Section 5
510(k) Summary

JAN 2 9 2014

Date: 6/20/2013

Applicant

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Contact person

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Device

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

Predicate Device

Medtronic Bio-Medicus Femoral Venous Cannula and Introducer (K924642). The dilator is identical to that used with the TandemHeart Transseptal Cannula (K052570 and K082425).

Device Description

The TandemHeart Venous Cannula Set consists of three components, as shown in **Figure 1**: a 21 Fr. Venous Cannula, 14 Fr. Obturator, and an optional 14/21 Fr. Two-stage Dilator, that accepts a 0.035 in. guidewire. 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 cannulae are available in two configurations:

1. 21 Fr. x 62 cm. with options for tip curvature of 0° and 50°
2. 21 Fr. x 72 cm. with tip curvature of 50°

The cannula has multiple side holes in addition to the tip opening for unimpeded flow of blood at the distal end and a 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 are incorporated in the cannula body from 10 to 62 or 72 cm, depending on the length option, measured from the distal tip.

The cannula includes a suture wing to provide a means for securing the cannula to the patient. Printing on the proximal region of the cannula indicates the area where a clamp should be applied if needed during the set-up or the removal process.

The 14 Fr. Obturator is provided to facilitate placement of the venous cannula, within the target vessel, and is designed with a tapered distal tip. The Obturator proximal end contains a luer hub to aid in the removal of the obturator. The Obturator body is constructed of a radiopaque material for visualization under fluoroscopy.

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

The 14/21 Fr. Dilator is provided to aid introduction of the obturator/cannula assembly at the insertion site.

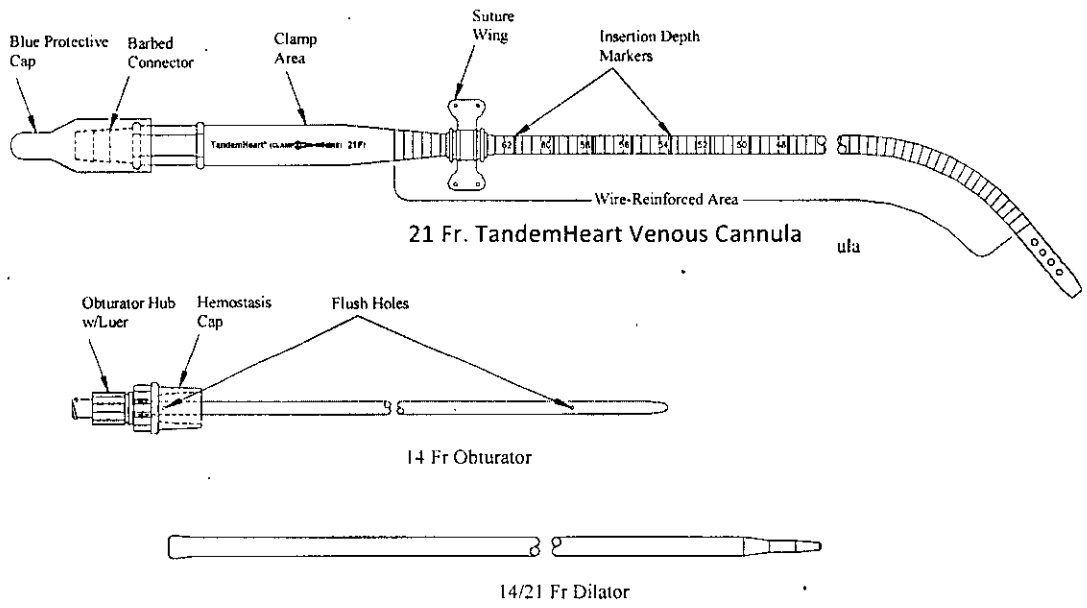

Figure 1: TandemHeart Venous Cannula Set

Intended Use

The TandemHeart Venous Cannula Set is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment. The cannula obturator and dilator are intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal circulatory support.

Comparison of Technological Characteristics

The TandemHeart Venous Cannula Set and the predicate Medtronic Bio-Medicus Femoral Venous Cannula and Introducer both consist of a wire-reinforced, polyurethane venous cannula and a polyurethane obturator. There are also a number of technological differences: 1) the TandemHeart Venous Cannula Set contains an additional component located on the exterior proximal portion of the cannula: a suture wing to provide a means of securing the cannula to the patient; 2) the 72 cm TandemHeart Venous Cannula Set contains two Suture Rings for securing the cannula to the patient; 3) the TandemHeart Venous Cannula Set's cannula includes a distal tip taper, while the predicate has a straight tip; 4) the TandemHeart Venous Cannula is longer than the predicate to allow improved flexibility in positioning within the venous system; 5) the TandemHeart Venous Cannula features three radiopaque disks at the distal tip of the cannula; and 6) the TandemHeart Venous Cannula Set includes a 14/21 Fr. dilator to be used at the physician's discretion for additional aid in inserting the obturator/cannula assembly. All of the technological differences are part of the set's design to aid in the insertion, positioning and securing of the cannula.

Performance Data

Non-clinical performance testing was conducted to demonstrate substantial equivalence of flow characteristics between the TandemHeart Venous Cannula Set and the predicate, Medtronic Bio-Medicus Femoral Venous Cannula. The performance testing included in-vitro system capacity testing and flow vs. pressure drop (HQ). This testing verified that despite the longer length of the TandemHeart Venous Cannula and distal tip taper relative to the Bio-Medicus Femoral Venous Cannula, it was able to sustain flows comparable to the predicate.

Flexibility, strength, biocompatibility, in-vitro hemolysis, leak testing, sterilization, and shelf life of the TandemHeart Venous Cannula are addressed by comparison with reference devices, specifically the CardiacAssist Transseptal Cannula Set-EF and EF-72 that were cleared under K052570 and K082425, respectively. Based on the performance test results and data from these two other devices, the TandemHeart Venous Cannula Set was found to meet established design input requirements and thus to be substantially equivalent to the predicate Medtronic Bio-Medicus Femoral Venous Cannula and Introducer.

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

January 29, 2014

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

Re: K133236
Trade/Device Name: TandemHeart Venous 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: December 6, 2013
Received: December 11, 2013

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): K133236

Device Name: TandemHeart Venous Cannula Set

Indications For Use:

The TandemHeart Venous Cannula Set is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment. The cannula obturator and dilator are intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal circulatory support.

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