CardiacAssist, Inc.

K08 2425

SEP 1 8 2008

Section VIII
510(k) Summary

Date 20 August 2008

Applicant
CardiacAssist, Inc.
240 Alpha Drive
Pittsburgh, PA 15238
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Contact: Robert Bollinger
Title: Director of Quality
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Device

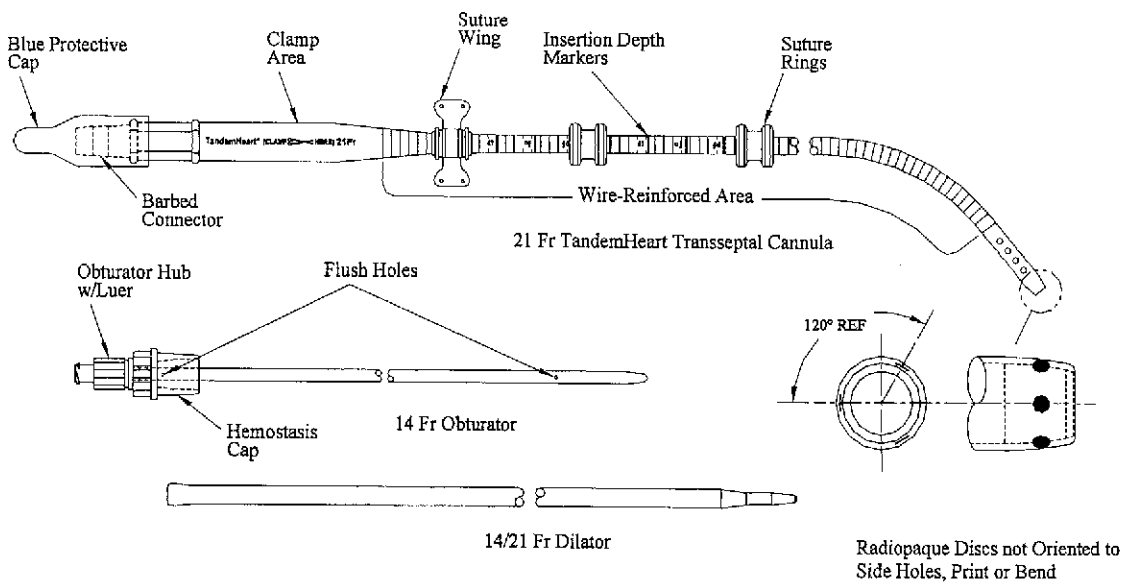
Trade/Proprietary Name: CardiacAssist TandemHeart Transseptal Cannula Set-EF 72
Common Name: Enhanced Flow Transseptal Cannula, 72 cm
Classification Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing

Predicate Devices

CardiacAssist TandemHeart Transseptal Cannula Set-EF (K052570)
CardiacAssist Transseptal Cannula Set (K030398)
Medtronic BioMedicus Pediatric Femoral Venous Cannula (K872033)

Device Description

The TandemHeart Transseptal Cannula Set-EF 72 consists of three main components, a 21 Fr Transseptal Cannula, a 14 Fr Obturator, and a 14/21 Fr Two-stage Dilator which are intended for the drainage of the left atrium during left ventricular bypass.



Intended Use

The TandemHeart Transseptal Cannula Set-EF 72 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 72 is identical in construction to the predicate Transseptal Cannula Set-EF, with the exception that it is 10 cm longer in length. The increase in length results in a slightly higher pressure drop in the cannula. The Transseptal Cannula Set-EF 72 also contains suture rings in a separate sterile pouch, which are manufactured from the same material used to make the suture wings in the predicate Transseptal Cannula Set-EF. These rings are identical to those in the predicate CardiacAssist Transseptal Cannula set that was cleared under K030398. The Transseptal Cannula Set-EF 72 also has encapsulated Radiopaque Marker discs at the cannula tip for clear visualization under fluoroscopy. These markers are identical to those utilized in the predicate BioMedicus Pediatric Femoral Venous Cannula that was cleared per K872033.

Performance Data

A risk assessment was conducted to determine the impact of the changes and the appropriate testing to perform. Subsequently, testing of the TandemHeart Transseptal Cannula Set-EF 72 was completed to verify flow vs. pressure drop (HQ), suture ring performance, mechanical integrity of the radiopaque marker disc encapsulation, and hemolysis. The Transseptal Cannula-EF 72 HQ testing results indicated a flow performance after six hour use that was consistent with the longer length, and substantially equivalent to the predicate THTC-EF cannula. The results of hemolysis testing, radiopaque marker disc testing and suture ring testing demonstrated that the THTC-EF 72 cannula was substantially equivalent in performance to the predicate devices.

Conclusions

The CardiacAssist TandemHeart Transseptal Cannula Set-EF 72 is substantially equivalent to the predicate CardiacAssist TandemHeart Transseptal Cannula Set-EF in design characteristics, performance, materials, method of construction, and intended use. The suture rings of the CardiacAssist TandemHeart Transseptal Cannula Set-EF 72 are also substantially equivalent to the predicate CardiacAssist Transseptal Cannula Set. The Radiopaque Marker disks at the tip of the CardiacAssist TandemHeart Transseptal Cannula Set-EF 72 are substantially equivalent to those in the BioMedicus Pediatric Femoral Venous Cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2008

Mr. Robert Bollinger
Director of Quality Assurance
CardiacAssist, Inc.
240 Alpha Dr.
Pittsburgh, PA 15238

Re: K082425
TandemHeart Transseptal Cannula Set-EF 72, Model No. 5140-6217
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: August 20, 2008
Received: August 22, 2008

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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchner

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

Enclosure

CardiacAssist, Inc.

Section VII

Indications for Use Statement

510(k) Number: K082425

Device Name: CardiacAssist TandemHeart Trannseptal Cannula- EF 72

Indication for Use: The TandemHeart Transseptal Cannula Set-EF 72 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.

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 IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vorhees

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082425