Section IV
510(k) Summary

Date 16 September 2005

Applicant

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Contact: Tim Krauskopf
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Device

Trade/Proprietary Name: CardiacAssist Transseptal Cannula Set-EF
Common Name: Enhanced Flow Transseptal Cannula
Classification Name: Catheter Cannula

Predicate Devices

CardiacAssist Transseptal Cannula Set (K030398)
MDT Biomedicus Femoral Cannula 96670-021 (K924642)

Device Description

The TandemHeart Transseptal Cannula Set-EF consists of three components, as shown in Figure 1: (1) 21 Fr Transseptal Cannula, (2) 14 Fr Obturator, and (3) 14/21 Fr Two-stage Dilator. The Obturator and Dilator are designed to accept a standard 0.035 in. guidewire.

The 21 Fr Transseptal Cannula allows for drainage of the left atrium during left ventricular bypass. It has 14 side holes in addition to the tip opening for unimpeded inflow of blood at the distal end, a barbed fitting at the proximal end, and insertion depth markings from 40 to 62 cm measured from the distal end. The Cannula also includes a Suture Wing to provide a means for securing the Cannula to the patient. The 21 Fr body of the Cannula includes a wire-reinforced area for clear visualization under fluoroscopy and for resistance to kinking. The wire-reinforcing also permits a thin-walled

construction. This feature allows for a larger inside diameter (lumen) while maintaining the predicate CAI cannula's outside diameter. Consequently, greater flow can be achieved with the same pressure drop across the cannula versus the predicate CAI cannula. Printing on a region of the cannula which is not wire-reinforced indicates the area where a clamp should be applied as needed during the set-up or removal process. The distal end of the Cannula is curved for natural anatomical placement from the inferior vena cava into the left atrium. The printing on the cannula is oriented to show the clinician that the distal tip curves to the right when the printing is on the top of the cannula body.

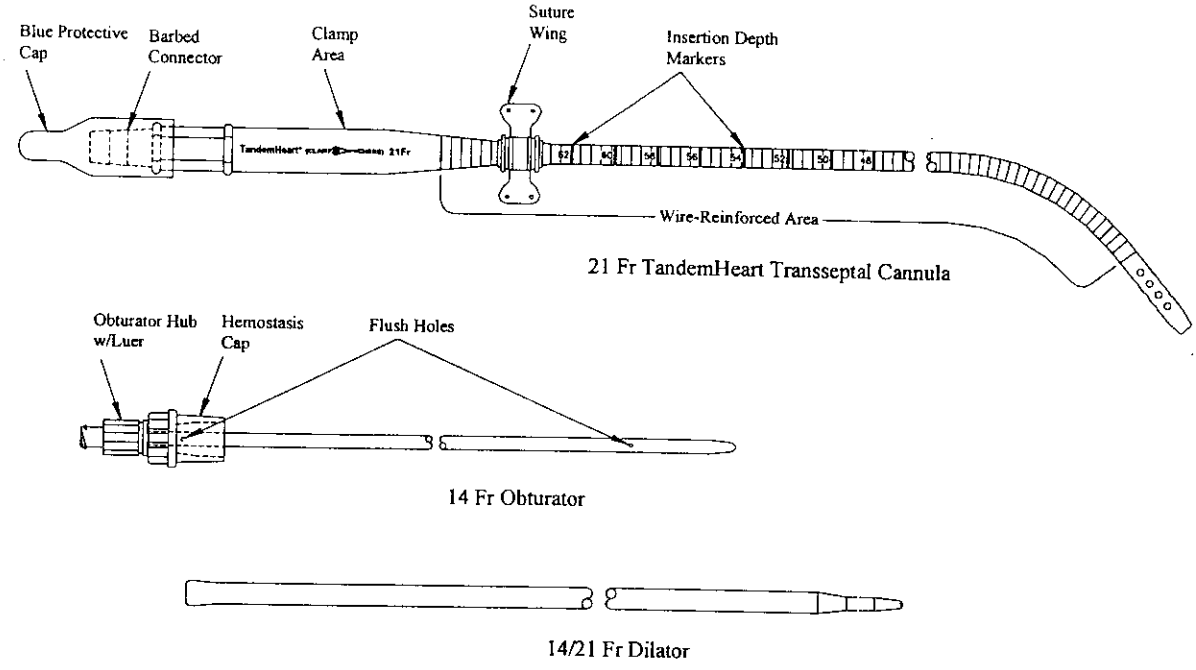

Figure 1. 21 Fr. Transseptal Cannula Set-EF

The 14 Fr Obturator is used to advance the Cannula over a guidewire to the right atrium from the inguinal area and then across the atrial septum into the left atrium. It contains a Luer hub and flush side holes at both the distal and proximal ends to facilitate de-airing and to allow for use of contrast material to confirm final positioning of the Cannula. An hemostasis cap prevents excessive blood loss when the Cannula/Obturator assembly is inserted into the femoral vein. The Obturator body is fabricated of radiopaque material for easy visualization under fluoroscopy.

The 14/21 Fr. Dilator is provided for pre-dilation of the fossa ovalis once left atrial access is achieved via standard transseptal technique and a guidewire has been placed into the left atrium. The stepped design of the distal tip of the Dilator provides tactile feedback to the clinician as the dilation is achieved. The Dilator is fabricated of radiopaque material for easy visualization under fluoroscopy.

Intended Use

The TandemHeart Transseptal Cannula Set-EF is intended for transseptal catheterization of the left atrium via the femoral vein for the purpose of providing a means for temporary (six hours or less) left ventricular bypass when connected to the TandemHeart extracorporeal blood pump which returns blood to the patient via the femoral artery or other appropriate site.

Comparison of Technological Characteristics

The Transseptal Cannula Set-EF contains a stainless-steel-wire-reinforced, polyurethane Transseptal Cannula with a Suture Wing, a polyurethane Obturator, and a polyethylene Two-stage Dilator. The predicate CAI Cannula Set contains a polyurethane Transseptal Cannula with a Suture Wing and two Suture Rings, a polyurethane Obturator, and a polyethylene Two-stage Dilator. The predicate MDT Cannula is a stainless-steel-wire-reinforced, polyurethane Transseptal Cannula. The Transseptal Cannula for the Transseptal Cannula Set-EF is made of the same materials and in substantially the same way as the predicate MDT cannula.

Performance Data

Testing of the Transseptal Cannula Set-EF was completed for flow vs. pressure drop (HQ), kink radius performance, tensile strength, leak testing, and deflection testing. The Transseptal Cannula-EF HQ and kink radius performance after six hour use was substantially better than that of the predicate CAI cannula. The results of the tensile strength and leak testing indicated that the Transseptal Cannula-EF met or exceeded the predicate CAI cannula testing thresholds. Deflection testing indicated that the Transseptal Cannula-EF performed substantially equivalent to the predicate CAI cannula. The obturator for the Transseptal Cannula Set-EF was shown to have tensile strength that met or exceeded the predicate CAI obturator testing threshold. The Transseptal Cannula-EF set uses the same dilator as the predicate CAI cannula.

Conclusions

The Transseptal Cannula Set-EF is substantially equivalent to the CardiacAssist Transseptal Cannula Set in design characteristics, performance, and intended use. The THTC-EF is substantially equivalent to the predicate MDT cannula in materials and method of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2006

CardiacAssist, Inc.
c/o Mr Tim Krauskopf
Sr. Vice President
240 Alpha Drive
Pittsburg, PA 15238

Re: K052570
TandemHeart Transseptal Cannula Set-EF
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Catheter, Cannula, or Tubing
Regulatory Class: Class II (Two)
Product Code: DWF
Dated: December 14, 2005
Received: December 15, 2005

Dear Mr. Krauskopf:

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.

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

510(k) Number (if known): K052570

Device Name: TandemHeart® Transseptal Cannula Set - EF

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052570

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