May 25, 2018

CardiacAssist Inc
Greg Johnson
VP, Regulatory Affairs and Quality Assurance
240 Alpha Drive
Pittsburg, Pennsylvania 15238

Re: K181150
Trade/Device Name: ProtekDuo Mini 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: April 30, 2018
Received: May 1, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181150

Device Name
ProtekDuo Mini Veno-Venous Cannula Set

Indications for Use *(Describe)*

The ProtekDuo Mini 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.

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TANDEM | LIFE

Date: 30 April 2018

Applicant

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Contact person

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Title: VP, Regulatory Affairs and Quality Assurance
Phone: 412-963-7770 x266
e-mail: gjohnson@tandemlife.com

Device

Trade/Proprietary Name:	ProtekDuo Mini Veno-Venous Cannula Set
Common Name:	Veno-Venous Cannula Set
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing. (21 CFR 870.4210, Product Code DWF)

Predicate Device

TandemHeart 31 Fr. (31 Fr. ProtekDuo) Veno-Venous Cannula Set (K160257) (marketed under Trade Name: 31 Fr. ProtekDuo)

Device Description

The ProtekDuo Mini 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 ProtekDuo Mini Veno-Venous Cannula Set is intended as a single patient, single use, sterile device.

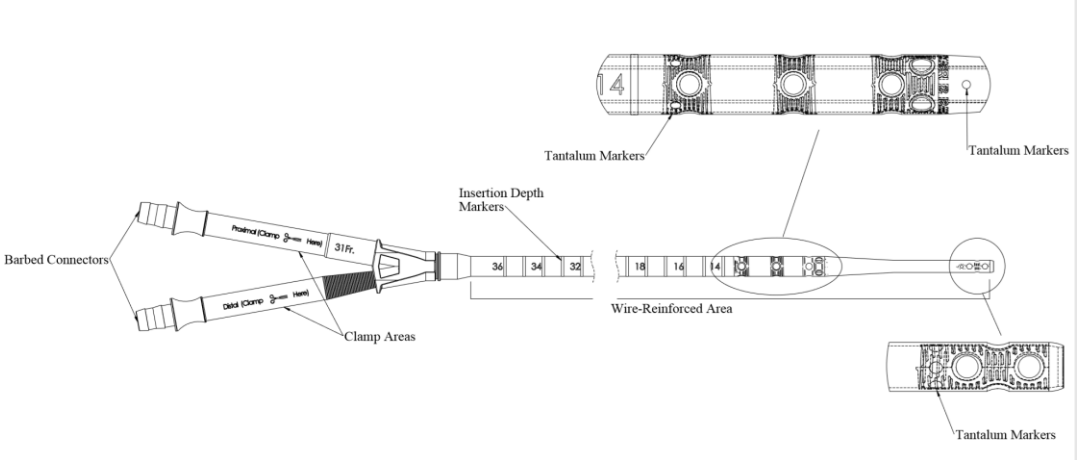

Figure 5-1. ProtekDuo Mini Veno-Venous Cannula

The ProtekDuo Mini Veno-Venous Cannula (**Figure 5-1**) 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 5-1**). 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 5-2**) 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.

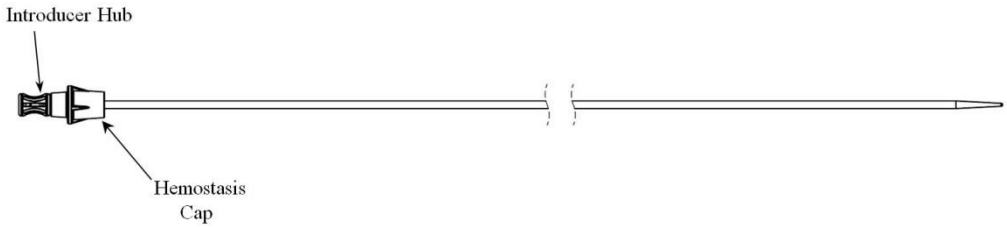

Figure 5-2: 15.5 Fr. Introducer

Indications for Use

The ProtekDuo Mini 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

ProtekDuo Mini Veno-Venous Cannula Set is an extension to the ProtekDuo Veno-Venous Cannula Family. It is identical to the TandemHeart 31 Fr. (31 Fr. ProtekDuo) Veno-Venous Cannula Set, except the distal lumen is approximately 14.2 cm shorter in length. The introducer is also approximately 14.2 cm shorter. It is designed for the same

intended use as the TandemHeart 31 Fr. (31 Fr. ProtekDuo) Veno-Venous Cannula Set. All materials and methods of manufacture are identical.

Summary of Non-clinical Testing

Testing of the ProtekDuo Mini 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 longer 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 ProtekDuo Mini 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 shorter length cannula and met established acceptance criteria. The ProtekDuo Mini Veno-Venous Cannula Set is determined to be substantially equivalent to the predicate TandemHeart 31 Fr. (31 Fr. ProtekDuo) Veno-Venous Cannula Set.

{End of Section}