



July 9, 2019

CardiacAssist Inc  
Greg Johnson  
Director of Regulatory Affairs  
620 Alpha Drive  
Pittsburgh, Pennsylvania 15238

Re: K183623

Trade/Device Name: LifeSPARC Pump, LifeSPARC Controller  
Regulation Number: 21 CFR 870.4360  
Regulation Name: Nonroller-type blood pump  
Regulatory Class: Class II  
Product Code: KFM, DWA  
Dated: June 5, 2019  
Received: June 6, 2019

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. 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Fernando Aguel  
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

510(k) Number (if known)

Device Name

LifeSPARC System

Indications for Use (Describe)

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:** 5/29/2019

## **Applicant**

CardiacAssist, Inc. (dba TandemLife)  
620 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: greg.johnson@livanova.com

## **Device**

Trade/Proprietary Name: LifeSPARC System  
Common Name: Cardiopulmonary Bypass System  
Classification Name: 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)

## **Predicate Device:**

TandemHeart System (K110493)

## **Reference Devices:**

TandemHeart Pump (K991783)  
Escort Controller (K061369)

## **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 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 LifeSPARC Pump and the predicate TandemHeart Pump have the same Indications for Use, the same principle of operation, the same tubing connections, and the same operating flow rate range. The LifeSPARC Pump is lighter in weight and has a larger priming volume. Technological differences between the subject LifeSPARC Pump and the predicate TandemHeart Pump are the bearing design, blood flow pathways, and materials of construction.

The subject LifeSPARC Controller has the identical function as the predicate Escort Controller; specifically, it energizes the brushless DC motor that powers the pump while providing device monitoring, alarms and interface with the user. The two controllers have the same principles of operation and are similar in design. Technological differences between the two units include:

- LifeSPARC does not include purge pump and system (LifeSPARC pump does not require);
- LifeSPARC Controller incorporates updated batteries;
- LifeSPARC dock / control unit configuration adds portability / flexibility and additional battery charging capability compared to predicate Escort Controller;
- LifeSPARC Controller has updated electronics and enclosure design;
- LifeSPARC Controller has updated software / user interface technology.

## 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**

The pressure-flow test data demonstrate that the LifeSPARC Pump performs at all points within the pressure-flow operating envelope of the TandemHeart Pump.

The subject LifeSPARC Pump produces blood damage (hemolysis) at equivalent rates to the predicate TandemHeart Pump.

The remaining tests of the LifeSPARC Pump establish that it is reliable for the intended duration of use, biocompatible for the intended duration of use, and supplied sterile with a SAL of  $10^{-6}$ .

Testing of the LifeSPARC Controller demonstrates that no concerns regarding safety and effectiveness result from the changes and updates to the technology; specifically, test data is provided regarding Software, Usability, Alarms, Electrical Safety, and Electromagnetic Compatibility.

**Conclusion**

Testing described in this notification demonstrates that the subject LifeSPARC System performance is substantially equivalent to the legally marketed predicate TandemHeart System (K110493) in terms of pressure-flow characteristics and hemolysis. Additional test results listed above and described in this notification demonstrate that the differences in design between the subject LifeSPARC System and the predicate TandemHeart System do not raise new concerns regarding safety and effectiveness.