

TandemHeart Escort Controller 510(k) Summary

AUG 22 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92.

A. Application Information:

Date Prepared: May 12, 2006

Submitter's Name & Address: CardiacAssist, Inc.
240 Alpha Drive
Pittsburgh, PA 15238

Contact Person: Mr. Robert Bollinger
Director of Quality Assurance
Ph: 412-963-7770 x229
Fax: (412) 963-0800
e-mail: RBollinger@cardiacassist.com

B. Device Information:

Trade or Proprietary Name: TandemHeart Escort Controller

Common or Usual Name: Cardiopulmonary bypass pump speed control

Classification Name: Class II, DWA, 21 CFR - 870.4380
Control, Pump Speed, Cardiopulmonary Bypass

Performance Standard: Performance standards do not currently exist for these devices. None established under section 514 of the Food, Drug and Cosmetic Act.

C. Predicate Device:

CardiacAssist Model AB-180 XD Blood Pump Controller, K991783, found substantially equivalent November 1, 2000. Name changed to TandemHeart PTVA Controller

D. Device Description:

The TandemHeart Escort (T.H.E) Controller is a microprocessor-based pump motor drive and infusion system. It is designed to operate on AC current (110/240 VAC, 50/60 Hz) or on internal, rechargeable batteries for intra-hospital transport.

The T.H.E Controller generates the signals required to power the drive motor of the TandemHeart Blood Pump, which turns the impeller to propel blood through the Pump. The system works independently of the heart. The Controller also serves to deliver the infusate into the TandemHeart Blood Pump and to provide information regarding system performance including measured flow. It is portable and designed to be pole mounted, hung from a horizontal bed rail, or placed on a table top. It is simple to use, with an integral backup motor control circuit, and backup batteries for redundant operation.

E. Intended Use:

The TandemHeart Escort Controller is intended to be used with the TandemHeart PTVA System. The TandemHeart PTVA System consists of the TandemHeart PTVA Blood Pump, a single use, disposable device; The TandemHeart Escort (T.H.E.) Controller, a reusable control system for the TandemHeart PTVA Blood Pump; and disposable accessory items used in conjunction with the TandemHeart PTVA System.

In the U.S., the TandemHeart PTVA 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.)

F. Technological Characteristics:

The TandemHeart Escort Controller employs the same functional scientific technology as its predicate device.

G. Comparison to Predicate Device

The TandemHeart Escort (T.H.E.) Controller has the same intended use and indications for use as its predicate, the AB-180 XD Blood Pump Controller. The primary function of the T.H.E. Controller remains the same as its predicate, which is to supply Blood Pump motor power and motor control. The T.H.E Controller has been designed to provide improved portability using the same technology as the AB-180 XD Controller.

The AB-180 XD (TandemHeart PTVA) Controller utilized a monochromatic display for the display of operational information whereas the T.H.E. Controller upgraded the display to a Color LCD. Other changes include a smaller case for the controller hardware while utilizing the same blood pump, and an optional blood flow sensor. The equivalency of the indications for use, the design features and the functional characteristics raise no new safety or effectiveness issues.

H. Summary of Performance Data:

The performance characteristics of the TandemHeart Escort Controller were tested and compared with CardiacAssist performance specifications established for the device, voluntary standards for EMC, Electrical Safety and with the commercially available predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2006

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

Re: K061369
TandemHeart Escort (T.H.E.) Controller
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II (two)
Product Code: DWA
Dated: August 1, 2006
Received: August 2, 2006

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 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.

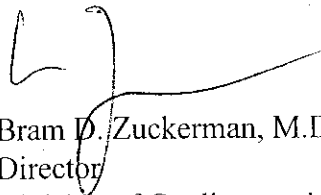
Page 2 – Mr. Robert Bollinger

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); 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 (240) 276-0120. 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/industry/support/index.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 Statement

510(k) Number K061369

Device Name CardiacAssist TandemHeart Escort Controller

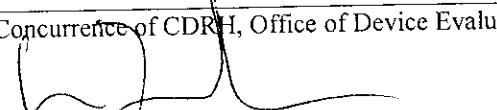
Indication for Use The TandemHeart Escort Controller is intended to be used with the TandemHeart PTVA System. The TandemHeart PTVA System consists of the TandemHeart PTVA Blood Pump, a single use, disposable device; The TandemHeart Escort (T.H.E.) Controller, a reusable control system for the TandemHeart PTVA Blood Pump; and disposable accessory items used in conjunction with the TandemHeart PTVA System.

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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 Sign-Off)
Division of Cardiovascular Devices

510(k) number K061369