



November 13, 2021

ALung Technologies, Inc.  
Joe Argyros  
Senior VP Regulatory Affairs and Quality Assurance  
2500 Jane Street, Suite 1  
Pittsburgh, Pennsylvania 15203

Re: DEN210006

Trade/Device Name: Hemolung Respiratory Assist System  
Regulation Number: 21 CFR 870.4150  
Regulation Name: Extracorporeal System for Carbon Dioxide Removal  
Regulatory Class: Class II  
Product Code: QOH  
Dated: August 27, 2021  
Received: August 30, 2021

Dear Joe Argyros:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Hemolung Respiratory Assist System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Hemolung Respiratory Assist System is indicated for respiratory support that provides extracorporeal carbon dioxide (CO<sub>2</sub>) removal from the patient's blood for up to 5 days in adults with acute, reversible respiratory failure for whom ventilation of CO<sub>2</sub> cannot be adequately or safely achieved using other available treatment options and continued clinical deterioration is expected.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact [CDRHProductJurisdiction@fda.hhs.gov](mailto:CDRHProductJurisdiction@fda.hhs.gov). FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Hemolung Respiratory Assist System, and substantially equivalent devices of this generic type, into Class II under the generic name Extracorporeal System for Carbon Dioxide Removal .

FDA identifies this generic type of device as:

**Extracorporeal System for Carbon Dioxide Removal.** An extracorporeal system for carbon dioxide removal is a system of devices and accessories that provides assisted extracorporeal carbon dioxide removal from the patient's blood in patients with acute respiratory failure, where other

available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, a gas exchanger, blood pump, cannulae, tubing, filters, and other accessories (e.g., monitors, detectors, sensors, connectors).

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 30, 2021, FDA received your De Novo requesting classification of the Hemolung Respiratory Assist System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Hemolung Respiratory Assist System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Hemolung Respiratory Assist System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Bleeding, Thrombocytopenia, Hemolysis, Thrombosis	In Vivo Evaluation, Non-clinical performance testing, Labeling
Infection	In Vivo Evaluation, Sterility, Shelf-life testing, Labeling
Adverse Tissue and/or Hematologic Reaction	In Vivo Evaluation, Biocompatibility, Labeling
Mechanical Failure	In Vivo Evaluation, Non-clinical performance testing, Labeling, Software Validation, verification, and hazard analysis
Hemodynamic Instability	In Vivo Evaluation, Non-clinical performance testing, Labeling
Hypothermia	In Vivo Evaluation, Non-clinical performance testing, Labeling
Mechanical Injury to Access Vessels	In Vivo Evaluation, Non-clinical performance testing, Labeling
Inadequate gas exchange	In Vivo Evaluation, Non-clinical performance testing, Labeling

Hemodilution	In Vivo Evaluation, Non-clinical performance testing, Labeling
Gas embolism	In Vivo Evaluation, Non-clinical performance testing, Labeling

In combination with the general controls of the FD&C Act, the Extracorporeal System for Carbon Dioxide Removal is subject to the following special controls:

- 1) In vivo evaluation, which may include animal testing and clinical data, of the devices and accessories in the circuit must demonstrate their performance over the intended duration of use, including a detailed summary of the in vivo evaluation pertinent to the use of the devices and accessories to demonstrate their effectiveness
- 2) 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
- 3) Non-clinical performance testing of the devices and accessories in the circuit must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
  - a. Mechanical integrity;
  - b. Durability; and
  - c. Reliability.
- 4) All patient contacting components of the device must be demonstrated to be biocompatible.
- 5) Performance testing must demonstrate the electrical safety and electromagnetic compatibility (EMC) of any electrical components.
- 6) Software validation, verification, and hazard analysis must be performed.
- 7) Performance testing must demonstrate the sterility of all patient-contacting components.
- 8) Performance testing must support the shelf life of the device by demonstrating continued sterility and device functionality over the identified shelf life.
- 9) Labeling must include the following:
  - a. A detailed summary of the non-clinical and in vivo evaluations pertinent to use of the device and accessories in the circuit; and
  - b. adequate instructions with respect to circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure; and
  - c. A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Extracorporeal System for Carbon Dioxide Removal they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Alejandra Cambonchi at 301-796-0552.

Sincerely,

for Bram Zuckerman, M.D.  
Director  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health