August 13, 2024

Ventis Medical, Inc.
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Drive NE
Saint Petersburg, Florida 33704

Re: K240807
Trade/Device Name: VM-2000
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: July 15, 2024
Received: July 15, 2024

Dear Paul Dryden:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240807

Device Name
VM-2000

Indications for Use *(Describe)*
The VM-2000 ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation in emergency and transport situations. The ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult patients, who require the following types of ventilatory support:
- Positive Pressure Ventilation, delivered invasively (via endotracheal tube or trach tube) or non-invasively (via mask).
- Assist/Control, SIMV, CPAP and NPPV modes of ventilation.
The ventilator is suitable for use in institutional or transport settings.

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.

Date Prepared: 09-Aug-2024

Sponsor:
Ventis Medical, Inc.
515 Executive Drive
Princeton, NJ 08540
(609) 373-6229

Sponsor Contact: Glenn W. Laub, M.D. - CEO

Submission Contact: Paul Dryden
ProMedic Consulting, LLC

Proprietary or Trade Name: VM-2000
Common/Usual Name: Emergency and Transport Ventilator
Classification Name: Continuous ventilator
CFR: 868.5895
Product Classification: CBK

Primary Predicate Device: Cardinal Health LTV 1200 - K083688
Classification Name: Continuous ventilator
CFR: 868.5895
Product Classification: CBK

Secondary Predicate Device: Respironics Trilogy EVO – K181166
Classification Name: Continuous ventilator
CFR: 868.5895
Product Classification: CBK and NOU

Reference Device: Inovytec – Ventway Sparrow – K202970
Classification Name: Continuous ventilator
CFR: 868.5895
Product Classification: CBK

Device Description:
The VM-2000 allows for rapid initiation of emergency ventilation based on default parameters. An operator can quickly begin ventilation by connecting the patient to the breathing circuit, and if necessary, adjusting ventilatory settings using the touch screen input before selecting start.

Once the therapy is initiated, breaths are delivered to the patient based on the configured settings. If the situation allows, qualified operators can adjust desired Mode, Tidal Vol, Respiratory Rate, PEEP, PIP, T Insp, P Insp and Sensitivity. Operators can monitor patients closely through a graphical breath-by-breath display to deliver high-quality care. Audio and visual alarm indicators help troubleshoot issues.

The VM-2000 uses a single-patient-use breathing circuit with a Pressure Monitoring Line, Control Line, and Flow Sensor to deliver air to patients using a motor-blower system. The unit has a Type BF Applied Part, which is the breathing circuit. The device can run on AC wall power and / or batteries. To support use in environments where compressed Oxygen is unavailable or ill-advised, the device does not require compressed Oxygen. The VM-2000 is compatible with low pressure oxygen sources and blenders but will function without supplemental FiO2.

Principle of Operation:

The VM-2000 Ventilator is a portable ventilator designed to provide continuous or intermittent ventilatory support for individuals who require mechanical ventilation. The VM 2000 is a blower based positive pressure ventilator. It includes pressure and flow sensors as well as alarms.

Indications for Use:

The VM-2000 ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation in emergency and transport situations. The ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult patients, who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via endotracheal tube or trach tube) or non-invasively (via mask).
- Assist/Control, SIMV, CPAP and NPPV modes of ventilation.

The ventilator is suitable for use in institutional or transport settings.

Comparison				
Features	**Subject Device Ventis - VM-2000**	**Primary Predicate – K083688 LTV 1200**	**Secondary Predicate – K181166 Respironics Trilogy Evo**	**Remarks, Substantial equivalence**
Picture				
Indications for Use	The VM-2000 ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation in emergency and transport situations. The ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult patients, who require the following types of ventilatory support: - Positive Pressure Ventilation, delivered invasively (via endotracheal tube or trach tube) or non-invasively (via mask). - Assist/Control, SIMV, CPAP and NPPV modes of ventilation. The ventilator is suitable for use in institutional or transport settings.	The LTV® 1200 ventilator is intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. The ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5kg (11 lbs.), who require the following types of ventilatory support: • Positive Pressure Ventilation, delivered invasively (via endotracheal tube or trach tube) or non-invasively (via mask). • Assist/Control, SIMV, CPAP, and NPPV modes of ventilation. The	The Trilogy Evo ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO2, FiO2, CO2, Respiratory Rate, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It may be used for both invasive and noninvasive ventilation.	All devices provide ventilatory support and can be considered substantially equivalent. The Indications for Use for the application device is a subset of the Indications for Use of the predicates. In particular, the application device treats only adult patients, whereas the predicate have a broader range of patients. The ventilation modes are identical between the subject and the primary predicate device, and are a subset of the secondary predicate. VM-2000 environment of use is a subset of the primary predicate.

Comparison				
Features	**Subject Device Ventis - VM-2000**	**Primary Predicate – K083688 LTV 1200**	**Secondary Predicate – K181166 Respironics Trilogy Evo**	**Remarks, Substantial equivalence**
		ventilator is suitable for use in institutional, home, or transport settings.		The VM-2000 is not intended for home use.
Environment of Use	Institutional and transport settings.	Institutional, home, and transport settings.	Institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle.	VM-2000 is intended to be used in a subset of environments (institutional and transport) of use of the primary predicate. The lack of home use does not raise different safety concerns for the intended Environments of Use.
Qualified users	Intended for use by qualified, trained personnel under the direction of a physician.	Intended for use by qualified, trained personnel under the direction of a physician.	Intended for use by qualified, trained personnel under the direction of a physician.	Identical
Patient population	Adult patients	Pediatric through adult patients weighing at least 5 kg.	Pediatric through adult patients weighing at least 2.5 kg.	The subject device is intended for adult patients. This is a subset of the intended cohorts of the predicate devices.
MRI suite	No	No	No	Identical
Ventilation Modes	• Assist/Control (AC) • SIMV • CPAP • NPPV	• Assist/Control (AC) • SIMV • CPAP • NPPV	• Assist/Control (AC) • SIMV • CPAP • NPPV • Other Modes	The subject device offers an identical set of modes as the Primary Predicate (LTV) and a subset of the Secondary Predicate (Trilogy EVO).

Comparison of Technological Characteristics

Features	Subject Device Ventis - VM-2000	Primary Predicate – K083688 LTV 1200	Secondary Predicate – K181166 Respironics Trilogy Evo	Remarks, Substantial equivalence
Use Interface	Graphical User Interface using a touch screen display, status LEDs and dedicated keys for user input.	Graphical User Interface using a 7-segment display, status LEDs and dedicated keys / knob for user input.	Graphical User Interface using a touch screen display, status LEDs and dedicated keys for user input.	Subject device use interface is similar to that of the Secondary Predicate (Trilogy EVO). Any difference in user interface would not be considered significant based upon Human Factors testing.
Waveform comparison	We have performed waveform comparison to the predicates, **K181166 Respironics Trilogy Evo and K083688 LTV 1200**			
Flow measurement	Proximal flow sensor	Proximal flow sensor	Proximal flow sensor	Identical
EtCO2	In-line EtCO2 sensor (conforms with ISO 80601-2-55)	External EtCO2 sensor available	In-line EtCO2 sensor (conforms with ISO 80601-2-55)	All devices can measure EtCO2. The subject device and the secondary predicate (Trilogy EVO) both support the use of an EtCO2 sensor
Accessories User supplied	Standard single limb ventilator circuit with Exhalation Valve In-line EtCO2 adapter	Standard single limb ventilator circuit with Exhalation Valve and Proximal flow sensor	Standard single limb ventilator circuit with Exhalation Valve In-line EtCO2 adapter	All devices utilize a single limb circuit. The subject device and secondary predicate are very similar to each other regarding the external patient circuit.

Features	Subject Device Ventis - VM-2000	Primary Predicate – K083688 LTV 1200	Secondary Predicate – K181166 Respironics Trilogy Evo	Remarks, Substantial equivalence
Sponsor supplied	Proximal flow sensor	Proximal flow sensor	Proximal flow sensor	Identical
Transport Case and Mounting System	Ambulance and Helicopter Transport Case and Mounting System	Transport mountings not specified	Not specified	There are similar third party supplied mounting systems for these transport modes. Shock and Acceleration testing was performed and when compared to the predicate mount does not raise new or different questions of safety or effectiveness.
Power supply	100 – 240VAC, 24VDC	110V or 220V AC power source, or 11V to 15V DC power source.	100 – 240VAC, 24VDC	Similar for all devices.
Battery	Rechargeable Li-Ion and disposable batteries	Rechargeable lead acid batteries	Rechargeable Li-Ion batteries	All devices contain backup batteries.
System architecture	Microprocessor controlled. VM-2000's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.	Microprocessor controlled. LTV 's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.	Microprocessor controlled. Trilogy EVO 's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.	All devices utilize similar technology.
Control architecture	User inputs become instructions for the VM-2000 pneumatics to deliver precisely controlled ventilation to the patient.	User inputs become instructions for the LTV pneumatics to deliver precisely controlled ventilation to the patient.	User inputs become instructions for the Trilogy EVO pneumatics to deliver precisely controlled ventilation to the patient.	All devices utilize similar technology and are substantially equivalent.

Features	Subject Device Ventis - VM-2000	Primary Predicate – K083688 LTV 1200	Secondary Predicate – K181166 Respironics Trilogy Evo	Remarks, Substantial equivalence
Exhalation Valve Control	During exhalation, a solenoid valve is modulated to allow airway pressure to return to PEEP via a pilot line to a single limb circuit. The blower is used as a pressure source for this control.	During exhalation, an accumulator is controlled via solenoids to allow airway pressure to return to PEEP via a pilot line to a single limb circuit. The blower is used as a pressure source for this control.	During exhalation, a valve module consisting of a solenoid and proportional valve are modulated to allow airway pressure to return to PEEP via a pilot line to a single limb circuit. The blower is used as a pressure source for this control.	All devices utilize similar technology and have substantially equivalent performance.
Gas source	Blower + low flow O2	Blower + low flow O2 High pressure O2 source	Blower + low flow O2	Similar and use of Reference K202970 for similarity of oxygen reservoir tube configuration.
Gas source and delivery	Electronically controlled pneumatic ventilation system with an integrated air compressing system. VM-2000 uses room air and low flow oxygen. Air enters through a fresh gas intake port and is compressed together with the oxygen by the blower. Low flow oxygen enters through a reservoir coupled to the intake port.	Electronically controlled pneumatic ventilation system with an integrated air compressing system. LTV uses room air and low flow oxygen. Air enters through a fresh gas intake port and is compressed together with the oxygen by the blower. Low flow oxygen enters through a reservoir coupled to the intake port.	Electronically controlled pneumatic ventilation system with an integrated air compressing system. Trilogy EVO uses air and low flow oxygen. Air enters through a fresh gas intake port and is compressed together with the oxygen by the blower. Low flow oxygen enters through a reservoir coupled to the intake port.	Similar

Features	Subject Device Ventis - VM-2000	Primary Predicate – K083688 LTV 1200	Secondary Predicate – K181166 Respironics Trilogy Evo	Remarks, Substantial equivalence
Exhalation	Gas exhaled by the patient passes through the flow sensor and exits through the expiratory exhalation valve with a membrane. The exhalation valve is part of the circuit thus ensuring that no exhaled gas comes into contact with any internal part of the VM-2000.	Gas exhaled by the patient passes through the flow sensor and exits through the expiratory exhalation valve with a membrane. The exhalation valve is part of the circuit thus ensuring that no exhaled gas comes into contact with any internal part of the LTV.	Gas exhaled by the patient passes through the flow sensor and exits through the expiratory exhalation valve with a membrane. The exhalation valve is part of the circuit thus ensuring that no exhaled gas comes into contact with any internal part of Trilogy EVO.	Similar
Sensors and Monitoring	VM-2000 receives inputs from the proximal Flow Sensor and other sensors within the ventilator. Monitored data is also displayed by the graphic user interface. A galvanic oxygen sensor (oxygen cell) monitors the concentration of the gas to be delivered	LTV receives inputs from the proximal Flow Sensor and other sensors within the ventilator. Monitored data is also displayed by the graphic user interface. An external galvanic oxygen sensor is available.	Trilogy EVO receives inputs from the proximal Flow Sensor and other sensors within the ventilator. Monitored data is also displayed by the graphic user interface. A galvanic oxygen sensor (oxygen cell) monitors the concentration of the gas to be delivered	All devices have similar sensors and technology.
Alarming	A comprehensive system of visual and audible alarms helps ensure the patient is monitored. Clinical alarms can indicate an abnormal physiological condition. Technical alarms, triggered by the ventilator's self-tests, including ongoing background checks, can indicate a hardware or software failure.	A comprehensive system of visual and audible alarms helps ensure the patient is monitored. Clinical alarms can indicate an abnormal physiological condition. Technical alarms, triggered by the ventilator's self-tests, including ongoing background checks, can indicate a hardware or software failure.	A comprehensive system of visual and audible alarms helps ensure the patient is monitored. Clinical alarms can indicate an abnormal physiological condition. Technical alarms, triggered by the ventilator's self-tests, including ongoing background checks, can indicate a hardware or software failure.	All devices have similar and applicable alarms. Use of reference K202970 for lack of overhead alarm / nurse call capabilities.

Features	Subject Device Ventis - VM-2000	Primary Predicate – K083688 LTV 1200	Secondary Predicate – K181166 Respironics Trilogy Evo	Remarks, Substantial equivalence
Safety Features	Conforms to ventilator consensus standard safety requirements for ISO 80601-2-12, ISO 80601-2-84 such as: *- Maximum limited pressure protection device* *- High airway pressure alarm condition and protection device* *- Obstruction alarm condition* *- Disconnection alarm condition* These safety requirements include ensuring minimal breathing resistance to prevent asphyxiation in case of power supply loss.	Conforms to ventilator consensus standard safety requirements for ISO 80601-2-12 such as: *- Maximum limited pressure protection device* *- High airway pressure alarm condition and protection device* *- Obstruction alarm condition* *- Disconnection alarm condition* These safety requirements include ensuring minimal breathing resistance to prevent asphyxiation in case of power supply loss.	Conforms to ventilator consensus standard safety requirements for ISO 80601-2-12 such as: *- Maximum limited pressure protection device* *- High airway pressure alarm condition and protection device* *- Obstruction alarm condition* *- Disconnection alarm condition* These safety requirements include ensuring minimal breathing resistance to prevent asphyxiation in case of power supply loss.	All devices meet relevant consensus standards for critical care ventilators.
Performance Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-8 IEC 60601-1-12 AIM 7351731 RFID ISO 80601-2-12 ISO 80601-2-55 ISO 80601-2-84 MIL-STD-810G Altitude Testing Human Factors	IEC 601-1 IEC 601-1-2 IEC 60601-1-1 IEC 60601-1-2 ISO 3864 IEC 417 IEC 60417 IEC 68-2-27 IEC 68-2-6 IEC 68-2-34 MIL-STD-810E	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-8 IEC 60601-1-12 AIM 7351731 RFID ISO 80601-2-12 ISO 80601-2-55 ISO 80601-2-84 Human Factors ISO 80601-2-72	All devices comply with the applicable standards at the time of clearance. Similar standards were applied, tested, and passed.

Discussion of the Comparison and Differences

We present the comparison to the predicate in the above tables. The main differences of the subject device and predicate are:

- Patient population is limited to adult patients.
  - This is a subset of the predicates but addresses the intended population
- Environment of use is a subset of the Primary Predicate
  - Subject device is not intended for home setting use
- Use of reference – K202970 for similarity of oxygen reservoir design, lack of overhead alarm / nurse call capabilities.

These differences do not raise different concerns of safety or effectiveness compared to the predicates.

Performance Testing

The VM-2000 was subjected to performance tests including: reliability testing, alarm tests, design control verification, software verification, and electromagnetic compliance, electrical safety, packaging verification, environmental testing, waveform testing and biocompatibility testing:

- Tested according to
  - ES 60601-1
  - IEC 60601-1-2
  - IEC 60601-1-8
  - IEC 60601-1-12
  - AIM Standard 7351731
  - ISO 80601-2-12
  - ISO 80601-2-55
  - ISO 80601-2-84
  - Altitude Testing
- Reliability testing has been performed for subject device.

The non-clinical performance testing included testing of a set of ventilation modes as described above. The data demonstrates that the technological characteristics of the VM-2000 ventilator are substantially equivalent with the predicate device.

Biocompatibility of Materials

The patient contact is Externally Communicating, Tissue, Prolonged. As for ventilators the testing included VOC (gas emission test method), CO, CO_2, Ozone and $PM_{2.5}$ and PM_{10} testing. We performed a risk based assessment for the results and the materials in patient contact meet the biological endpoints. Use of Reference device – K202970 for a prolonged duration of use.

Usability

Summative usability tests was performed with a user group of respiratory therapists.

Substantial Equivalence Conclusion

Ventis Medical concludes that the VM-2000 ventilator is substantially equivalent in Indications for Use, technology, design, performance, user base, user interface, and use context to the primary predicate LTV 1200 (K083688) and the secondary predicate, the Respironics Trilogy EVO (K181166). The sponsor has demonstrated via comparative bench testing and through non-clinical testing that the subject device does not raise different concerns of safety when compared to the predicates.