Vyaire Medical Inc
Colleen Watson
Director, Regulatory Affairs
26125 N. Riverwoods Blvd.
Mettawa, Illinois 60045

Re: K201082
Trade/Device Name: LTV2 Series Ventilators
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: November 5, 2021
Received: November 8, 2021

Dear Colleen Watson:

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,

Brandon Blakely, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory, and
Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201082

Device Name
LTV2 Series Ventilator (LTV2 model 2200 and 2150)

Indications for Use *(Describe)*
LTV2 model 2200 and 2150 ventilators are intended to provide continuous or intermittent ventilator support for the care of the individuals who require mechanical ventilation. The use environment is for institutional use. Institutional use includes ICU or other hospital environments including intra-hospital transport. The model 2200 can operate with high pressure O2. The model 2150 operates with low pressure oxygen.

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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Summary of Safety and Effectiveness
510k summary complying with 21 CFR 807.92.

1. **SUBMITTER [21 CFR § 807.92(a)]**

VYAIRE MEDICAL INC.
26125 North Riverwoods Blvd.
Mettawa, IL 60045. USA

Contact Person: Colleen Watson. MSc. RAC.
Alternate Contact Person: Jayme Yamaguchi-Owens

Date Prepared: November 10, 2021

2. **Device [21 CFR § 807.92(a)(2)]**

Product Name: LTV2 Series Ventilator (LTV2 model 2200 and 2150)

Device Name: Ventilator, Continuous

Common Name: Continuous or intermittent Ventilator

Classification Name: Ventilator, continuous, facility use (21CFR 868.5895)

Regulatory Class: II

Product Code: CBK

3. **Predicate Device [21 CFR § 807.92(a)(3)]**
This submission demonstrates substantial equivalence to the LTV 1200 Ventilator K060647 cleared on May 25th, 2006 and LTV 1100 cleared under K101643 on January 26th, 2011.

Table 1: Predicate Device Information

Predicate Device Information			
Predicate Device	**Manufacturer**	**510(k) Number**	**Cleared Device**
LTV 1200 Ventilator	Pulmonetic Systems, Inc. (Vyaire Medical, Inc.)	K060647	25 May 2006
LTV 1100 Ventilator	Carefusion (Vyaire Medical, Inc.)	K101643	26 January 2011

Table 2: Reference Device Information

Reference Device Information

Predicate Device	Manufacturer	510(k) Number	Cleared Device
TBird Vela Ventilator	Bird Product Corporation (Vyaire Medical, Inc.)	K032451	17 March 2004
PALMTop PTV Models 8/10	Pulmonetic Systems, Inc. (Vyaire Medical, Inc.)	K070594	01 August 2007
bellavista 1000/1000e	Imtmedical AG Gewerbestrasse 8 Buchs Sg, CH 9470	K183364	13 September 2019

4. **Device Description [21 CFR § 807.92(a)(4)]**

   The LTV2 Series ventilator supports adult and pediatric patients weighing at least 10 kg (22 lb) in professional healthcare facilities response with invasive or noninvasive ventilation pre-sets. These settings can be easily refined using the touch-turn-touch interface on the LED display. The ventilator also provides a wide range of ventilation therapies to meet demanding patient needs, including volume control, pressure control, pressure support and spontaneous breath types. Combined with the spontaneous breathing trial function, the ultra-sensitive flow trigger facilitates weaning patients weighing at least 10 kg (22lb).

5. **Intended Use [21 CFR § 807.92(a)(5)]**

   LTV2 model 2200 and 2150 ventilators are intended to provide continuous or intermittent ventilator support for the care of the individuals who require mechanical ventilation. The use of environment is for institutional use. Institutional use includes ICU or other hospital environments including intra-hospital transport. The model 2200 can operate with high pressure O2. The model 2150 operates with low pressure oxygen.

   Indication for use

   TheLTV2 Series Ventilators are intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. The ventilator is a restricted 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 10 kg (22 lbs.), who require the following types of ventilatory support:

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

   The ventilator is suitable for use in professional healthcare facilities, including during intra-hospital transport.

6. **Summary of Substantial Equivalence [21 CFR § 807.92(a)(6)]**

The fundamental scientific technology is the same for both proposed and predicate devices. It is based on mechanical control of breathing gas with a predetermined percentage of oxygen to provide control ventilation or to assist patient breathing. The LTV2 Series Ventilators are substantially equivalent to the predicate LTV1200 Ventilator and LTV 1100 regarding safety, design materials and intended use.

The proposed ventilator is designed to operate the same as the predicate devices. Successful test results (electrical safety testing, mechanical testing, software V&V, and waveform verification tests) ensured the proposed ventilator does not raise any different questions of safety and effectiveness. The table below outlines the similarities and differences between the device and predicate device.

Table 3: Substantial Equivalence Comparison

Element of Comparison	Proposed Device LTV2 Series Ventilators (LTV2 2150 & LTV2 2200)	Primary Predicate Device LTV 1200 – (K060647)	Secondary Predicate Device LTV 1100 - (K101643)	Discussion of Differences
Intended Use	Intended to provide continuous or intermittent ventilator support for the care of individuals who require mechanical ventilation.	Intended to provide continuous or intermittent ventilator support for the care of individuals who require mechanical ventilation.	Intended to provide continuous or intermittent ventilator support for the care of individuals who require mechanical ventilation.	Same
Indications for Use	The LTV2 Series Ventilators are intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. The ventilator is a restricted 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 10kg (22 Ibs.), who require the following types of ventilatory support: ▪ Positive Pressure Ventilation, delivered invasively or non-invasively. ▪ Assist/Control, SIMV, CPAP, and NPPV modes of ventilation. The ventilator is suitable for use in healthcare institutional 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 restricted 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 Ibs.), who require the following types of ventilatory support: ▪ Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask). ▪ Assist/Control, SIMV, CPAP, and NPPV modes of ventilation. The ventilator is suitable for use in institutional, home, or transport settings.	The LTV 1100 ventilator is intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. The ventilator is a restricted 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 Ibs.), who require the following types of ventilatory support: ▪ Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask). ▪ Assist/Control, SIMV, CPAP, and NPPV modes of ventilation. The ventilator is suitable for use in institutional, home, or transport settings.	Same

Element of Comparison	Proposed Device LTV2 Series Ventilators (LTV2 2150 & LTV2 2200)	Primary Predicate Device LTV 1200 – (K060647)	Secondary Predicate Device LTV 1100 - (K101643)	Discussion of Differences
Principles of Operation	Positive pressure mechanical ventilator	Positive pressure mechanical ventilator	Positive pressure mechanical ventilator	Same
Patient population	Targeted for adult and pediatric patients weighing at least 10kg (22 lbs.).	Targeted for adult and pediatric patients weighing at least 5kg (11 lbs.).	Targeted for adult and pediatric patients weighing at least 5kg (11 lbs.).	Substantial equivalent, increase in lower weight limit
Environment	The ventilator is suitable for use in healthcare institutional settings.	The ventilator is suitable for use in institutional, home, or transport settings.	The ventilator is suitable for use in institutional, home, or transport settings.	Substantial equivalent for healthcare institutional settings
Compatibility with the environment and other devices;	Storage: Temperature: -20 degrees C without relative humidity control to + 60 degrees C at 93% relative humidity, non-condensing. Operating: Temperature: +5 to +40 degrees C Humidity: 15% to 95% non-condensing EMC: IEC 60601-1-2 Issue 2007/03/30 Edition 3 class B for Emissions, Immunity for Life Supporting Equipment Sound level: Not exceed 55 dBA (RMS) at one meter	Storage: Temperature: -20 to +60 degrees C. Humidity: 10% to 95% Relative, non-condensing Operating: Temperature: +5 to +40 degrees C Humidity: 15% to 95% non-condensing EMC: 60601-1-2 IEC:2001(E) Sound level: Not exceed 50 dBA (RMS) at one meter	Storage: Temperature: -20 to +60 degrees C. Humidity: 10% to 95% Relative, non-condensing Operating: Temperature: +5 to +40 degrees C Humidity: 15% to 95% non-condensing EMC: 60601-1-2 IEC:2001(E) Sound level: Not exceed 50 dBA (RMS) at one meter	Substantial equivalent, designed and tested to latest EMC standards
Electrical safety	Class II Type BF	Class II Type BF	Class II Type BF	Same
Battery	Internal battery Removable battery optional	Internal battery: lower panel door access for trained service technician.	Internal battery: lower panel door access for trained service technician.	Substantial equivalent

Element of Comparison	Proposed Device LTV2 Series Ventilators (LTV2 2150 & LTV2 2200)	Primary Predicate Device LTV 1200 – (K060647)	Secondary Predicate Device LTV 1100 - (K101643)	Discussion of Differences
Internal PEEP/PEEP Compensation	Range: 0-20 cmH_2O ± 1 cmH2O or 10%, whichever is greater, within 3 breaths. (Mechanical/pneumatic control)	Range: 0-20 cmH_2O ± 1 cmH2O or 10%, whichever is greater, within 3 breaths. (Mechanical/pneumatic control)	Range: 0-20 cmH_2O ± 1 cmH2O or 10%, whichever is greater, within 3 breaths. (Mechanical/pneumatic control)	Same
Bias Flow	Off or 5 to 15 LPM in increments of 1 LPM.	Off or 10 LPM 10% or 1 LPM, whichever is greater	Off or 10 LPM 10% or 1 LPM, whichever is greater	Substantially Equivalent (Reference device K032451, K070594)
Ventilation Mode	Control Mode Assist/Control Mode SIMV Mode CPAP NPPV Apnea Backup	Control Mode Assist/Control Mode SIMV Mode CPAP NPPV Apnea Backup	Control Mode Assist/Control Mode SIMV Mode CPAP NPPV Apnea Backup	Same
Breath types	Pressure Control Volume Control Pressure Support Spontaneous	Pressure Control Volume Control Pressure Support Spontaneous	Volume Control Pressure Support Spontaneous	Same as predicate
Breath rate	0-80 BPM	0–80 BPM	0–80 BPM	Same
Tidal volume	50–2,000 mL	50–2,000 mL	50–2,000 mL	Same
Inspiratory time	0.3 – 9.9 seconds	0.3–9.9 sec	0.3–9.9 sec	Same
Pressure control	4 – 98 cmH2O (assist/Control & SIMV/CPAP) Off – 60 cmH2O (NPPV)	1–99 cmH2O	Pressure control not present	Substantially equivalent
Pressure support	1–60 cmH2O	1–60 cmH2O	1–60 cmH2O	Same
Sensitivity	Off, 1–9 LPM	Off, 1–9 LPM	Off, 1–9 LPM	Same
O_2%	21–100% (LTV2200); oxygen bleed flow (LTV 2150 and LTV 2200)	21–100%; oxygen bleed flow	oxygen bleed flow	Same as predicate
O_2 flush	1–3 min (LTV 2200 only)	1–3 min	N/A	Same as predicate
PEEP/CPAP	0 – 20 cmH_2O	0–20 cmH2O	0–20 cmH2O	Same

Element of Comparison	Proposed Device LTV2 Series Ventilators (LTV2 2150 & LTV2 2200)	Primary Predicate Device LTV 1200 – (K060647)	Secondary Predicate Device LTV 1100 - (K101643)	Discussion of Differences
Blender	LTV2 2200: High and low oxygen inlet pressure LTV2 2150: Low oxygen inlet pressure	High and low oxygen inlet pressure	Low oxygen inlet pressure	Same
VOXP (VENTILATOR OPEN XML PROTOCOL)	Present	Not present	Not present	Substantially equivalent

7. Performance Data [21 CFR § 807.92(b)(1)]

The LTV2 Series Ventilators was designed and tested in accordance with the following and FDA guidance documents and international standards

Standards / FDA guidance

Table 4: List of Standards

Standard #	Title
ANSI AAMI ES60601-1:2005 + A1:2012 + C1:2009 + A2:2010	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1:2005 + A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 3.0 2007-03 IEC 60601-1-2:2014	Medical electrical equipment – part 1-2: general requirements for basic safety and essential performance – collateral standard: electromagnetic compatibility – requirements and tests. (General II (ES/EMC))
IEC 60601-1-2 Edition 4.0 2014-02	Medical electrical equipment – part 1-2: general requirements for basic safety and essential performance – collateral standard: electromagnetic compatibility – requirements and tests. (General II (ES/EMC))
IEC 60601-1-6 Edition 3.0 2010-01	Medical electrical equipment – part 1-6: general requirements for basic safety and essential performance – collateral standard: usability. (General I (QS/RM)

IEC 60601-1-8 Edition 2.1 2012-11	Medical electrical equipment – part 1-8: general requirements for basic safety and essential performance – collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. (General I (QS/RM))
IEC 62304 First edition 2006-05 IEC Edition 1.1 2015-08	Medical device software – software life cycle processes. (Software/Informatics)
IEC 62366:2007 ANSI AAMI IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices
ISO 80601-2-12 First Edition: 2011	Medical electrical equipment – part 2-12: particular requirements for the safety of lung ventilators – critical care ventilators [including: technical corrigendum 1 (2011)
ISO 5356-1 Third edition 2004-05-15	Anaesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
ISO 5367:2014	Anaesthetic and respiratory equipment -- Breathing sets and connectors
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
ISO 14971:2007	Medical devices - Applications of risk management to medical devices

Design Verification included:

- Waveform
- Alarms
- Ventilation Controls
- Ventilation Displays
- Endurance
- Patient Circuit Testing

Clinical Data **[21 CFR § 807.92(b)(2)]**
Based on the similarities in the safety and effectiveness profiles of the subject, predicate and reference devices, no clinical studies were deemed to needed to support this submission.

8. Conclusion [21 CFR § 807.92(b)(2)]

The non-clinical data support the safety and effectiveness of the proposed device. Also, test results demonstrate that the device is as safe and effective as the predicate and therefore substantially equivalent to the predicate device.