August 3, 2023

CardiacAssist, Inc.
Arielle Drummond
Director of Regulatory Affairs
620 Alpha Drive
Pittsburgh, Pennsylvania 15238

Re: K232132
Trade/Device Name: LifeSPARC System
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-Type Blood Pump
Regulatory Class: Class II
Product Code: KFM, DWA
Dated: July 17, 2023
Received: July 18, 2023

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 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.

Submission 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Date: 07/17/2023

Applicant

CardiacAssist, Inc. (dba TandemLife)
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Contact person

Arielle Drummond, PhD
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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:
LifeSPARC System (K183623)

Reference Device:
LifeSPARC System (K211830)

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 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 reference device.

Summary of Non-clinical Testing

Software
Electromagnetic Compatibility

Substantial Equivalence Comparison

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 and Electromagnetic Compatibility.

Conclusion

Testing described in this notification demonstrates that the subject LifeSPARC System performance is substantially equivalent to the legally marketed predicate LifeSPARC System (K183623).