August 20, 2026

Convergence Medical Sciences , Ltd.
Marvin Cervantes
Director of Quality
4121 23b St. NE
Calgary, AB T2E 7V9
Canada

Re: K253807
Trade/Device Name: Valence InVent Xtend™ (CVG-4101-VXA)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MOD
Dated: November 26, 2025
Received: November 28, 2025

Dear Marvin Cervantes:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,
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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)*
K253807

Device Name
Valence InVent Xtend

Indications for Use *(Describe)*
Valence InVent Xtend™ is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other (e.g. for unilateral chest trauma, asymmetric ARDS).

Valence InVent Xtend™ is intended to be used with a ventilator in a pressure regulated mode (e.g. Pressure Control mode or equivalent). Valence InVent Xtend™ is intended for patients 10 years or older.

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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Valence InVent Xtend
510(k) Summary

Applicant Name and Address:

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510(k) Summary Preparation Date:

2026-08-19

Device Name:

Trade Name:	Valence InVent Xtend
Common Name(s):	Differential Ventilation Circuit Adapter with Adjustable Valve Enclosure
Device Identifier:	CVG-4101-VXA

Device Classification:

Classification:	Class II
Regulation No.:	21 CFR 868.5895 (Continuous Ventilator)

Intended Use:

Valence InVent Xtend™ is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. It is a restricted medical device intended for use by qualified physicians or by a registered respiratory therapist under the direction of a qualified physician.

Indications for Use:

Valence InVent Xtend™ is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for unilateral chest trauma, asymmetric ARDS.

Valence InVent Xtend™ is intended to be used with a ventilator in a pressure regulated mode (e.g. Pressure Control mode or equivalent). Valence InVent Xtend™ is intended for patients 10 years or older.

Environment of Use: Hospital

Device Description & Technical Characteristics

Device Description:

Valence InVent Xtend™ is a single-use, single-patient breathing circuit accessory designed to facilitate independent, differential lung ventilation using a single pressure-controlled mechanical ventilator. The device eliminates the traditional clinical requirement for two separate synchronized mechanical ventilators when managing asymmetric pulmonary pathology.

Technical Characteristics:

The device consists of a custom enclosure manifold (base and cap) that houses standard, commercially available mechanical PEEP valves attached to standard 22mm connectors.

- **Expiratory Pressure Modulation (Additive PEEP):** When positioned in an expiratory circuit limb, the inline PEEP valve spring tension opposes exhaled gas flow against the baseline ventilator PEEP. Total delivered PEEP to the individual lung is additive:

$$PEEP_{lung} = PEEP_{ventilator} + PEEP_{valve}$$

- **Inspiratory Pressure Modulation (Subtractive PIP):** When positioned in an inspiratory circuit limb, the inline PEEP valve creates a controlled pressure drop during inspiration. Net Peak Inspiratory Pressure (PIP) delivered to the individual lung is subtractive:

$$PIP_{lung} = PIP_{ventilator} - \Delta P_{valve}$$

- **Unidirectional Flow & Anti-Rebreathing**: The integrated spring-loaded PEEP diaphragms act as unidirectional check valves. An auxiliary bypass circuit containing a dedicated check valve prevents CO_2 rebreathing and allows the host ventilator to continuously sense system pressure.
- **Materials & Dimensions:** Manufactured from biocompatible thermoplastic polycarbonate meeting ISO 18562 standards. Connectors conform to ISO 5356-1:2015 for standard ventilator circuits.

Substantial Equivalence Comparison

Legally Marketed Device to which Substantial Equivalence is claimed:

510(k) No.:	Trade Name	Company
K051767	LTV 1000	Pulmonetic Systems, Inc.

Summary of Substantial Equivalence:

	Proposed Device Valence InVent Xtend	**Primary Predicate Device** LTV 1000 (K051767)	Comparison & Equivalence Rationale
Intended Use	Valence InVent Xtend™ is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. It is a restricted medical device intended for use by qualified physicians or by a registered respiratory therapist under the direction of a qualified physician.	The LTV 1000 ventilator is intended to provide continuous or intermittent ventilatory support for the care of 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.	Substantially Equivalent: The therapeutic purpose is identical, to provide continuous or intermittent ventilatory support for individuals who require mechanical ventilation, and both are restricted medical devices. The subject device states the operator qualifications, which fall within the predicate's qualified, trained personnel under the direction of a physician.
Indications for Use	Valence InVent Xtend™ is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for unilateral chest trauma, asymmetric ARDS. Valence InVent Xtend™ is intended to be used with a ventilator in a pressure regulated mode (e.g. Pressure Control mode or equivalent). Valence InVent Xtend™ is intended for patients 10 years or older.	Applicable for adult and pediatric patients weighing at least 5 kg (11 lbs.) who require positive pressure ventilation delivered invasively or non-invasively; Assist/Control, SIMV or CPAP modes; and breath types including Volume, Pressure Control and Pressure Support.	Substantially Equivalent: The indications for use fall entirely within the scope of the predicate's cleared indications. The subject device addresses a specific clinical subset of that population, limited to pressure-regulated ventilation in patients 10 years and older. Narrowing an indication does not create a new intended use.

	Proposed Device Valence InVent Xtend	**Primary Predicate Device** LTV 1000 (K051767)	Comparison & Equivalence Rationale
Environment of Use	Hospital	Hospital, Home, or Transport	Substantially Equivalent: The subject device claims a subset of the predicate's cleared environments.
Ventilation Modes	Used with a ventilator in a pressure regulated mode (e.g. Pressure Control mode or equivalent). The device is passive and does not select, generate or alter the ventilator's mode.	Per the predicate labeling: Control, Assist/Control, SIMV, CPAP, NPPV and Apnea Backup modes, with Volume Control, Pressure Control, Pressure Support and Spontaneous breath types.	Substantially Equivalent: The subject device is used with Pressure Control mode or equivalent, which the predicate already provides and which is a subset of those the predicate is cleared for.
Peak Inspiratory Pressure (PIP) adjustment	Up to 20 cmH_2O per lung, set by reading the graduated cap of the in-circuit mechanical PEEP valve. The minimum decrement is determined by the lowest setting of the valve in use. The adjustment is subtractive, reducing the peak inspiratory pressure reaching that lung by the amount set.	Peak inspiratory pressure is set at the ventilator and titrated in Pressure Control.	Substantially Equivalent: Peak inspiratory pressure is titrated to the patient in both the subject device and the predicate device. In the subject device the titration is made in the breathing circuit, using the same mechanical spring PEEP valve technology the predicate uses to adjust pressure in the circuit. The adjustment is subtractive only and cannot present a lung with a pressure higher than the ventilator already delivers. Bench testing at representative settings showed a predictable relationship between the setting and the pressure delivered.
Positive End-Expiratory Pressure (PEEP) adjustment	Up to 20 cmH_2O per lung, set by reading the graduated cap of the in-circuit mechanical PEEP valve. The minimum increment is determined by the lowest setting of the valve in use. The adjustment is additive, raising the end expiratory pressure of that lung by the amount set.	In-circuit mechanical PEEP valve, 0 to 20 cmH_2O.	Identical: The adjustment is made by the same means, an in-circuit mechanical spring PEEP valve, to the same 20 cmH_2O maximum. The subject device places one valve in each limb of each lung circuit.
Compatible ventilation settings and parameters	Used only in pressure-regulated modes. Peak inspiratory pressure and positive end expiratory pressure are the only parameters the device adjusts, and they are adjusted for each lung. Tidal volume is not a set parameter; the volume each lung receives results from the pressure set for that lung. All other ventilation controls remain on the ventilator. The compatible ventilator settings are specified in the labeling.	All ventilation settings are made at the ventilator. In Pressure Control, the delivered volume follows the set pressure.	Substantially Equivalent: Ventilation is pressure controlled in both, and the delivered volume follows the pressure that is set. Pressure is the only parameter the subject device adjusts, and it adjusts it for each lung.

	Proposed Device Valence InVent Xtend	**Primary Predicate Device** LTV 1000 (K051767)	Comparison & Equivalence Rationale
Alarm requirements	The device is mechanical and requires no electrical power. All alarms are set and managed on the ventilator. The labeling addresses the ventilator high pressure, low pressure and volume alarms, and provides guidance on setting the high pressure and low tidal volume limits.	All alarms are set and managed on the ventilator. The ventilator provides high pressure, low pressure and volume alarms.	Substantially Equivalent: Alarms are set and managed on the ventilator in both, and the subject device adds no alarm. The alarms its labeling addresses are the same ventilator alarms the predicate provides.
Conformance to Connector Consensus Standards	Yes (ISO 5356-1:2015)	Yes (ISO 5356-1:2015)	Identical: Standard circuit interface.
Gas Path Materials	Biocompatible Thermoplastic (Polycarbonate)	Biocompatible Thermoplastic (Polycarbonate)	Identical: Common medical grade ventilator circuit materials.
Cleaning of Circuit/PEEP valve	Disposable	Disposable	Identical: Disposable.

Basis for the Predicate:

The LTV 1000 (K051767) is the primary predicate device for the Valence InVent Xtend.

The Valence InVent Xtend is a passive breathing circuit accessory rather than a full-function ventilator. The predicate is appropriate because the subject device delivers its effect entirely through the same physiological parameters the predicate is cleared to titrate, peak inspiratory pressure and positive end expiratory pressure, and does so using the same technology the predicate uses to adjust pressure in the breathing circuit: a mechanical spring PEEP valve. The predicate provides that adjustment by the same means and to the same 20 cmH_2O maximum.

The subject device has the same intended use as the predicate. The differences in technological characteristics do not raise different questions of safety and effectiveness. The subject device adjusts only the two pressures the predicate is cleared to titrate, and it adjusts them within the range of the mechanical valve, up to 20 cmH_2O per lung, subtractively on inspiration and additively at end expiration. Every ventilator control and every alarm remains at the ventilator and is set there by the user. The subject device is indicated for a narrower patient population, in a narrower environment, and for pressure-regulated ventilation only, and each of these is a subset of the predicate's cleared use.

Summary of Supporting Performance Evidence

Non-clinical bench testing, pre-clinical cadaveric testing, and human factors evaluations were conducted to evaluate unique safety risks associated with differential circuit branching.

A. Non-Clinical Bench Performance Testing

- **Conical Connector & Mechanical Integrity (ISO 5356-1:2015):** Passed the dimensional requirements for standard conical connectors.
- **Biocompatibility Evaluation (ISO 18562:2024):** Confirmed compliance for breathing gas pathways regarding particulate matter and volatile organic substances.
- **Ventilation Independence & Pressure Modulation Validation:** Bench testing verified that the device allows individualization of inspiratory and expiratory pressures settings for each lung independently.

B. Non-Clinical Cadaveric Performance Testing

- A human cadaveric model of asymmetric lung pathology evaluated ventilatory mechanics using single-lumen ventilation versus dual-lumen ventilation with Valence InVent Xtend.
- **Driving Pressure Reduction:** Dual-lung ventilation using Valence InVent Xtend™ achieved a statistically significant reduction in static driving pressure compared to single-lumen ventilation ($p = 0.0078$).
- **Ventilation Balance:** Electrical Impedance Tomography (EIT) demonstrated improved regional right-to-left ventilation distribution, preventing over-distension of compliant lung tissue.

C. Human Factors & Usability Validation

- **Study Cohort:** Tested across seventeen (17) participants from the intended user group, healthcare professionals experienced in ventilating patients and managing ventilated patients.
- **Results:** No uncorrected use error occurred in any participant. All 17 participants completed the critical tasks evaluated and all three scenarios.

Conclusion

The Valence InVent Xtend™ has the same intended use as the cleared predicate device, and is indicated for a subset of the predicate's cleared patient population, environment of use and ventilation modes. It has the same breathing gas pathway materials and the same standard circuit interface. It acts on the same two parameters the predicate is cleared to titrate, peak inspiratory pressure and positive end expiratory pressure, using the same in-circuit mechanical spring PEEP valve technology the predicate uses to adjust pressure in the breathing circuit.

The differences in technological characteristics do not raise different questions of safety and effectiveness, and the subject device is as safe and as effective as the predicate device. Performance bench testing, pre-clinical cadaveric models, and human factors validation demonstrate that the device performs as intended.

Therefore, Valence InVent Xtend™ is substantially equivalent to the predicate device.