



January 19, 2024

CardiacAssist, Inc.
Wendy Perreault
Consultant
620 Alpha Drive
Pittsburgh, Pennsylvania 15238

Re: K233736

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 Codes: QNR, KFM, DWA
Dated: November 21, 2023
Received: November 22, 2023

Dear Wendy Perreault:

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

Indications for Use

Submission Number (if known)

K233736

Device Name

LifeSPARC System

Indications for Use (Describe)

Extracorporeal Membrane Oxygenation

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.

Cardiopulmonary Bypass

The LifeSPARC System is intended to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

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: 16-Jan-2024

Applicant:

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

Contact Person:

Wendy Perreault
Title: Regulatory Affairs Consultant
e-mail: tl.regulatory@livanova.com

Device:

Trade/Proprietary Name: LifeSPARC System

Common Name: ECMO Pump and Controller/Cardiopulmonary Bypass System

Classification Name: Extracorporeal Circuit and Accessories for Long-Term
Respiratory/Cardiopulmonary Failure (21 CFR 870.4100, Product
Code QNR)

Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type (21 CFR
870.4360 / Product Code KFM)
Control, pump speed, cardiopulmonary bypass (21 CFR 870.4360 /
Product Code DWA)

Primary Predicate Device:

LifeSPARC System (K211830)

Reference Device:

LifeSPARC System (K232132)

This is a bundled submission for the devices cleared under submissions K211830 and K232132.
The same device is cleared for two different indications, under two different regulations.

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:Extracorporeal Membrane Oxygenation

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

Cardiopulmonary Bypass

The LifeSPARC System is intended to pump the blood through an extracorporeal circuit for periods **lasting less than 6 hours** for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Comparison of Technological Characteristics:

The subject of this submission is an update to the software version of the currently cleared device. All other aspects of the Subject device are identical to the Predicate and Reference devices.

Summary of Non-clinical Testing:

Software Verification and Validation testing (including Cybersecurity) was completed for the Subject device with the new software.

Substantial Equivalence Comparison:

Testing of the LifeSPARC Controller demonstrates that no concerns regarding safety and effectiveness result from the software changes; specifically, software test data supports substantial equivalence of the Subject device to the Predicate and Reference devices.

Conclusion:

Testing described in this notification demonstrates that the Subject LifeSPARC System performance is substantially equivalent to the legally marketed Predicate LifeSPARC System (K211830) and Reference device (K232132).