CardiacAssist, Inc.

K133293

FEB 12 2014

Section 8
510(k) Summary

Date: 2/11/14

Applicant

CardiacAssist, Inc.
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Contact Person

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Device

Trade/Proprietary Name:	15 French TandemHeart Femoral Arterial Cannula Set
Common Name:	Femoral Arterial Cannula and Introducer
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing. (21 CFR 870.4210, Product Code DWF)

Predicate Devices

17 French TandemHeart Femoral Arterial Cannula Set (K120543)
Medtronic Bio-Medicus Femoral Cannula and Introducer (K924642)

Device Description

The 15 French TandemHeart Femoral Arterial Cannula Set consists of two components, as shown in **Figure 1**: a 15 Fr. Femoral Arterial Cannula and a 10 Fr. Introducer. The device is intended to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal circulatory support equipment. The product is intended to be single patient, single use, sterile device.

The cannula has multiple side holes in addition to the tip opening for unimpeded flow of blood at the distal end and a vented barbed fitting at the proximal end to enable the connection of 3/8" tubing. Radiopaque markers are embedded at the distal tip of the cannula, and the cannula body is wire-reinforced for visualization under fluoroscopy. Insertion depth markings have been incorporated in the cannula body working length from 5 to 17 cm measured from the distal tip.

The cannula includes a suture wing to provide a means for securing the cannula to the patient and a stop component to minimize cannula insertion depth beyond its working length. Printing on the proximal region of the cannula indicates the area where a clamp should be applied if needed during the set-up or removal process.

The 10 Fr. introducer is provided to facilitate placement of the arterial cannula, within the target vessel, and is designed with a tapered distal tip. The introducer proximal end contains a luer hub to aid in the removal of the introducer. The introducer body is also constructed of a radiopaque material for visualization under fluoroscopy.

The introducer includes a hemostasis cap that provides the interface between the cannula proximal connector and introducer body. The hemostasis cap aids in minimizing blood loss during the insertion of the cannula/introducer assembly into the target vessel.

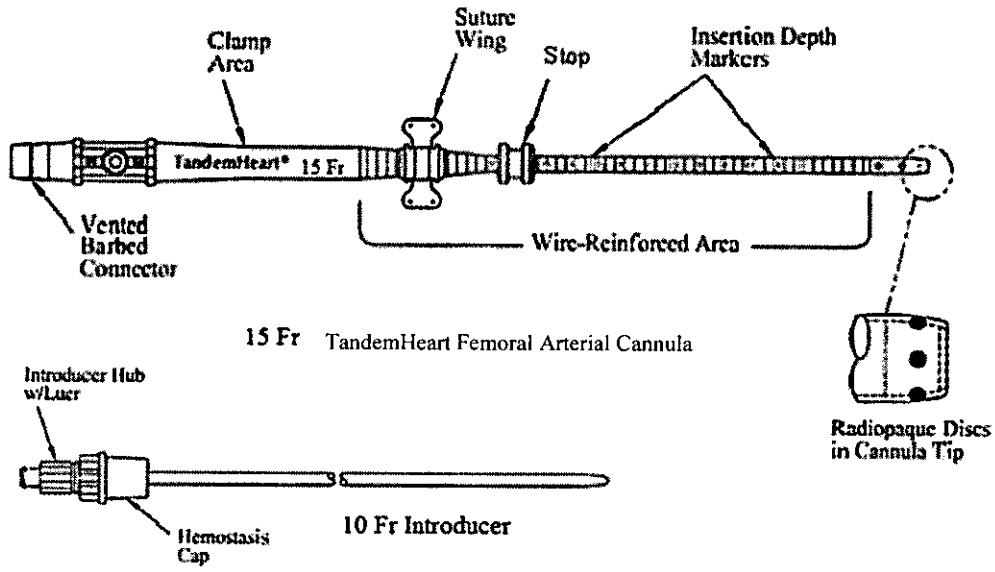

Figure 1: TandemHeart Femoral Arterial Cannula Set

Intended Use

The 15 French TandemHeart Femoral Arterial Cannula Set is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment. The cannula introducer is intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal circulatory support. These devices are to be used by a trained physician only.

Comparison of Technological Characteristics

The 15 French TandemHeart Femoral Arterial Cannula Set is identical to the predicate 17 French TandemHeart Femoral Arterial Cannula Set, with the exception that it is two French smaller in diameter along the working length of the device. It is designed for the same intended use as the 17 French Femoral Arterial cannula, but in smaller patients and/or those who require less blood flow. Both products consist of a wire-reinforced, polyurethane arterial cannula and a polyurethane introducer. All materials and methods of manufacture are identical.

Performance Data

The 15 French TandemHeart Femoral Arterial Cannula Set has a slightly lower maximum achievable flow rate compared to the 17 French TandemHeart Arterial Cannula Set, due to the smaller diameter. However, the maximum achievable flow rate is equivalent to that of the 15 Fr Bio-Medicus Femoral Arterial Cannula.

Non-clinical performance testing was performed to demonstrate substantial equivalence between the 15 French TandemHeart Femoral Arterial Cannula Set and the predicate 17 French TandemHeart Femoral Arterial Cannula Set. For size-dependent performance characteristics, the 15 Fr Bio-Medicus Femoral Arterial Cannula was used for comparison.

The performance testing included in-vitro hemolysis testing, in-vitro system capacity testing, kink testing, leak testing, and deflection testing. All performance tests were conducted on both the 15 French TandemHeart Femoral Arterial Cannula Set and the applicable control device (either the 17 French TandemHeart Femoral Arterial Cannula Set or the 15 Fr Bio-Medicus Femoral Arterial Cannula). Based on the performance test results, the TandemHeart Femoral Arterial Cannula Set was found to meet the established design input requirements as well as to perform comparably to the predicate devices.

Conclusions

The 15 French TandemHeart Femoral Arterial Cannula Set is substantially equivalent to the 17 French TandemHeart Femoral Arterial Cannula Set in design characteristics, performance, and intended use. For size-dependent performance characteristics such as flow rate, the 15 French TandemHeart Femoral Arterial Cannula Set is substantially equivalent to the 15 French Bio-Medicus Femoral Arterial Cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

CardiacAssist, Inc.
Greg Johnson
240 Alpha Drive
Pittsburgh, PA 15238

Re: K133293
Trade/Device Name: 15 French TandemHeart Femoral Arterial Cannula Set
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing.
Regulatory Class: Class II
Product Code: DWF
Dated: January 10, 2014
Received: January 13, 2014

Dear Greg Johnson:

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 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. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K133293

Device Name: 15 Fr TandemHeart Femoral Arterial Cannula Set

Indications For Use:

The 15 French TandemHeart Arterial Cannula Set (15 Fr. THAC) is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment. The cannula introducer is intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal circulatory support. These devices are to be used by a trained physician only.

Prescription Use __X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)