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

March 4, 2016

Cardiac Assist, Inc.
Greg Johnson, PhD
Director of Regulatory Affairs
240 Alpha Drive
Pittsburgh, PA 15238

Re: K160257
Trade/Device Name: PROTEK Duo 31 Fr. Veno-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: January 27, 2016
Received: February 1, 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 yours,

Bram D. Zuckerman -S

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)*
K160257

Device Name
PROTEK Duo 31 Fr. Veno-Venous Cannula Set

Indications for Use *(Describe)*
The PROTEK Duo 31 Fr. Veno-Venous Cannula Set is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

CardiacAssist, Inc.

**Section 5**
**510(k) Summary**
**510(k) Special**

**Date:** 3/3/2016

**Applicant**

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

**Contact person**

Greg Johnson, PhD
Title: Director of Regulatory Affairs
Phone: 412-963-7770 x266
e-mail: gjohnson@tandemheart.com

**Device**

| | |
|---|---|
| Trade/Proprietary Name: | PROTEK Duo 31 Fr. Veno-Venous Cannula Set |
| Common Name: | Veno-Venous Cannula and Introducer |
| Classification Name: | Cardiopulmonary bypass vascular catheter, cannula, or tubing. (21 CFR 870.4210, Product Code DWF) |

**Predicate Device**

PROTEK Duo 29 Fr. Veno-Venous Cannula (K140999)

**Reference Device**

Avalon Elite 31 Fr. Veno-Venous Cannula (K081820)

**Device Description**

The PROTEK Duo 31 Fr. Veno-Venous Cannula Set consists of two components: a 31 Fr. Dual lumen Veno-Venous Cannula and a 15.5 Fr. Introducer. The Introducer is designed to accept a standard 0.038 inch guidewire. The PROTEK Duo 31 Fr. Veno-Venous Cannula Set is intended as a single patient, single use, sterile device.

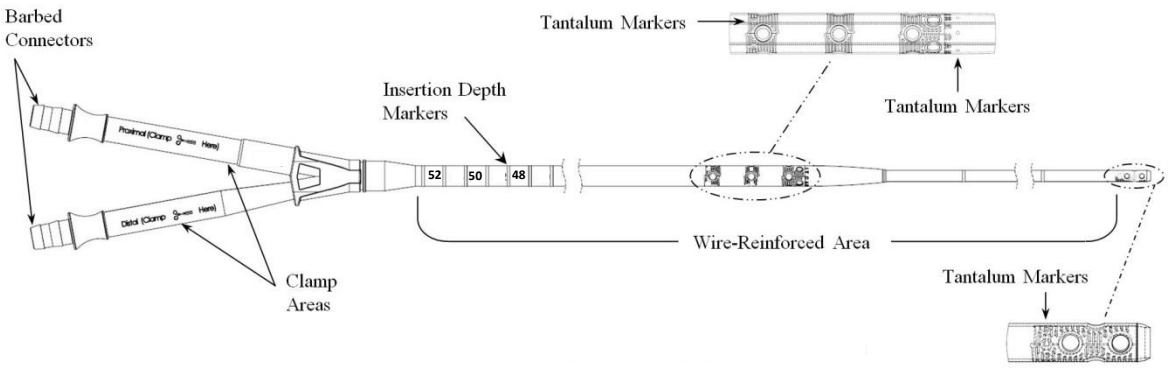


**Figure 1.** PROTEK **Duo 31 Fr. Veno-Venous Cannula**

The PROTEK Duo 31 Fr. Veno-Venous Cannula (**Figure 1**) consists of two distinct lumens with a wire-reinforced cannula body. The inner lumen is located entirely within the outer lumen forming two concentric channels

The distal section (inner lumen/cannula) of the cannula body has six side holes near the distal tip opening. The proximal sections of each lumen are clear and not wire-reinforced to allow visualization of blood and to enable clamping to prevent blood flow during set-up and removal of the cannula from the extracorporeal circulatory support equipment (see Figure 1). A non-vented barbed connector is affixed to both proximal ends (inner/distal and outer/proximal lumens) of the cannula and allow for connection of standard 3/8 inch blood circuit tubing for subsequent connection to extracorporeal circulatory support equipment.

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

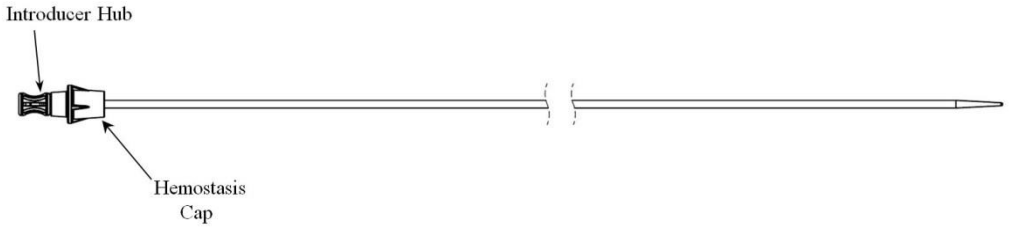


**Figure 2: 15.5 Fr. Introducer**

## Indications for Use

The PROTEK Duo 31 Fr. Veno-Venous Cannula Set is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.

## Comparison of Technological Characteristics

The PROTEK Duo 31 Fr. Veno-Venous Cannula Set is identical to the predicate PROTEK Duo 29 Fr. Veno-Venous Cannula Set, with the exception that it is two French larger in diameter along the proximal length, 2.5 Fr larger in diameter along the distal portion of the device, and approximately 1.97 inches (5.0 cm) longer. It is designed for the same intended use as the PROTEK Duo 29 Fr. Veno-Venous Cannula Set, but in larger patients and/or those who require additional blood flow. All materials and methods of manufacture are identical.

## Summary of Non-clinical Testing

Testing of the PROTEK Duo 31 Fr. Veno-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 Duo 31 Fr. Veno-Venous Cannula Set is made from the same materials, using the same manufacturing processes and sterilization techniques as the predicate device. 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 Duo 31 Fr. Veno-Venous Cannula Set is determined to be substantially equivalent to the predicate PROTEK Duo 29 Fr. Veno-Venous Cannula Set.

*{End of Section}*