510(k) Summary

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Sponsor	Ventec Life Systems, Inc. 19021 120th Ave. NE, Suite 101 Bothell, WA 98011 Tel: 425-686-1750
Contact Information	Joseph Cipollone VP Quality & Regulatory 19021 120th Ave. NE, Suite 101 Bothell, WA 98011 Tel: 909-213-3691 jcipollone@venteclife.com
Device Proprietary Name:	VOCSN Unified Respiratory System
Common name	Mechanical ventilator / Oxygen concentrator / Cough assist / Suction pump
Primary Classification and Product Code	Mechanical ventilator • Classification number 21 CFR 868.5895 • Class II • Code: CBK - Continuous Ventilator, Facility Use
Subsequent Product Codes of Additional Integrated Functions	Mechanical ventilator • Code: NOU - Continuous Ventilator, Home Use Oxygen concentrator • Code: CAW - Portable oxygen generator Cough Assist • Code: NHJ - Noncontinuous ventilator (IPPB) Suction Pump • Code: BTA - Powered suction pump Heated Patient Circuits • Code: BZE - Heater, Breathing System, W/Wo Controller Bacteria Filter • Code: CAH - Filter, Bacterial, Breathing-Circuit

Primary Predicate Device Information:	Mechanical ventilator component Respironics Trilogy Series Ventilator (K111610)
Reference Predicate Device Information:	Mechanical ventilator component CareFusion Palmtop Ventilator PTV-8 & -10 (K070594) CareFusion LTV 1200 Ventilator (K060647) Oxygen concentrator component Omni 3 (eQuinox) Oxygen System (K120785) Cough Assist component Respironics Cough Assist T70 (K121955) Suction Pump component Precision Medical Easy Go Vac PM66 (K140179) Heated Patient Circuits Respironics (Philips) Disposable Heated Wire Circuits (K110398) Bacteria Filter Respironics (Philips) Bacteria Filter PN 342077 - Supplied by King Systems under (K973797)

Indications for Use (VOCSN Unified Respiratory System)

The VOCSN Unified Respiratory System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. It may be used in invasive and non-invasive applications. The VOCSN is intended for pediatric through adult patients weighing at least 5 kg. It is intended for use in home, hospital, institutional and transport settings, including portable applications.

The integral oxygen concentrator is intended for the administration of supplemental oxygen. The integral suction pump is intended for airway fluid removal and oral/ pharyngeal hygiene. The integral cough assist option is intended for patients who are additionally unable to cough or clear secretions effectively.

Discussion of Differences in the Indications for Use from the Primary Predicate Device

The VOCSN and primary predicate Trilogy ventilator have substantially equivalent indications for use with regard to the ventilation therapy, except that the VOCSN is indicated for transport settings whereas the Trilogy is not intended for use as a transport ventilator. This additional use setting is equivalent to a secondary predicate that is identified.

The indications for use statement of the VOCSN encompasses additional intended uses for oxygen concentrator, cough assist, and suction pump therapies that are not available in the Trilogy ventilator. These therapies are complementary adjunct therapies to the ventilation therapy, for which secondary predicates are identified.

The Trilogy ventilator indicates an optional Oximetry Interface Kit that is not indicated in the VOCSN indications for use. Oximetry is an ancillary therapy that is not critical to the therapeutic benefit of the ventilation, oxygen concentration, cough assist and suction therapies provided by VOCSN.

Device Description Overview

The VOCSN unified respiratory support system is a mechanical ventilator which combines additional conventional therapies into a single device. Additional therapies include oxygen, cough assist, and suction.

The device description will be broken down by therapy; i.e., ventilation, oxygen concentration and delivery, cough assist, and suction.

Ventilation

Description

The ventilator function of the VOCSN device is a conventional positive pressure ventilator that supplies volume breaths, pressure breaths, and spontaneous breaths. These breath types are incorporated into the following traditional modes of ventilation:

- Assist Control
- SIMV (Synchronized Intermittent Mandatory Ventilation)
- Bi-Level

The VOCSN uses a conventional radial blower working in conjunction with valves and transducers under the control of a microprocessor to provide breath delivery. Oxygen is provided to the patient from the internal concentrator, or from external sources. The ventilator is connected to the patient via one of three available circuits: an active circuit, a passive circuit, or a mouthpiece circuit. An optional Secretion Trap can be placed between the patient connection and the patient circuit to collect liquids to help prevent obstructing the patient circuit. The VOCSN provides a conventional alarm and monitoring package to alert users to hazard conditions.

A central user interface provides adjustment of the controls and display of monitored data. The VOCSN is a portable device that can be operated from common AC and DC supply power sources, as well as internal batteries.

Substantial Equivalence

The intended use, performance, and technology of the ventilator system have been compared to predicate devices, the Trilogy Series Ventilator (K111610), and the Palmtop Ventilator PTV-8 & -10 (K070594). A summary table of key characteristics compared to the predicate device(s) is shown below.

Characteristic	VOCSN	Predicate, Trilogy (K111610)	Comparison
Intended Use	• continuous or intermittent ventilatory support • invasive and non-invasive • ped through adult ≥ 5 kg • home, hospital, institutional and transport settings, including portable applications	• continuous or intermittent ventilatory support • invasive and non-invasive • ped through adult ≥ 5 kg • home, hospital, and mobile applications.	*Substantially Equivalent* Equivalent except the Trilogy does not specify transport settings. The secondary predicate Palmtop ventilator specifies transport use.
FDA Product Code	NOU, CBK	NOU, CBK	*Equivalent*

Characteristic	VOCSN	Predicate, Trilogy (K111610)	Comparison
Modes of ventilation			*Substantially Equivalent*
	• Spontaneous	• Spontaneous ventilation (S)	Equivalent
	• Bi-Level	• Spontaneous ventilation with timed back-up (S/T) Timed ventilation (T)	VOCSN Bi-level mode is equivalent to Trilogy (S/T) and (T) modes with appropriate settings of patient trigger
	• Assist/Control-Pressure	• Pressure A/C (Palmtop ventilator K070594)	Equivalent to the secondary predicate Palmtop ventilator.
	• Assist/Control-Volume	• Volume A/C (Palmtop ventilator K070594)	Equivalent to the secondary predicate Palmtop ventilator.
	• SIMV-Pressure	• Pressure SIMV (Palmtop ventilator K070594)	Equivalent to secondary predicate Palmtop ventilator.
	• SIMV-Volume	• Volume SIMV (Palmtop ventilator K070594)	Equivalent to secondary predicate Palmtop ventilator. Reference Tab 5, TPR-00049, TPR-00050 and TPR-00055 for test results
Significant breath control parameters	• Breath Rate • PEEP/ EPAP • Pressure/Pressure Control/ IPAP • Inspiratory Time • Sigh • Tidal volume • FIO2	• Breath Rate • PEEP/ EPAP • Pressure/Pressure Control/ IPAP • Inspiratory Time • Sigh • Tidal volume • FIO2	*Substantially Equivalent*
Core technology	Conventional radial blower working in conjunction with valves and transducers under the control of a microprocessor to provide breath delivery.	Conventional radial blower working in conjunction with valves and transducers under the control of a microprocessor to provide breath delivery.	*Substantially Equivalent*
Circuits	• Single limb with active exh. valve • Single limb with passive exh. valve • Single limb with mouthpiece	• Single limb with active exh. valve • Single limb with passive exh. valve • Single limb with mouthpiece	*Equivalent*
Circuit Interfaces	Invasive and non-invasive	Invasive and non-invasive	*Equivalent*
User Interface	LCD touch screen with additional hard keys	LCD screen with hard keys	Substantially Equivalent The Palmtop ventilator (K070594) includes a touch screen

Characteristic	VOCSN	Predicate, Trilogy (K111610)	Comparison
Nebulizer	Provides pneumatic drive to external OEM 6 L/min nebulizer	No nebulizer drive provided	*Substantially Equivalent* The alternate predicate Palmtop ventilator provides a pneumatic drive to an external OEM 6 L/min nebulizer
Power	AC, DC, and internal battery	AC, DC, and internal battery	*Equivalent*

Performance Testing (non-clinical)

The company completed Validation testing to validate performance against the User Requirements Document under simulated use conditions, and test reports were generated summarizing the test results. Verification testing was completed to verify system performance against the Product Requirements Specification, and test reports were generated summarizing the test results. This testing included biocompatibility and comparative waveform testing. Biocompatibility testing of breathing gases comprised evaluation of volatile organic compounds (VOC), particulate matter, carbon dioxide, carbon monoxide and ozone. Biocompatibility testing of the portion of the gas pathway in contact with humidification or aerosolized medications additionally included cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, bacterial reverse mutation genotoxicity, and chemical characterization with risk assessment. These tests demonstrated that the VOCSN ventilator is compliant with the user and product requirements.

The product is compliant with and has been verified to the following standards:

Critical care ventilators	ISO 80601-2-12
Home care ventilators	ASTM F1246
Anesthetic and respiratory equipment -- Conical connectors	ISO 5356-1
Respiratory gas monitors	ISO 80601-2-55
Nebulizing system	ISO 27427
Breathing sets and connectors	ISO 5367
Medical electrical equipment	IEC 60601-1
Electromagnetic compatibility	IEC 60601-1-2
Medical devices for home use	IEC 60601-1-11
Alarm system	IEC 60601-1-8

Oxygen Concentrator

Description

An optional internal oxygen concentrator can be selected to provide oxygen to the patient. Oxygen from the internal oxygen concentrator is delivered as a pulse dose via a tube directly to the patient interface.

The oxygen is separated from the nitrogen in room air using a conventional Pressure Swing Adsorption (PSA) oxygen concentration process. The system consists of a reciprocating compressor, sieve bed, and valves under the control of the microprocessor system. As part of the VOCSN system it uses the central user interface and can be operated from common AC and DC supply power sources, as well as internal batteries. The VOCSN provides an alarm and monitoring package to alert users to hazard conditions.

Substantial Equivalence

The intended use, performance, and technology of the oxygen concentrator system have been compared to the Omni 3 (eQuinox) Oxygen System (K120785) predicate device. A summary table of key characteristics compared to the predicate device is shown below.

Characteristic	VOCSN	Predicate, Omni 3 (K120785)
Intended Use	The integral oxygen concentrator is intended for the administration of supplemental oxygen	The administration of supplemental oxygen.
FDA Product Code	CAW	CAW
Oxygen %	Nominal 90 %	Nominal 90 %
Modes	• Pulse Dose	• Pulse Dose • Continuous
Core technology	Pressure Swing Adsorption (PSA) oxygen concentration process.	Pressure Swing Adsorption (PSA) oxygen concentration process.
User Interface	LCD touch screen with additional hard keys	LCD screen with hard keys
Power	AC, DC, and internal battery	AC, DC, and internal battery

Performance Testing (non-clinical)

The company completed Validation testing to validate performance against the User Requirements Document under simulated use conditions, and test reports were generated summarizing the test results. Verification testing was completed to verify system performance against the Product Requirements Specification, and test reports were generated summarizing the test results. This testing included biocompatibility testing, as listed in the Ventilation section. These tests demonstrated that the VOCSN oxygen concentrator is compliant with the user and product requirements.

The oxygen concentrator option is compliant with and has been tested to the following standards:

Oxygen concentrators	ISO 80601-2-69

Oxygen conserving equipment	ISO 80601-2-67
Medical electrical equipment	IEC 60601-1
Electromagnetic compatibility	IEC 60601-1-2
Medical devices for home use	IEC 60601-1-11
Alarm system	IEC 60601-1-8

Cough Assist

Description

The Cough Assist option clears secretions from the lungs by applying positive pressure (insufflation) to the airway followed by a sudden negative pressure (exsufflation). This creates a high expiratory flow, simulating a natural cough. The device attaches to standard patient interfaces using the VOCSN patient circuits.

The VOCSN uses a conventional radial blower working in conjunction with a cough assist valve under the control of a microprocessor to provide the insufflation and exsufflation cough phases. The cough assist function is integral to the ventilator and is connected to the patient via the patient circuit.

The VOCSN provides an alarm and monitoring package to alert users to hazard conditions.

Substantial Equivalence

The intended use, performance, and technology of the cough assist system have been compared to the Cough Assist T70 (K121955) predicate device. A summary table of key characteristics compared to the predicate device is shown below.

Characteristic	VOCSN	Cough Assist T70 (K121955)
Intended Use	• Mechanically ventilated patient unable to cough or clear secretions effectively • pediatric through adult ≥ 5 kg • invasive and non-invasive • home, hospital, institutional and transport settings, including portable applications	• patient unable to cough or clear secretions effectively. • adult or pediatric patients • used with facemask, mouthpiece, endotracheal, or tracheostomy tube. • hospital, institutional environment, or in the home.
FDA Product Code	NHJ	NHJ
Significant control parameters	• Breath Sync • Exsufflation Pressure • Exsufflation Time • Insufflation Rise Time • Insufflation Time • Pause Time	• Cough Trak • Exsufflation Pressure • Exsufflation Time • Inhale Flow (controls rise time) • Insufflation Time • Pause Time

Characteristic	VOCSN	Cough Assist T70 (K121955)
Core technology	Radial blower working in conjunction with a cough assist valve under the control of a microprocessor	Radial blower working in conjunction with two cough assist valves under the control of a microprocessor
User Interface	LCD touch screen with additional hard keys	LCD screen with hard keys
Power	AC, DC, and internal battery	AC, DC, and internal battery

Performance Testing (non-clinical)

The company completed validation testing to validate performance against the User Requirements Document under simulated use conditions, and test reports were generated summarizing the test results. Verification testing was completed to verify system performance against the Product Requirements Specification, and test reports were generated summarizing the test results. This testing included biocompatibility testing, as listed in the Ventilation section. These tests demonstrated that the VOCSN is compliant with the user and product requirements.

The cough assist option is compliant with and has been verified to the following standards:

Medical electrical equipment	IEC 60601-1
Medical devices for home use	IEC 60601-1-11
Alarm system	IEC 60601-1-8

Suction

Description

The VOCSN includes an optional integrated suction function and detachable VLS suction canister. If enabled, Suction therapy can be initiated at any time during Ventilation or Cough therapy, to help remove secretions from the patient airway or patient circuit.

When enabled, the Cough+Suction feature activates both therapies simultaneously to help remove secretions from the patient airway and/or patient circuit. Suction will begin at the start of the first Cough therapy insufflation, and run throughout the configured number of Cough Cycles plus an additional 30 seconds.

The VOCSN suction function uses a conventional reciprocating piston pump working in conjunction with a selector valve under the control of a microprocessor to provide the negative pressure. Suction is routed to the canister, and a suction tube connects the suction catheter to the canister.

The VOCSN provides an alarm and monitoring package to alert users to hazard conditions.

Substantial Equivalence

The intended use, performance, and technology of the suction function have been compared to the Precision Medical Easy Go Vac PM66 (K140179) predicate device. A summary table of key characteristics compared to the predicate device is shown below.

Characteristic	**VOCSN**	**Easy Go Vac PM66 (K140179)**
Intended Use	• intended for airway fluid removal and oral/pharyngeal hygiene. • home, hospital, institutional and transport settings, including portable applications	• provides a portable, AC/DC powered medical vacuum source. • It is intended for use in the homecare / healthcare environments
FDA Product Code	BTA	BTA
Vacuum Control	-50 to -300 mmHg	-50 to -533 mmHg
Core technology	reciprocating piston pump working in conjunction with a selector valve under the control of a microprocessor	reciprocating piston pump working in conjunction with a vacuum regulator and mechanical gage
User Interface	LCD touch screen with additional hard keys	Manual physical controls
Power	AC, DC, and internal battery	AC, DC, and internal battery

Performance Testing (non-clinical)

The company completed Validation testing to validate performance against the User Requirements Document under simulated use conditions, and test reports were generated summarizing the test results. Verification testing was completed to verify system performance against the Product Requirements Specification, and test reports were generated summarizing the test results. These tests demonstrated that the VOCSN is compliant with the user and product requirements.

The suction option is compliant with and has been tested to the following standards:

FDA Guidance Document for Powered Suction Pump 510(k)s	
Electrically powered suction equipment	ISO 10079-1
Medical electrical equipment	IEC 60601-1
Medical devices for home use	IEC 60601-1-11
Alarm system	IEC 60601-1-8

Heated Wire Patient Circuit Accessory

Description

The VOCSN system includes a heated patient circuit accessory to connect the ventilator to the patient connection. The circuits are single patient use pediatric & adult heated patient circuits, with a passive or active exhalation valve. Passive circuits use a fixed leak for exhalation. Active circuits use a piloted diaphragm valve for exhalation control. The VOCSN heated wire patient circuits are to be used only with the VOCSN Unified Respiratory System.

Feature	VOCSN	Respironics (Philips) Disposable Heated Wire Circuits (K110398)
Operating principle	Connects ventilator to patient connection. Passive circuit uses a fixed leak for exhalation port. Active circuit uses a piloted diaphragm valve for exhalation control. Includes heated wire for use with a humidifier.	Connects ventilator to patient connection. Passive circuit uses a fixed leak for exhalation port. Active circuit uses a piloted diaphragm valve for exhalation control. Includes heated wire for use with a humidifier.
Classification	Class II	Class II
Product Code	BZE	BZE
Intended use	The patient circuit is intended to be used only with the VOCSN Unified Respiratory System which is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. It may be used in invasive and non-invasive applications. The VOCSN is intended for pediatric through adult patients weighing at least 5 kg. It is intended for use in home, hospital, institutional and transport settings, including portable applications.	Intended to provide warmed and/or humidified breathing gases before they enter the patient's airway. The disposable heated wire circuit is indicated for use by a single adult or pediatric patient in the home, hospital, and or institutional setting. It may be used for both invasive and non-invasive ventilation
Humidifier compatibility	Fisher Paykel HC550 & MR850 humidifiers	HC500
Reuseable	Single patient use	Single patient use
Heating mode	Applied voltage through heating wires.	Applied voltage through heating wires.
Sterility	Non-Sterile	Non-Sterile
Materials	Compliant with ISO 10993-1 Biological Evaluation	Compliant with ISO 10993-1 Biological Evaluation
Breathing gases	Air and supplemental oxygen	Air and supplemental oxygen

Feature	VOCSN	Respironics (Philips) Disposable Heated Wire Circuits (K110398)
Tube diameter	Adult: 22 MM Pediatric 15 mm	Adult: 22 MM Pediatric 15 mm
Tube length	1.85 M	1.8 m
Tube connectors	22 mm conical Compliant with ISO-5356-1 Conical connectors	22 mm conical Compliant with ISO-5356-1 Conical connectors
Heating wire	Resistive, encased	Resistive, encased
Wire resistance (ohms)	16	30
Rated power	60 watts	Not stated
Patient Leakage current	Compliant with the requirements of IEC 60601-1	Claims compliance with IEC 60601-1
Resistance to airflow	Complaint with ISO 8185	Complaint with ISO 5367
Tube volume	Pediatric: approx. 326 ml Adult: approx. 703 ml Compliant with ISO 5367	Not stated, claims compliance with ISO 5367
Exhalation valve type	Passive Option – fixed orifice type Active Option – Piloted diaphragm type	Passive Option – fixed orifice type Active Option – Piloted diaphragm type
Enthalpy	Per ISO 8185	Not stated
Condensate performance	The VOCSN circuit was demonstrated to control condensate over a wide range of patient ventilation conditions.	Not stated.
ISO-5367 Breathing tubes	Complies	Complies
ISO-8185 Respiratory humidification systems	Complies as applied to breathing circuits	Complies as applied to breathing circuits
ISO-60601-1 Medical Electrical Equipment	Complies with applicable parts as specified in ISO 8185	Complies with applicable parts

Performance Testing (non-clinical)

The company completed Validation testing to validate performance against the User Requirements Document under simulated use conditions, and test reports were generated summarizing the test results. Verification testing was completed to verify system performance against the Product Requirements Specification, and test reports were generated summarizing the test results. This testing included biocompatibility testing, as listed in the Ventilation section. These tests demonstrated that the VOCSN is compliant with the user and product requirements.

The heated wire patient circuit accessory is compliant with and has been tested to the following standards:

Biological Evaluation	ISO 10993-1
Respiratory tract humidifiers for medical use	ISO 8185
Conical connectors	ISO 5356-1
Breathing sets and connectors	ISO 5367

Bacteria Filter Accessory

Description

The VOCSN system includes a bacteria filter accessory connected between the VOCSN and the patient circuit. The filter is intended to reduce bacterial/viral transmissions between the patient and equipment. The VOCSN bacteria filter is to be used only with the VOCSN Unified Respiratory System.

Feature	VOCSN	Respironics (Philips) Bacteria Filter PN 342077 - Supplied by King Systems under (K973797)
Classification	Class II	Class II
Product Code	CAH	CAH
Intended use	To be used only as part of the VOCSN integrated respiratory care system to reduce bacterial/viral transmissions between the patient and equipment.	It is designed to reduce bacterial/viral transmissions between the patient and equipment.
Operating principle	Electrostatic	Electrostatic
Filtration efficiency	99.99% BFE & VFE	99.99% BFE & VFE
Approximate Volume (ml)	31	74
Connectors	22 mm conical, compliant with ISO 5356-1 Conical Connectors	22 mm conical
Resistance @ 30 lpm	0.4 cmH2O	0.7 cmH2O

Performance Testing (non-clinical)

The company completed testing to validate performance against the User Requirements Document under simulated use conditions, and test reports were generated summarizing the test results. Verification testing was completed to verify system performance against the Product Requirements Specification, and test reports were generated summarizing the test results. This testing included biocompatibility testing, as listed in the Ventilation section. These tests demonstrated that the VOCSN is compliant with the user and product requirements.

The bacteria filter accessory is compliant with and has been tested to the following standards:

Conical connectors	ISO 5356-1

Conclusion

The indications for use, performance characteristics, and core technology of the VOCSN are substantially equivalent to the predicate devices. Extensive validation and verification testing has demonstrated that the device is compliant with the product requirements and relevant regulatory standards. The information provided supports the claim that the device is substantially equivalent to predicate devices.