

SEP 20 2011

**Section VIII  
510(k) Summary****Date:** 4, February 2011**Applicant**

CardiacAssist, Inc.  
240 Alpha Drive  
Pittsburgh, PA 15238  
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**Contact:** Robert Bollinger  
Title: Director of Quality and Regulatory  
e-mail: rbollinger@cardiacassist.com

**Device**

Trade/Proprietary Name: TandemHeart System  
Common Name: TandemHeart System Controller and TandemHeart Pump  
Classification Name: Pump, Blood, Non-Roller Type Cardiopulmonary Bypass (21 CFR Part 870.4360 / Code 74 KFM)

**Predicate Devices**

CardiacAssist AB-180 XC System (K991783)  
Levitronix Centrimag Extracorporeal Blood Pumping System (K020271)  
Levitronix/Thoratec Centrimag Primary Console (K083340)

**Device Description**

The TandemHeart System consists of two major components, the TandemHeart System Controller, and the TandemHeart Blood Pump, along with a number of accessory components required to setup and utilize the Pump. The system is intended for extracorporeal circulatory support using an extracorporeal bypass circuit.

**Indications for Use**

The TandemHeart System consists of the TandemHeart Blood Pump, a single use device, the TandemHeart Controller, a reusable control system for the Blood Pump, and disposable accessory items used in conjunction with the Blood Pump.

The TandemHeart System is intended for extracorporeal circulatory support using an extracorporeal bypass circuit. Intended duration of use is for periods appropriate to cardiopulmonary bypass, up to six hours. It is also intended to be used as an extracorporeal circulatory support system (for periods up to six hours) for procedures not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, mitral valve reoperation, surgery of the vena cava and/or aorta, liver transplant, etc.)



### **Comparison of Technological Characteristics**

The TandemHeart System is equivalent in design and construction to the predicate CardiacAssist AB-180 XC System. The labeling of the TandemHeart System is being revised to allow the use of a user supplied Oxygenator in the extracorporeal circuit. The labeling is also being revised to modify a warning statement. These revisions to the labeling result in labeling that is consistent with the labeling of the Levitronix Centrimag Extracorporeal Blood Pumping System (K020271), and Levitronix/Thoratec Centrimag Primary Console (K083340).

### **Performance Data**

A risk assessment was conducted to determine the impact of the change to the labeling, and the appropriate testing to perform. Subsequent testing of the TandemHeart System was completed to verify flow vs. pressure drop (HQ) when utilized with an Oxygenator. The HQ testing results demonstrated adequate flow performance with the inclusion of an Oxygenator in the extracorporeal circuit, and that the flows were substantially equivalent to those provided by the predicate AB-180 XC System.

### **Conclusions**

The CardiacAssist TandemHeart System is substantially equivalent to the predicate CardiacAssist AB-180 XC System in design characteristics, performance, materials, method of construction, and intended use. Changes to the labeling have no impact on device performance.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

CardiacAssist, Inc.  
c/o Mr. Robert Bollinger  
Director, Quality Assurance  
240 Alpha Drive  
Pittsburgh, PA 15238

SEP 20 2011

Re: K110493  
TandemHeart System  
Regulatory Number: 21 CFR 870.4360  
Regulation Name: Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type  
Regulatory Class: III (three)  
Product Code: KFM  
Dated: August 12, 2011  
Received: August 15, 2011

Dear Mr. Bollinger:

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 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.

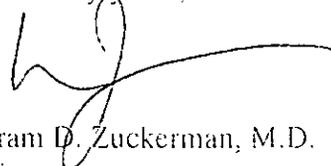
Page 2 - Mr. Robert Bollinger

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

**Section VII**

**Indications for Use Statement**

510(k) Number: K110 493

**Device Name:** CardiacAssist TandemHeart System

**Indication for Use:** The TandemHeart System consists of the TandemHeart Blood Pump, a single use device, the TandemHeart Controller, a reusable control system for the Blood Pump, and disposable accessory items used in conjunction with the Blood Pump.

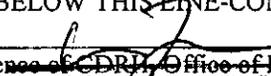
The TandemHeart System is intended for extracorporeal circulatory support using an extracorporeal bypass circuit. Intended duration of use is for periods appropriate to cardiopulmonary bypass, up to six hours. It is also intended to be used as an extracorporeal circulatory support system (for periods up to six hours) for procedures not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, mitral valve reoperation, surgery of the vena cava and/or aorta, liver transplant, etc.)

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division of Cardiovascular Devices)

**Division of Cardiovascular Devices**

510(k) Number 16