October 6, 2023

CardiacAssist, Inc.
Mariah McMinn
Regulatory Affairs Specialist
620 Alpha Drive, Suite 2
Pittsburgh, Pennsylvania 15238

Re: K232480
Trade/Device Name: ProtekDuo Veno-Venous Cannula Sets
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulatory Class: Class II
Product Code: PZS
Dated: August 16, 2023
Received: August 16, 2023

Dear Mariah Mcminn:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.
Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232480

Device Name
ProtekDuo Cannula Sets

Indications for Use *(Describe)*
The ProtekDuo Veno-Venous Cannula is a single use dual lumen cannula, which provides both venous drainage and reinfusion of blood via the jugular vein, that is indicated for use in adult patients with acute respiratory failure requiring Veno-Venous Extracorporeal Membrane Oxygenation, where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent.

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.

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Date: 10/04/2023

Applicant:

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Telephone: 412-963-7770
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Contact Person:

Mariah McMinn
Title: Regulatory Affairs Specialist
Phone: 412-963-7770
e-mail: mariah.mcminn@livanova.com

Device:

Trade/Proprietary Name:	ProtekDuo Veno-Venous Cannula Sets
Common Name:	Dual lumen ECMO cannula
Classification Name:	Extracorporeal Circuit and Accessories for Long-Term Respiratory/Cardiopulmonary Failure (21 CFR 870.4100, Product Code PZS)

Primary Predicate Device: 81 FR 7451, Feb. 12, 2016

Secondary (Reference) Devices:

ProtekDuo 29 Fr. Veno-Venous Cannula (K140999)
ProtekDuo 31 Fr. Veno-Venous Cannula (K160257)
ProtekDuo 31 Fr. RD Veno-Venous Cannula (K181150)
Avalon Elite Bi-Caval Dual Lumen Catheter (K081820)
MC3 Jugular Dual Lumen Catheter (K180151)

Device Description:

Each ProtekDuo Veno-Venous Cannula Set includes a dual lumen cannula and an introducer. The introducer is designed to accept a standard 0.038-inch guidewire. The ProtekDuo Veno-Venous Cannula Sets are intended as single patient, single use, sterile devices.

Cannula

Each ProtekDuo Veno-Venous Cannula consists of two (2) distinct lumens, each made of polyurethane 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 is the smaller diameter lumen with six (6) 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. 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 cannula has two suture wings that can be used for securing the cannula in place to the patient. The cannulas also have printed insertion depth markings measured from the distal tip.

Introducer

Each introducer consists of a tube and 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 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 polyvinyl chloride material for visualization under fluoroscopy.

Indications for Use:

The ProtekDuo Veno-Venous Cannula is a single use dual lumen cannula, which provides both venous drainage and reinfusion of blood via the jugular vein, that is indicated for use in adult patients with acute respiratory failure requiring Veno-Venous Extracorporeal Membrane Oxygenation, where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent.

Comparison of Technological Characteristics:

The only modifications to the currently-cleared ProtekDuo Veno-Venous Cannulas are to the Indication for Use statement and modification to the depth markings on the device. All other aspects of the Subject devices are identical to the currently-cleared ProtekDuo devices listed as Reference devices.

Summary of Non-clinical Testing:

Simulated Use / Reliability (30 days)
Hemolysis
Pressure/Flow Characteristics
Tensile Strength
Leak
Deflection/Stiffness (Cannula, Introducer and Assembly)
Kink Resistance
Biocompatibility
Recirculation
In vivo Animal Study

Substantial Equivalence Comparison:

Substantial equivalence analysis includes comparison to: 1) the special controls of FDA's Final Order, 81 FR 7451, Feb. 12, 2016, and 2) comparison to the secondary (Reference) devices.

Special Controls:

The ProtekDuo Cannula Sets meet all special controls required by 21 CFR 870.4100.

- ***Special Control #1 - The technological characteristics of the device must ensure that the geometry and design parameters are consistent with the intended use, and that the devices and accessories in the circuit are compatible:*** The technological characteristics of the ProtekDuo Cannulas have been established through use in extracorporeal membrane oxygenation procedures. The Subject devices are designed to be compatible with other extracorporeal circuit devices and accessories.

- **Special Control #2 -** ***The devices and accessories in the circuit must be demonstrated to be biocompatible:*** The Subject devices are demonstrated to be biocompatible for prolonged (24 hours to 30 days) contact with circulating blood in accordance with ISO 10993-1.
- **Special Control #3 -** ***Sterility and shelf-life testing must demonstrate the sterility of any patient-contacting devices and accessories in the circuit and the shelf life of these devices and accessories:*** Testing demonstrates the sterility of the Subject device as provided and that it maintains its sterility, integrity, durability, and reliability over the stated shelf-life of the device.
- **Special Control #4 -** ***Non-clinical performance evaluation of the devices and accessories in the circuit must demonstrate substantial equivalence of the performance characteristics on the bench, mechanical integrity, electromagnetic compatibility***

(where applicable), software, durability, and reliability: Substantial equivalence is demonstrated by performance characteristics assessed through reliability, hemolysis, pressure/flow, tensile strength, leak, stiffness, recirculation, and kink resistance testing.

- **Special Control #5 -** ***In vivo evaluation of the devices and accessories in the circuit must demonstrate their performance over the intended duration of use, including a detailed summary of the clinical evaluation pertinent to the use of the devices and accessories to demonstrate their effectiveness if a specific indication (patient population and/or condition) is identified:*** 14-day *in vivo* evaluation demonstrated performance over a long-term duration of use in a biologic test system.

- **Special Control #6 -** ***Labeling must include a detailed summary of the non-clinical and in vivo evaluations pertinent to use of the devices and accessories in the circuit and adequate instructions with respect to anticoagulation, circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure:*** The Directions for Use contain the information detailed in this Special Control.

Predicate Devices:

The Subject devices are substantially equivalent to the Predicate device.

The Subject devices are substantially equivalent to the secondary (Reference) devices.

Conclusion:

The information and data included in this 510(k) notification demonstrates that the ProtekDuo Veno-Venous Cannula Sets are *substantially equivalent* to the Predicate device for venous drainage and reinfusion of blood via the internal jugular vein in patients with acute respiratory failure requiring Veno-Venous Extracorporeal Membrane Oxygenation, where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent.

{End of Section}