



April 15, 2024

Fresenius Medical Care Renal Therapies Group, LLC
Amelia Huynh
Senior Lead Regulatory Affairs North America
920 Winter Street
Waltham, Massachusetts 02451

Re: K232926

Trade/Device Name: Novalung ultimate kit (US)
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term
Respiratory/Cardiopulmonary Failure
Regulatory Class: Class II
Product Code: QJZ, BYS, QWF
Dated: March 15, 2024
Received: March 15, 2024

Dear Amelia Huynh:

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

510(k) Number (if known)
K232926

Device Name
Novalung ultimate kit (US)

Indications for Use (Describe)

The Novalung System is indicated for long-term (> 6 hours) respiratory/cardiopulmonary support that provides assisted extracorporeal circulation and physiologic gas exchange (oxygenation and CO₂ removal) of the patient's blood in adults 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

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.

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5. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

5.1. Submitter's Information

Name: Fresenius Medical Care Renal Therapies Group, LLC
Address: 920 Winter Street
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02451-1457
Phone: (781) 460-1204
Fax: (781) 699-9635
Contact Person: Amelia Huynh, Senior Lead
Preparation Date: 19 September 2023

5.2. Device Name

Trade Name: Novalung ultimate kit (US)
Common Name: Oxygenator, Blood Pump, Tubing, Extracorporeal Circuit Accessories, Console, Console Accessories, Long Term Support Greater Than 6 Hours
Regulation Name: Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulatory Class: Class II per 21 CFR § 870.4100
Product Code: QJZ, BYS, QWF
Product Code Name: QJZ – Extracorporeal System for Long-Term Respiratory/Cardiopulmonary Failure
BYS – Oxygenator, Long Term Support Greater Than 6 Hours
QWF – Tubing, Long Term Support Greater Than 6 Hours
FDA Review Panel: Cardiovascular

5.3. Legally Marketed Predicate Device

The legally marketed predicate device is the Novalung System XLung kit cleared under K191407. This predicate has not been subject to a design-related recall.

5.4. Device Description

5.4.1. Device Identification:

The Novalung ultimate kit (US) is the subject of this 510(k). The Novalung ultimate kit (US) is a component of the Novalung System.

5.4.2. Device Characteristics

The Novalung ultimate kit (US) is a single use, ethylene oxide (EO) sterilized device comprised of a disposable tubing set and accessories.

5.4.3. Environment of Use

The Novalung ultimate kit (US) is intended to be used as part of the Novalung System (K191407).

The Novalung System is used in the hospital environment (e.g., intensive care units, cardiac catheterization laboratories, emergency rooms) to provide extracorporeal cardiac and/or pulmonary support.

5.4.4. Brief Written Description of the Device

The Novalung ultimate kit (US) contains a disposable tubing set, pump head, oxygenator with heat exchanger, and accessories (gas line, priming line, stopcocks, luer caps, Christmas tree connector, tubing clamps, cable ties). The tubing set is pre-connected to a hollow fiber membrane oxygenator and blood pump head (Deltastream DP3 3/8"), which forms an extracorporeal circuit. All blood-contacting surfaces of the tubing set, except for the blood pump head, are coated with x.ellence coating.

The Novalung ultimate kit (US) tubing set has three (3) integrated pressure sensors (IPS) that connect to the Novalung System sensor box. The flow sensor detects air bubbles in the extracorporeal circuit and measures blood flow. The Novalung ultimate kit (US) provides treatment for a blood flow range of 1–6.5 L/min and has a total extracorporeal priming volume of 670 mL ± 10%.

In the Novalung ultimate kit (US), blood flows from the patient through the tubing set with IPSs, through the pump head and the oxygenator, and back to the patient. Blood flow is driven through the oxygenator by the pump head that is powered by the Novalung System console's pump drive.

5.5. Indications for Use

The Novalung System is indicated for long-term (> 6 hours) respiratory/cardiopulmonary support that provides assisted extracorporeal circulation and physiologic gas exchange (oxygenation and CO₂ removal) of the patient's blood in adults 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

5.6. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Novalung ultimate kit (US) are substantially equivalent to those of the predicate Novalung System XLung kit (K191407):

- Indications for Use
- Design characteristics
- Principle of operation
- Performance requirements
- Sterilization method
- Shelf life
- Coating materials

The Novalung ultimate kit (US) meets all special controls required by 21 CFR § 870.4100 as described below:

- **Technological Characteristics:** Geometry and design parameters of the Novalung ultimate kit (US) are consistent with its intended use in extracorporeal life support procedures. The Novalung ultimate kit (US) and its accessories are designed to be compatible with the Novalung System.
- **Biocompatibility:** The Novalung ultimate kit (US) and its accessories have been demonstrated to be biocompatible as a prolonged use device in accordance with ISO 10993-1 Fifth edition 2018-08, and *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* (4 September 2020)
- **Sterility and Shelf-life:** Testing demonstrated that the sterility, integrity, durability, and reliability of the Novalung ultimate kit (US) were maintained over the intended shelf-life.
- **Non-clinical Performance:** Substantial equivalence of the Novalung ultimate kit (US) performance characteristics was demonstrated through bench testing, mechanical integrity testing, and performance testing conducted to support stability.
- **In vivo Evaluation:** The Novalung ultimate kit (US) does not impact the *in vivo* evaluation testing previously conducted to support the predicate device.
- **Labeling:** The labeling includes a detailed summary of the non-clinical evaluations pertinent to the device's use in extracorporeal membrane oxygenation and physiologic gas exchange. Adequate instructions are included with respect to anticoagulation, circuit setup, maintenance during a procedure, and performance

characteristics relevant to compatibility among different devices and accessories in the circuit. A 9-day duration of use is specified.

5.7. Performance Data

The following performance tests were conducted on the Novalung ultimate kit (US) to support the determination of substantial equivalence:

- Simulated shipping and distribution
- Package integrity validation
- 9-day leaching testing
- 18-day integrity testing (Blood pathway integrity and heat exchanger fluid/water pathway integrity)
- Gas pathway integrity
- Heat exchanger performance
- Blood volume capacity
- Pull test
- Blood cell damage
- Gas transfer and pressure drop performance

All testing met predetermined acceptance criteria.

5.7.1. Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2018 and FDA guidance document Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” (4 September 2020). The following tests were conducted to support the biological safety of the Novalung ultimate kit (US).

- Cytotoxicity, ISO Elution Method with MEM
- Sensitization, ISO Guinea Pig Sensitization Maximization Test
- ISO Intracutaneous Irritation
- ISO Acute Systemic Toxicity
- Systemic toxicity, Short-Term (14-Day) Repeated Exposure
- Material-Mediated Pyrogenicity
- Genotoxicity, ISO Bacterial Reverse Mutation Assay
- Genotoxicity, *in vitro* Mouse Lymphoma Gene Mutation Assay
- Hemocompatibility, ASTM Hemolysis (Direct and Indirect – Extract)

- Hemocompatibility, Platelet and Leukocyte Counts
- Hemocompatibility, Complement Activation, SC5b-9
- Hemocompatibility, Partial Thromboplastin Time (PTT)

5.7.2. Human Factors Validation Testing

A comparative usability analysis was performed in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016) to demonstrate that all critical aspects of device use, including general function, safety, and risk considerations in relation to the user interface, are not significantly modified for the Novalung ultimate kit (US) when compared to the predicate Novalung System XLung kit (K191407).

5.7.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The Novalung ultimate kit (US) is not an electrical mechanical device.

5.7.4. Software Verification and Validation Testing

Not applicable. The Novalung ultimate kit (US) does not contain software.

5.7.5. Animal Studies

No animal studies were conducted.

5.7.6. Clinical Studies

No clinical studies were conducted.

5.8. Conclusion

The information provided in this Traditional 510(k), including design verification, risk management, and biocompatibility, demonstrates the Novalung ultimate kit (US) is substantially equivalent to the predicate device for long-term (> 6 hours) respiratory/cardiopulmonary support that provides assisted extracorporeal circulation and physiologic gas exchange (oxygenation and CO₂ removal) of the patient's blood in 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.