DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 26, 2016

Cardiac Assist, Inc.
Greg Johnson, Ph.D.
Director of Regulatory Affairs
240 Alpha Dr.
Pittsburgh, PA 15238

Re: K153295
Trade/Device Name: TandemLung Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: January 26, 2016
Received: January 27, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153295

Device Name
TandemLung Oxygenator

Indications for Use *(Describe)*

The TandemLung Oxygenator (TLO) is intended to be used for adult patients for extracorporeal circulation during cardiopulmonary bypass in the field of open-heart surgery. Within the indicated flow rates, blood is oxygenated and carbon dioxide is removed. The utilization period of this device is restricted to six hours.

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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CardiacAssist, Inc.

K153295

Date: 11/11/2015

Applicant

CardiacAssist, Inc.
240 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: gjohnson@tandemheart.com

Device

Trade/Proprietary Name:	TandemLung Oxygenator
Common Name:	Cardiopulmonary Bypass Oxygenator
Classification Name:	Oxygenator, Cardiopulmonary Bypass (21 CFR 870.4350, Product Code DTZ)

Predicate Device
Novalung sLA Membrane Lung (K072362).

Device Description
The TandemLung Oxygenator TLO consists of an injection molded exterior shell containing a bundle of Polymethylpentene (PMP) hollow fiber membranes in which blood is oxygenated and decarbonated. Sweep gas, primarily oxygen, is supplied to interior lumens of the fibers and diffuses from the fiber wall to the blood plasma via simple diffusion. Similarly, carbon dioxide diffuses from the blood into the inner lumen of the fibers and is exhausted. Arterialized blood exits out of the blood outlet port and is delivered to the patient.

A two part polyurethane "potting" compound is used to both mechanically fix the end of the hollow fiber membranes in place and to create a barrier between the blood and gas pathways within the TLO.

Use of the TLO requires use of a pump and cannula(s), as well as tubing and connectors/fittings.

Intended Use

The TandemLung Oxygenator (TLO) is intended to be used for adult patients for extracorporeal circulation during cardiopulmonary bypass in the field of open-heart surgery. Within the indicated flow rates, blood is oxygenated and carbon dioxide is removed. The utilization period of this device is restricted to six hours.

Comparison of Technological Characteristics

The TandemLung Oxygenator is functionally and technologically similar to the predicate Novalung sLA Membrane Lung (K072362). Both products consist of polymethylpentene hollow fiber membrane material encased in polycarbonate shell material. Technological differences between the TandemLung Oxygenator and the predicate Novalung sLA Membrane Lung include: 1) The geometry and the blood flow paths of the two devices differ. The Novalung has a square overall shape, whereas the TandemLung is cylindrical with flow moving from the top to bottom of the cylinder, 2) The TandemLung incorporates a flow separator designed to optimize flow and move blood in a radial (i.e. transverse) direction across the hollow fiber membranes. The Novalung does not have a flow separator, and 3) The TandemLung has a smaller priming volume than the predicate Novalung.

Performance Data

In vitro bench tests were carried out to demonstrate performance and substantial equivalence to the predicate Novalung, according to the requirements of FDAs document "Guidance for Cardiopulmunary Bypass Oxygenators 510(k) Submission", issued on November 13, 2000. Specifically hemolysis, gas exchange, pressure drop, blood pathway integrity, gas pathway integrity, and physical properties were tested. This testing confirmed that the TandemLung Oxygenator does not raise any new issues of safety or effectiveness and that it is substantially equivalent to the predicate.

{End of Section}