DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 17, 2016

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

Re: K110493
Trade/Device Name: TandemHeart System
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-Roller Type Cardiopulmonary Bypass Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: August 12, 2011
Received: August 15, 2011

Dear Mr. Bolinger:

This letter corrects our substantially equivalent letter of September 20, 2011.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Eric E. Richardson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K110493

Device Name
TandemHeart System

Indications for Use *(Describe)*
The TandemHeart pump is intended to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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CardiacAssist, Inc.

Section VIII
510(k) Summary

Date: 29 July 2015

Applicant
CardiacAssist, Inc.
240 Alpha Drive
Pittsburgh, PA 15238
Telephone: 412-963-7770 x266
Fax: 412-963-0800

Contact: Greg Johnson
Title: Director of Regulatory Affairs
e-mail: gjohnson@tandemheart.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 Escort Controller (K061369), and the TandemHeart Blood Pump (K991783), 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 pump is intended to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

CardiacAssist, Inc.

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.