December 23, 2022

CardiacAssist, Inc.
Arielle Drummond
Manager, Regulatory Affairs
620 Alpha Drive, Suite 2
Pittsburgh, Pennsylvania 15238

Re: K211830
Trade/Device Name: LifeSPARC System
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulatory Class: Class II
Product Code: QNR

Dear Arielle Drummond:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 15, 2022. Specifically, FDA is updating this SE Letter due to a missing signature as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Nicole Gillette, OHT2: Office of Cardiovascular Devices, 240-402-6630, Nicole.Gillette@fda.hhs.gov.

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

November 15, 2022

CardiacAssist, Inc.
Arielle Drummond
Manager, Regulatory Affairs
620 Alpha Drive, Suite 2
Pittsburgh, Pennsylvania 15238

Re: K211830
Trade/Device Name: LifeSPARC System
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term Respiratory/Cardiopulmonary Failure
Regulatory Class: Class II
Product Code: QNR
Dated: November 8, 2022
Received: November 9, 2022

Dear Arielle Drummond:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211830

Device Name
LifeSPARC System

Indications for Use *(Describe)*
The LifeSPARC System is a centrifugal blood pump system intended to assist in circulation of the patient's blood when part of an extracorporeal circuit including physiologic gas exchange of the patient's blood in adult patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. These may include:
• Failure to wean from cardiopulmonary bypass following cardiac surgery in adult patients
• ECMO-assisted cardiopulmonary resuscitation in adult

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.

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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."

Date: 11/14/2022

Applicant

CardiacAssist, Inc. (dba TandemLife)
620 Alpha Drive
Pittsburgh, PA 15238
Telephone: 412-963-7770
Fax: 412-963-0800

Contact person

Arielle Drummond, PhD
Title: Director of Regulatory Affairs
e-mail: arielle.drummond@livanova.com

Device

Trade/Proprietary Name:	LifeSPARC System
Common Name:	ECMO Pump and Controller
Classification Name:	Extracorporeal Circuit and Accessories for Long-Term Respiratory/Cardiopulmonary Failure (21 CFR 870.4100, Product Code QNR)

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

Reference Devices:
TandemHeart System (K202751)
LifeSPARC System (K183623)

Device Description

The LifeSPARC Pump is a sterile, single-use, low prime volume centrifugal pump with an integrated motor and a single-point, pivot bearing. It is sterilized using ethylene oxide (EO) and sized to fit in the palm of the hand or to secure to the patient.

The LifeSPARC Controller provides the interface between pump and user, as well as the power and electrical signals to drive the pump. It is a microprocessor-based electromechanical pump drive system designed to operate on standard AC current (100/240 VAC, 50/60 Hz) or on internal, rechargeable batteries for intra-hospital transport.

Indications for Use

The LifeSPARC System is a centrifugal blood pump system intended to assist in circulation of the patient's blood when part of an extracorporeal circuit including physiologic gas exchange of the patient's blood in adult patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. These may include:

- Failure to wean from cardiopulmonary bypass following cardiac surgery in adult patients
- ECMO-assisted cardiopulmonary resuscitation in adults

Comparison of Technological Characteristics

The only modification to the currently-cleared devices is to the Indication for Use Statement. All other aspects of the subject devices are identical to the reference devices.

Summary of Non-clinical Testing

Reliability
Hemolysis
Pressure/Flow Characteristics
Biocompatibility
Sterilization and Shelf Life
Software
Alarms
Electrical Safety
Electromagnetic Compatibility
Usability

Substantial Equivalence Comparison

Substantial equivalence analysis includes comparison to the special controls of FDA's Final Order, 81 FR 7451, Feb. 12, 2016, as well as comparison to the reference devices.

Special Controls

Special Control Number #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 device are consistent and compatible with the use of the device to pump the blood through an extracorporeal circuit.

Special Control Number #2: ***The devices and accessories in the circuit must be demonstrated to be biocompatible.***

The LifeSPARC Pump meets all relevant biological endpoints per ISO 10993-1 for a device in contact with circulating blood for a prolonged duration of use (24 hours to 30 days).

Special Control Number #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 Number #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 of the LifeSPARC System performance characteristics was demonstrated through bench testing, mechanical integrity testing, electrical safety and electromagnetic compatibility testing, and software testing. Results of the reliability testing demonstrate the system achieves 85% reliability at 90% confidence for a 28-day mission.

Special Control Number #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*****.**

Animal Study:

The submission includes Animal Data of the LifeSPARC System in order to demonstrate that the system could operate for a period of 14 days without causing device-related clinically significant adverse reactions or events in the animal or experiencing product performance failures / malfunctions as close monitoring of the systems identified early problems allowing repairs or pump exchange before becoming clinically significant. Nine calves were placed on support using a LifeSPARC Pump and Controller, a TandemLung Oxygenator, and a 31Fr RD ProtekDuo Veno-Venous Cannula inserted into the vena cava. Eight (8) of nine (9) animals survived to the protocol defined timepoint of 14 Days ±1 day. There were no clinically significant thromboembolic or bleeding complications, vascular or myocardial injuries, adherent thrombus, or end organ damage related to the test devices. Additionally, a control group of five (5) calves were placed on support using a TandemHeart Pump and Controller, a TandemLung Oxygenator, and 31Fr RD ProtekDuo Veno-Venous Cannula inserted into the vena cava. The LifeSPARC System met the study criteria in a bovine model without any significant device related adverse clinical events or thromboembolic responses. The study demonstrated that the LifeSPARC system can be used for extended duration in a clinically relevant bovine model.

The conclusion of the animal study shows the test article, the LifeSPARC Pump (reference device K183623), performed in a similar manner to the control article, the TandemHeart Pump (reference device K202751).

Clinical Evaluation:

The submission includes an independent statistical analysis of data from the ELSO Registry, conducted by the Extracorporeal Life Support Organization. The propensity score analysis provided by the statistical group at ELSO clearly demonstrates the ability of LifeSPARC Pump to provide assisted extracorporeal circulation of the patient's blood in adult patients. Clinical data (observational data in a real-world setting) supporting the performance of the LifeSPARC Pump related to the relevant health risks described in the reclassification order was obtained from the independent Extracorporeal Life Support Organization (ELSO) Registry for patients supported with extracorporeal membrane oxygenation (ECMO). A propensity score analysis was performed by the ELSO group. The primary analysis compared the occurrence of ten extracorporeal membrane oxygenation (ECMO)-related clinical outcomes between the LifeSPARC Blood Pump versus other centrifugal pumps (i.e. the comparator group also includes the TandemHeart blood pump [reference device K202751]). The five outcomes of primary interest were pump failure, hemolysis, thrombosis or clots in circuit component, patient death within 24 hours of stopping ECMO, and patient death at discharge. The five outcomes of secondary interest were the use of renal replacement therapy (RRT during ECMO, pulmonary hemorrhage, circuit change, central nervous system (CNS) hemorrhage, and CNS infarction. A secondary analysis was conducted comparing the occurrence of the same ten ECMO-related clinical outcomes between the LifeSPARC Blood Pump versus the TandemHeart Blood Pump (i.e. reference device K202751). The results of the analyses are summarized below.

The results of the independent prespecified primary overlap-weighted analysis did not identify a statistically significant difference in the clinical outcomes in either the LifeSPARC Pump vs. Other Centrifugal Pump group or the LifeSPARC Pump vs. TandemHeart Pump group (i.e. comparator devices and TandemHeart Pump reference device K202751) when used in the same manner (off label for ECMO > 6 hours) for the primary endpoints attributable to or associated with the pump component of an ECMO circuit for primary outcomes/health risks of pump failure, hemolysis and thrombosis/thromboembolism (clots in circuit component). While not directly related to pump component of an ECMO circuit, results of outcomes/health risks of death prior to 24 hours post ECMO, discharged dead from hospital, CNS hemorrhage, CNS infarction, pulmonary hemorrhage, renal replacement therapy and circuit change, results from the overlap-weighted analysis did not identify a statistically significant difference in the clinical outcomes between the LifeSPARC Pump and comparators (i.e. devices used off-label for ECMO and TandemHeart Pump reference device K202751) when used in the same manner (off label for ECMO > 6 hours), as identified in the Final Order.

NOTE: The study is an enumerative study where all available ECMO data collected in the ELSO registry database that met the study criteria were analyzed. No hypothesis testing was prespecified and no multiplicity adjustment was made.

Special Control Number #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.

Conclusion

The LifeSPARC System (Pump and Controller) meets the special controls in FDA's final order (81 FR 7451, February 12, 2016) and is substantially equivalent to the Predicate Device, for assisted circulation of the patient's blood when part of an extracorporeal circuit including gas exchange of the patient's blood in adult patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. These may include:

- Failure to wean from cardiopulmonary bypass following cardiac surgery in adult patients
- ECMO-assisted cardiopulmonary resuscitation in adults.