DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 30, 2016

Cardiac Assist, Inc.
Greg Johnson
VP Regulatory Affairs and Quality Assurance
240 Alpha Dr.
Pittsburgh, Pennsylvania 15238

Re: K162214
Trade/Device Name: Protek Solo 24 Fr 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: August 5, 2016
Received: August 8, 2016

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162214

Device Name
Protek Solo 24 Fr Venous Cannula Set

Indications for Use *(Describe)*

The Protek Solo 24 Fr Venous Cannula is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment. The 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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CardiacAssist, Inc.

Section 5
510(k) Summary
510(k) Traditional

Date: 8/5/2016

Applicant

CardiacAssist, Inc.
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Contact person

Greg Johnson, PhD
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e-mail: gjohnson@tandemheart.com

Device

Trade/Proprietary Name:	Protek Solo 24 Fr Venous Cannula Set
Common Name:	Venous Cannula and Introducer
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing. (21 CFR 870.4210, Product Code DWF)

Predicate Device

TandemHeart 21 Fr Venous Cannula (K133236)

Protek Duo Veno-Venous Cannula Introducer (K140999)

Device Description

The Protek Solo 24 Fr Venous Cannula Set consists of two components: a 24 Fr single lumen cannula and a 21 Fr. Introducer. The Introducer is designed to accept a standard 0.038 inch guidewire. The Protek Solo 24 Fr Venous Cannula Set is intended as a single patient, single use, sterile device.

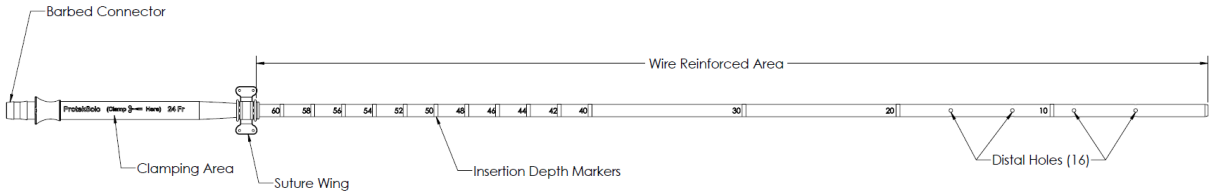

Figure 1. Protek 24 Fr Venous Cannula

A. 24 Fr Venous Cannula

The 24 Fr Venous Cannula (**Figure 1**) consists of a single lumen made of polyurethane with a wire-reinforced cannula body. The cannula has an insertable length of 60 cm. The distal section (insertable length) is 24 Fr with sixteen side holes spanning the distal 6.6" (16.8 cm) of the cannula. The proximal section of the cannula is clear and not wire-reinforced to allow visualization of blood and to enable clamping to prevent blood flow during set-up and removal. A non-vented barbed connector is affixed to the proximal end of the cannula and allows for connection of standard 3/8" blood circuit tubing. The cannula has printed insertion depth markings every 10 centimeters from 10 to 40 cm followed by every 2 centimeters for the rest of the insertable length measured from the distal end. The cannula also has a suture wing that can be used for securing the cannula in place to the patient.

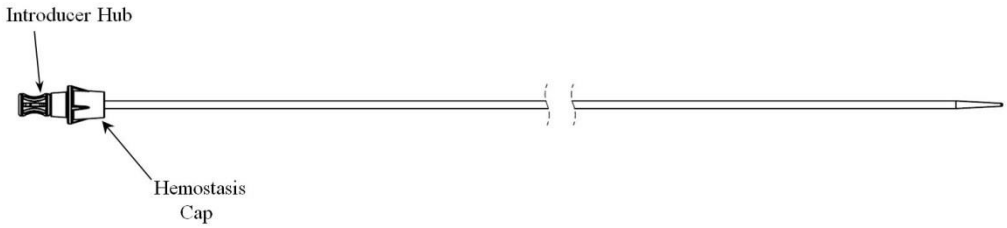

Figure 2: 21 Fr. Introducer

B. Introducer

The 21 Fr introducer (**Figure 2**) consists of a PVC tube with a PVC hub. The introducer fits inside the inner lumen of the cannula during insertion of the cannula/introducer assembly. The introducer **(Figure 2**) is used to advance the cannula over a guidewire and facilitate cannula placement within the target vessel. The introducer has a hub at its proximal end to manage introducer insertion and removal from the cannula. The hemostasis cap minimizes blood loss when the cannula/introducer assembly is inserted into the target vessel. The introducer body is constructed from radiopaque PVC material for visualization under fluoroscopy.

Indications for Use

The Protek Solo 24 Fr. Venous Cannula is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment. The 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 Protek Solo 24 Fr Venous Cannula is substantially equivalent to the TandemHeart 21 Fr. Venous Cannula (Catalog Number 5140-2163) in design characteristics, performance, and

intended use. The two cannula products differ in diameter (24 Fr vs 21 Fr), length (24 Fr is 2 cm longer than the predicate), and the number and precise location of side holes. All materials and methods of manufacture are identical. The Protek Solo 24 Fr Venous Cannula Introducer is substantially equivalent in design characteristics and intended use to the Protek Duo Veno-Venous Cannula Set Introducers. The two components differ only in length and diameter. All materials and methods of manufacture are identical.

Summary of Non-clinical Testing

Testing of the Protek Solo 24 Fr Venous Cannula Set included comparative hemolysis, pressure-flow testing, tensile strength, pathway integrity, kink radius, and stiffness.

Test	Method	Conclusion
Comparative Hemolysis	Side-by-side comparison with predicate of bench top hemolysis levels over 6 hours.	No difference in hemolysis levels between test articles and predicate controls.
Pressure-Flow	Measure pressure losses across cannula at different flow rates.	Measured flow rates exceed the smaller predicate at all levels of pressure difference across the cannula. Design specifications were met.
Tensile Strength	Pull testing of both cannula and introducer	Acceptance criteria were identical to those of the predicate and were met in all tests.
Pathway Integrity	Pressure testing	Acceptance criterion was identical to that of the predicate and was met in all tests.
Kink Radius	Flow rate reduction caused by specified minimum bend radius was measured	Acceptance criterion was identical to that of the predicate and was met in all tests.
Stiffness	Deflection testing to measure force required to bend cannula a specified distance	The cannula, the introducer, and the cannula/introducer assembly met acceptance criteria established to ensure the cannula is stiff enough to insert while remaining flexible enough to avoid vessel injury.

Conclusion

The Protek Solo 24 Fr Venous Cannula is made from the same materials, using the same manufacturing processes and sterilization techniques as the predicate TandemHeart 21 Fr Venous Cannula. Testing demonstrated that hemolysis, tensile strength, pathway integrity, and kink radius are identical to the predicate. Stiffness and pressure-flow properties differed as

expected for the larger diameter cannula and met established acceptance criteria. The Protek Solo 24 Fr Venous Cannula Introducer is made from the same materials, using the same manufacturing processes and sterilization techniques as the predicate Protek Duo Veno-Venous Cannula Introducer. Stiffness differed as expected for the larger diameter introducer and met established acceptance criteria. The Protek Solo 24 Fr Venous Cannula Set is determined to be substantially equivalent to the predicates.

{End of Section}