K030398

CardiacAssist, Inc.

MAY 23 2003

510(k) Summary

Date February 4, 2003

Applicant

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

Contact: Tim Krauskopf
Title: Sr. Vice President
e-mail: tkrauskopf@cardiacassist.com

Device

Trade/Proprietary Name: CardiacAssist Transseptal Cannula Set
Common Name: Transseptal Cannula
Classification Name: Catheter Cannula

Predicate Device

Elecath Percutaneous Left Atrial Cannulation Set (K854511)

Device Description

The Transseptal Cannula Set consists of three components: (1) 21 Fr. Transseptal Cannula, (2) 13 Fr. Obturator, and (3) 14/21 Fr. Two-stage Dilator, that accept a 0.035 in. guidewire.

The 21 Fr. Transseptal Cannula (Figure 1) allows for drainage of the left atrium during ventricular bypass. It has 14 side holes in addition to the tip opening for inflow 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 Transseptal Cannula also includes a Suture Wing and 2 Suture Rings to provide a means for securing it to the patient.

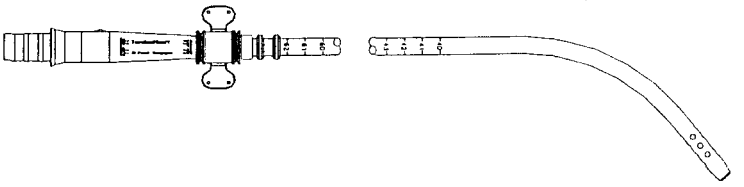


Figure 1. 21 Fr. Transseptal Cannula

The 13 Fr. Obturator (Figure 2) is used to advance the Cannula to the right atrium from the inguinal area and then across the atrial septum into the left atrium. It contains a luer hub and aspiration side holes at both the distal and proximal ends to facilitate de-airing and to allow for use of contrast material to facilitate final positioning of the Cannula. It also contains a radiopaque marker band proximal to the Cannula drainage holes when the Obturator is inserted in the Cannula.

Figure 2. 13 Fr. Obturator

The 14/21 Fr. Dilator (Figure 3) is provided for pre-dilation of the fossa ovalis once left atrial access is achieved via standard transseptal technique.

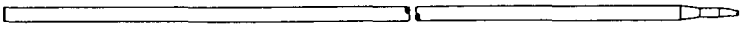


Figure 3. 14/21 Fr. Dilator

Intended Use

The Transseptal Cannula Set 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 a suitable extracorporeal blood pump unit which returns blood to the patient via the femoral artery or other appropriate site.

Comparison of Technological Characteristics

The Transseptal Cannula Set contains a polyurethane Transseptal Cannula with a Suture Wing and two Suture Rings, a polyurethane Obturator, and a polyethylene Two-stage

Dilator. An introducer needle, transseptal puncture kit and guidewire are to be provided by the user. The Elecath device contains a vinyl transseptal cannula and a stainless steel obturator with an extension plus an introducing catheter and needle, guidewire, and transseptal needle.

Performance Data

Testing of the Transseptal Cannula Set was completed for flow vs. pressure drop (HQ) and kink radius performance, tensile strength, leak testing and biocompatibility. The Transseptal Cannula HQ and kink radius performance after six hour use was substantially better than that of the Elecath cannula. The results of the tensile strength and leak testing indicated that the device exceeded the design requirements. The biocompatibility test results indicated that the transseptal Cannula Set successfully met the requirements of FDA's Blue Book Memorandum #G95-1 guidance and ISO 10993-1.

Conclusions

The Transseptal Cannula Set is substantially equivalent to the Elecath Percutaneous Left Atrial Cannulation Set

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Cardiac Assist, Inc.
c/o Mr. Tim Krauskopf
Sr. Vice President
240 Alpha Drive
Pittsburgh, PA 15238

Re: K030398
Cardiac Assist Transseptal Cannula Set
Regulation Number: 21 CFR 870.1300
Regulation Name: Catheter cannula
Regulatory Class: Class II (two)
Product Code: DQR
Dated: April 15, 2003
Received: April 16, 2003

Dear Mr. Krauskopf:

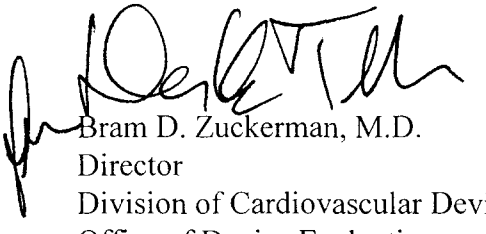
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

CardiacAssist, Inc.

Indications For Use

510(k) Number: K030398

Device Name: CardiacAssist Transseptal Cannula Set

Indications For Use:

The CardiacAssist Transseptal Cannula Set 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 a suitable extracorporeal blood pump unit which returns blood to the patient via the femoral artery or other appropriate site.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030398

Prescription Use Only