. Summary of Physical Characterization / Integrity and Performance Testing

The table below summarizes the tests and results that were performed on the CORx System to ensure that it conforms to specificationsand is as safe and effective as the predicate devices:

Test Type	Purpose	Summary of Results
Blood pathway integrity- 6 hours	To ensure that the blood pathway does not leak under worst case conditions	The blood pathway was exposed to pressures of 750 mmHg (1.5X rated maximum pressure) for 6 hours with no failures of integrity detected.
Gas Pathway Integrity- 10 minutes	To ensure that the gas pathway does not leak under worst case conditions	The gas pathway was exposed to pressures of 30 mmHg (1.5X rated maximum pressure) for 10 minutes with no failures of integrity detected.
Blood Pathway Volume	To determine the static priming volume of the blood pathway	The volume of the blood pathway was determined to be 328 mls.
Oxygen Transfer Rate- 6 hours	To compare oxygen transfer and outlet saturations at minimum, nominal, and maximum rated flow rates to the predicate device.	Oxygen transfer was greater than or equal to the predicate device at all blood/gas flow rates over 6 hours. Arterial saturation (outlet) was 100% at all conditions and timepoints. No loss in performance occurred over the 6 hours.
Carbon Dioxide Transfer Rate- 6 hours	To compare oxygen transfer and outlet saturations at minimum, nominal, and maximum rated flow rates to the predicate device.	Carbon dioxide transfer was greater than or equal to the predicate device at all blood/gas flow rates over 6 hours. No loss in performance occurred over the 6 hours.

Transmembrane pressure drop- 6 hours	To compare transmembrane pressure drop at minimum, nominal, and maximum rated flow rates to the predicate device.	Transmembrane pressure drop was lower than the predicate device. No clinically significant pressure increases occurred over the 6 hours.
Blood Cell Damage	To compare blood cell damage to the predicate devices at their respective maximum rated flow rates.	Blood cell damage (plasma free hemoglobin, index of hemolysis, modified index of hemolysis, platelet count, white blood cell count) was equal to or less than the predicate devices.
Air Handling	To compare venous air handling performance to the predicate devices.	Arterial return bubble counts were equal or less than the predicate devices.

Based on a descriptive comparison of the CORx System and its predicate systems and the performance data summarized above, the CORx System is substantially equivalent to the currently marketed predicate systems for its intended use.

Class III Summary and Certification

CardioVention, Inc. certifies to the best of our knowledge that a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the nonroller-type cardiopulmonary bypass blood pump. We further certify that we are aware of the types of complications to which the device is susceptible and that, to the best of our knowledge, the following summary of the types and causes of safety or effectiveness problems about the nonroller-type cardiopulmonary bypass blood pump is complete and accurate.

Problem	**Potential Causes**
Blood Leak	Compromised physical integrity
Inadequate pumping	Bearing / seal failure, decoupling
Biocompatibility	Material selection
Blood damage	Heat generation, bearing / seal failure, sheer stresses

The section below includes citations of the materials upon which the above summary is based:

- Kolff J, RN Ankney, D Wurzel, R Devineni. Centrifugal pump failures. J Extra Corpor Technol 1996 Sep; 28(3)118-22.
- Curtis JJ, TM Boley, JT Walls, TL Demmy, and RA Schmaltz. Frequency of seal disruption with Sarns centrifugal pump in postcardiotomy circulatory assist. Artif Organs 1994 Mar; 18(3):225-7.
- Curtis JJ, JT Walls, CC Wagner-Mann, RA Schmaltz, TL Demmy, CA NcKenney, FA Mann. Centrifugal pumps: description of devices and surgical techniques.
- Crane TN. Causes of cardiopulmonary bypass accidents 1996. http://www.perfusion.com/perfusion/articles/general/9610-accidents.html

Tessa Yamut
Director of QA/RA

Date of Submission: July 20, 2001

510(k) Number:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2002

Ms. Tessa Yamut
Director of Quality Assurance/Regulatory Affairs
CardioVention, Inc.
3045 Stender Way
Santa Clara, CA 95054

Re: K012325
Trade Name: CardioVention CORx System, Model FG0001
Regulation Number: 21 CFR 870.4350, 870.4360, 870.4230
Regulation Name: Oxygenator, Pump, Defoamer
Regulatory Class: Class III (three)
Product Code: DTZ, KFM, DTP
Dated: November 7, 2001
Received: November 9, 2001

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.

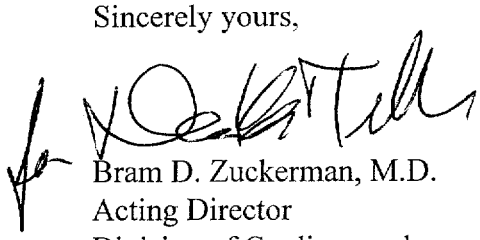
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): k012325

Device Name: CardioVention CORx System

Indications for Use:

The CardioVention CORx System is intended to be used in surgical procedures requiring extracorporeal gas exchange support. This device can be used with a legally marketed thermal regulating system. The device is indicated for use in procedures requiring a maximum blood flow rate of six liters/minute and lasting up to six hours.

The CORx System is intended for use with the Medtronic Bio-medicus Bio-Console.

✓

Prescription Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012325