Wednesday, November 13, 2024

CorVent Medical, Inc.
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K241135
Trade/Device Name: RESPOND(R) Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: October 14, 2024
Received: October 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.

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)*
K241135

Device Name
RESPOND(R) Ventilator

Indications for Use *(Describe)*
The RESPOND(R) Ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. The RESPOND(R) Ventilator is intended for pediatric through adult patients weighing at least 38 kg.

The RESPOND(R) Ventilator is intended for use in a hospital including intra-hospital transport, and institutional environments such as long-term acute care, skilled nursing facilities, long-term care, and subacute care facilities.

The RESPOND(R) Ventilator is intended for use by qualified, trained personnel under the direction of a licensed clinician.

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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510(k) Summary
12-Nov-24

Sponsor: CorVent® Medical, Inc.
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Sponsor Contact: Richard S. Walsh, CEO

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131 Bay Point Dr NE
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Tel – 239-307-6061

Proprietary or Trade Name: RESPOND® Ventilator
Common/Usual Name: Ventilator, Continuous, Facility Care
Classification Name: Continuous ventilator
Classification CFR: 868.5895
Product Code: CBK

Predicate Device: Respironics – Trilogy EVO – K181166
Common/Usual Name: Ventilator, Continuous, Facility Care and Continuous, Ventilator, Home Use
Classification Name: Continuous ventilator
Classification CFR: 868.5895
Product Code: CBK & NOU

Device Description:

The RESPOND® Ventilator is a multi-patient continuous ventilator intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen/air to the breathing gas.

The ventilator provides both pressure control and volume modes of therapy and can provide both invasive and non-invasive ventilation. The device is compatible with both passive HME and heated humidification patient circuits, as well as nebulization with an ultrasonic nebulizer. The ventilator is equipped with an oxygen mixing module, which allows oxygen to be delivered to the patient within a range of 21% to 95% concentration.

The RESPOND® Ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. RESPOND® is intended for pediatric and adult patients weighing at least 38 kg (84 lbs.) and is intended for use in a hospital including intra-hospital transport, and institutional environments such as long-term acute care, skilled nursing facilities, long-term care, and subacute care facilities. The RESPOND® Ventilator is intended for use by qualified and trained personnel.

Principles of Operation

The RESPOND® is electro-mechanically and pneumatically operated, providing mechanical ventilation using:

- Using blowers in the generation of pressure and flow:
  - the Main blower to control inspiration pressure and
  - the PEEP blower to control the PEEP pilot pressure which controls exhalation pressure during exhalation

- Exhalation System
  - An exhalation solenoid valve is used to switch the pilot pressure from the inspiratory limb during inspiration to the PEEP blower during exhalation to the exhalation valve. This ensures the exhalation valve is closed during inspiration and open during exhalation.
  - An area ratio exhalation valve is used to perform two functions:
    - Prevent gas venting through the exhalation valve during inspiration.
    - Control PEEP expiratory pressure during exhalation.

- Safety System
  - A safety solenoid valve is used to switch the pilot pressure from the inspiratory limb to atmosphere to the area ration safety valve in the event of a sustained occlusion.
  - An area ratio safety valve is used to perform two functions:
    - Prevent gas venting through the exhalation valve during normal operation.
    - Direct gas from the inspiratory limb to atmosphere in the event of a sustained occlusion via the Safety Valve.

Indications for Use:

The RESPOND® Ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. The RESPOND® Ventilator is intended for pediatric through adult patients weighing at least 38 kg.

The RESPOND® Ventilator is intended for use in a hospital including intra-hospital transport, and institutional environments such as long-term acute care, skilled nursing facilities, long-term care, and subacute care facilities.

The RESPOND® Ventilator is intended for use by qualified, trained personnel under the direction of a licensed clinician.

Environments of use:

The RESPOND® Ventilator is intended for use in a hospital including intra-hospital transport, and institutional environments such as long-term acute care, skilled nursing facilities, long-term care, and subacute care facilities.

Characteristic	Subject Device: RESPOND® Ventilator	Predicate Device: Trilogy EVO Ventilator – K181166	Determination
Indications for Use	The RESPOND® Ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. The RESPOND® Ventilator is intended for pediatric through adult patients weighing at least 38 kg. The RESPOND® Ventilator is intended for use in a hospital including intra-hospital transport, and institutional environments such as long-term acute care, skilled nursing facilities, long-term care, and subacute care facilities. The RESPOND® Ventilator is intended for use by qualified, trained personnel under the direction of a licensed clinician.	[1]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. [2]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.	**Equivalent** [1]The RESPOND® Ventilator targeted patient population ≥38 kg (84 lbs.) represents lower risk in comparison with the predicate targeted population of ≥2.5kg (5.51 lbs.) as this corresponds to a Neonatal representing a much higher risk requiring higher levels of control, safety, performance, accuracy, and efficacy. Therefore, this difference does not raise different questions of safety and/or effectiveness. [2]These are related to oximetry capabilities of the Trilogy EV300. RESPOND does not offer oximetry. Therefore, is not applicable this difference does not raise different questions of safety and/or effectiveness.
Users	The RESPOND Ventilator is intended for use by qualified, trained personnel under the direction of a licensed clinician.	Clinicians (respiratory and non-respiratory) and physicians.	**Equivalent**
Ventilation Types	Invasive and Non-Invasive.	Invasive and Non-Invasive.	**Equivalent**
Ventilator Modes	PC (Pressure Control) VC (Volume Control) PSV (Pressure Support Ventilation) SIMV-PC (Synchronized Intermittent Mandatory Ventilation – Pressure Control) SIMV-VS (Synchronized Intermittent Mandatory Ventilation – Volume Control) PSV at 0 cmH2O PSV (Pressure Support Ventilation) with Apnea Backup Vent Does not have AVAPS-AE mode	A/C-PC: Assisted Control (Pressure Control) A/C-VC: Assisted Control (Volume Control) PSV: Pressure Support Ventilation SIMV-PC: Synchronized Intermittent Mandatory Ventilation (Pressure Control) SIMV-VC: Synchronized Intermittent Mandatory Ventilation (Volume Control) CPAP: Continuous Positive Airway Pressure S/T: Spontaneous/Timed Ventilation AVAPS-AE: Average Volume Assured Pressure Support	**Equivalent** Predicate offer an additional ventilation mode (AVAPS-AE), but this difference does not raise different questions of safety and/or effectiveness. AVAPS-AE is a patented breath mode.
Patient Contact Type	Indirect Contact with Gas Pathway	Indirect Contact with Gas Pathway	**Equivalent**
Contraindications	• Active Pneumothorax. • Neonatal, Infant, and Pediatric patients (less than 38 kg). • Where non-invasive ventilation is precluded by clinical practice.	• Inability to maintain a patent airway or adequately clear secretions. • Risk aspirating gastric contents. • Acute sinusitis or otitis media. • Epistaxis, causing pulmonary aspiration of blood. • Hypotension. • AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10kg. • AVAPS feature is contraindicated for patients less than 10kg.	**Equivalent** Differences in contraindications are based on the differences in intended use populations that do not raise different questions of safety and/or effectiveness.
TECHNICAL CHARACTERISTICS			
Alarms	**HIGH PRIORITY ALARMS** System Inoperable System Inoperable Occlusion High Pressure High Pressure Flow Sensor Not Connected Flow Sensor Not Connected Flow Sensor Not Connected Flow Sensor Reversed (Medium Priority) Adjust O2 Wall Flow (Medium Priority) Apnea Disconnect / High Leakage Low Total Exhale Minute Ventilation (Medium Priority) Apnea High Pressure Total Loss of Power Temp Loss of Power	**HIGH PRIORITY ALARMS** Ventilator Inoperative Ventilator Service Required Obstruction High Expiratory Pressure High Inspiratory Pressure External Flow Sensor Failed External Flow Sensor Cable Disconnected External Flow Sensor	**Equivalent** Both devices are compliant with the alarm's required per ISO 80601-2-12 and IEC 60601-1-8. Therefore, differences in alarms do not raise different questions of safety and/or effectiveness.

	Battery Low (≤5 mins) and Battery Low (≤10 mins) Battery Depleted Speaker Fault Watchdog Failure High / Low Currents High / Low Voltages System Signal Failure Ambient Temperature Too High or Low System Temperature Too High or Low **MEDIUM PRIORITY ALARMS** Set Volume Not Reached (Covered in the High Priority Alarm above) Low Inspiratory Pressure Low Inspiratory Pressure O2 Supply Failure O2 Supply Failure High Exhale Tidal Volume Low Exhaled Tidal Volume High Total Exhale Minute Ventilation High Respiratory Rate Low Total Exhale Minute Ventilation FiO2 Too Low FiO2 Too High Battery Low (≤10 mins) Loss of Main Power (On Battery) Battery Not Present Battery Not Charging Battery Over Temperature High PEEP Low PEEP Flow Sensor Reverse Adjust O2 Wall Flow Settings Data Corrupt Request Ventilation Stop	Not Connected External Flow Sensor Reversed Active Exhalation Valve Filed Check AEV Pilot Line Proximal Pressure Line Disconnected Oxygen Regulation Apnea Circuit Disconnected Low MinVent (Low Minute Ventilation) Low Respiratory Rate High Inspiratory Pressure (Volumes Modes) Loss of All Power Low Battery at 10 Minutes Internal Battery Depleted (Low Priority) **MEDIUM PRIORITY ALARMS** Circuit Leakage Rebreathing Detected Volume Under Delivery Loss of CO_2 Signal Loss of SpO_2 Signal CO_2 Sensor Adapter Zero Required Check/Change CO_2 Airway Adapter CO_2 Sensor Failure FiO_2 Sensor Disconnected Replace FiO_2 Sensor Low Expiratory Pressure Low Inspiratory Pressure (Pressure Modes) Low Oxygen Inlet Pressure High Oxygen Inlet Pressure High Tidal Volume Low Tidal Volume High Min Vent (High Minute Ventilation) High Respiratory Rate Low Inspiratory Pressure Alarm (Volume Modes) Low SpO_2 High SpO_2 Low $EtCO_2$ High $EtCO_2$ Low FiO_2 High FiO_2 Low Battery at 20 Minutes Replace Detachable Battery (Low Priority) Replace Detachable Battery (Low Priority)	

		Replace Detachable Battery (Low Priority) Replace Detachable Battery (Low Priority)	
Principle of Operation	Microprocessor Controlled. Electronic Control. Software Driven.	Microprocessor Controlled. Electronic Control. Software Driven.	**Equivalent**
Setting/Range Breath Rate	Range: 3 – 70 bpm Resolution: 1 bpm Accuracy: ± 1 bpm	Range: 0 – 80 bpm Resolution: 1 bpm	**Equivalent** Differences in breath rate are nonsignificant, thus do not raise different questions of safety and/or effectiveness, as ultimately the clinician is responsible for setting the patient breath rate based on their expertise and the patient needs.

Characteristic	Subject Device: RESPOND® Ventilator	Predicate Device: Trilogy EVO Ventilator	Determination
Setting/Range Pressure Control	Range: 5 – 40 cmH2O Resolution: 1 cmH2O Accuracy: ± (2 + 4% of setting) cmH2O	Range: 0 – 60 cmH2O Resolution: 1 cmH2O Accuracy: ± (2 + 4% of setting) cmH2O	**Equivalent** Differences in pressure control range are nonsignificant, thus do not raise different questions of safety and/or effectiveness, as ultimately the clinician is responsible for setting the pressure control based on their expertise and the patient needs.
Setting/Range Support Pressure	Range: 0 – 40 cmH2O Resolution: 1 cmH2O Accuracy: ± (2 + 4% of setting) cmH2O	Range: 0 – 60 cmH2O Resolution: 1 cmH2O Accuracy: ± (2 + 4% of actual) cmH2O	**Equivalent** Differences in support pressure are nonsignificant, thus do not raise different questions of safety and/or effectiveness, as ultimately the clinician is responsible for setting it based on their expertise and the patient needs.
Setting/Range Tidal Volume	Range: 150 – 2000 ml BTPS Resolution: 5 ml for values 100 to 295; 10 ml for values ≥300 ml to 790 ml and 50 ml for values ≥800 Accuracy: ± (4 + 15% of setting with no leak) mL	Range: 35 – 2000 ml (70 to 2000 ml for adult) Resolution: 1 ml Accuracy: ± (4 ml + 15% of setting)	**Equivalent** Differences in Tidal Volume range is related to differences in patient populations (i.e., Neonatal, Pediatric), thus do not raise different questions of safety and/or effectiveness, as ultimately the clinician is responsible for setting the tidal volume based on their expertise and the patient needs.
Setting/Range Inspiratory Time	Range: 0.4 – 3.0 sec Resolution: 0.1 sec Accuracy: ± (0.1 + 1% of setting)	Range: 0.3 – 5.0 sec* Controls min/max: 0.3 – 3.0 Resolution: 0.1 sec *Constrained to prohibit an inverse I:E ratio	**Equivalent** Difference in inspiratory range time is nonsignificant, thus do not raise different questions of safety and/or effectiveness, as ultimately, the clinician is responsible for setting it based on their expertise and the patient needs.

Setting/Range PEEP	Range: 0 – 20 cmH2O Resolution: 1 cmH2O Accuracy: ± (2 + 4% of setting) cmH2O	Range: 0 – 35 cmH2O for active exhaust circuits Resolution: 1 cmH2O Accuracy: Not shown	Equivalent The trilogy PEEP range is higher but such high PEEPs are rarely used clinically and increase patient mortality.
Leak Compensation	The RESPOND Ventilator estimates leaks in PC, VC, and PS breaths where pressure increases nonlinearly as a function of pressure, compensating for the displayed inspired (Vti) and exhaled tidal volume (Vte) measurements for leak losses. It does not compensate exhaled minute ventilation (MVe), or leaks lost to delivered volume in VC mode.	The ventilator compensates for a leak that occurs between the ventilator and the external flow sensor. Leaks that are downstream of the external flow sensor are not compensated for in measurement of inhaled or exhaled tidal volume. Leaks that are downstream of the external flow sensor are compensated for triggering.	**Equivalent**

Characteristic	**Subject Device: RESPOND® Ventilator**	**Predicate Device: Trilogy EVO Ventilator**	**Determination**
MEASURED & DISPLAYED VALUES			
Measured/Displayed Tidal Volume (Vti / Vte)	Name: Vti and Vte Range: 0 to 2000 ml (max in VC) but capable up to 9999 ml (see note below) Resolution: in increments of 1 ml Accuracy: ± (4 ml + 15% of actual)	Name: Vti and Vte Range: 0 to 2000 ml Resolution: in increments of 1 ml Accuracy: ± (4 ml + 15% of actual) for volumes ≥ 35 ml ± 10 ml for volumes < 35 ml	**Equivalent** Differences in Tidal Volume measured/displayed capabilities do not raise different questions of safety and/or effectiveness.
Measured/Displayed Minute Ventilation (MVe)	Name: MVe Range: 0 to 99 L/min Resolution: in increments of 0.1 L/min < 10 L/min and 1 L/min ≥ 10 L/min Accuracy: ± (0.1 L/min + 15% of actual)	Name: MVe Range: 0 to 30 L/min Resolution: in increments of 0.1 L/min Accuracy: Not stated	**Equivalent** Differences in Minute Ventilation measured / displayed capabilities do not raise different questions of safety and/or effectiveness. The RESPOND Ventilator does not limit the displayed value.
Measured/Displayed FiO_2	Name: FiO_2 Range: 16% to 100% Resolution: in increments of 1% Accuracy: ± (3% O2 of actual reading) The oxygen flow range may be set between 0 and 60 L/min. The ventilator only be used with a low flow oxygen source (i.e., maximum 10 psi at inlet).	Name: FiO_2 Range: 21% to 100% Resolution: in increments of 1% Accuracy: ± (2.5% FiO_2 + 2.5% of actual reading) within a 24-hour sensor calibration period, or a change in altitude	**Equivalent** Differences in FiO_2 measured/displayed capabilities do not raise different questions of safety and/or effectiveness. The RESPOND Ventilator does not limit the displayed value.
Measured/Displayed Leak%	Name: Leak% Range: 0% to 100% Resolution: in increments of 1% Accuracy: function of delivered volume and Vti accuracy	Not Shown	**Equivalent** Differences in Leak% measured/displayed capabilities do not raise different questions of safety and/or effectiveness.
Measured/Displayed Est. Leak Flow	Name: Leak Range: 0 to 200 L/min Resolution: in increments of 1 L/min Accuracy: Not stated	Name: Leak Range: 0 to 200 L/min Resolution: in increments of 0.1 L/min Accuracy: Not stated	**Equivalent**
Measured/Displayed Respiratory Rate	Name: RR Range: 0 to 99 BPM Resolution: in increments of 1 BPM Accuracy: ± 1 BPM	Name: RR Range: 0 to 90 BPM Resolution: in increments of 1 BPM Accuracy: Not stated	**Equivalent** The RESPOND Ventilator does not limit the displayed value.

Measured/Displayed PEEP	Name: PEEP Range: 0 to 60 cmH2O Resolution: in increments of 0.1 cmH2O Accuracy: ± (2 cmH2O + 4% of actual)	Not Shown	**Equivalent** Differences in PEEP measured/displayed capabilities do not raise different questions of safety and/or effectiveness. ISO 80601-2-12 requires the measurement of PEEP.
Measured/Displayed Peak Inspiratory Flow	Name: PF Range: 0 to 250 L/min Resolution: in increments of 1 L/min Accuracy: ± (1 L/min + 7% of reading)	Name: PIF Range: 0 to 200 L/min Resolution: in increments of 0.1 L/min Accuracy: Not stated	**Equivalent** Differences in Peak Inspiratory Flow measured/displayed capabilities do not raise different questions of safety and/or effectiveness.
Characteristic	**Subject Device: RESPOND® Ventilator**	**Predicate Device: Trilogy EVO Ventilator**	**Determination**
Measured/Displayed Peak Inspiratory Pressure	Name: PIP Range: 0 to 60 cmH2O Resolution: in increments of 1 cmH2O Accuracy: ± (2 cmH2O + 4% of actual)	Name: PIP Range: 0 to 90 cmH2O Resolution: in increments of 0.1 cmH2O Accuracy: ± (2 cmH2O + 4% of actual)	**Equivalent** Differences in Peak Inspiratory Pressure measured/displayed capabilities do not raise different questions of safety and/or effectiveness. The RESPOND Ventilator does not limit the displayed value.
Measured/Displayed Mean Airway Pressure	Name: MAP Range: 0 to 60 cmH2O Resolution: in increments of 0.1 cmH2O for MAP < 10 Accuracy: ± (2 cmH2O + 4% of actual)	Name: MAP Range: 0 to 90 cmH2O Resolution: in increments of 0.1 cmH2O Accuracy: ± (2 cmH2O + 4% of actual)	**Equivalent** Differences in Mean Airway Pressure measured/displayed capabilities do not raise different questions of safety and/or effectiveness. The RESPOND Ventilator does not limit the displayed value.
Measured/Displayed I:E Ratio	Name: I:E Range: 1: XXX and XXX:1 where XXX = 0.1 to 999 Accuracy: ± (50ms of inspiratory time)	Name: I:E Range: 9.9:1 to 1:9.9 Accuracy: Not stated	**Equivalent** Differences in I:E Ratio measured/displayed capabilities do not raise different questions of safety and/or effectiveness.
Measured/Displayed Plateau Pressure	Name: P_{PL} Resolution: in increments of 1 cmH2O Accuracy: ± (2 cmH2O + 4% of actual)	Not Shown	**Equivalent** Differences in Plateau Pressure measured/displayed capabilities do not raise different questions of safety and/or effectiveness.
Bluetooth Connection for Export Data Functions	RESPOND Ventilator has Bluetooth connection capability for future data export.	Trilogy EV300 utilizes a Bluetooth connection for export data functions (refer to Trilogy EVO User Manual Section 7.4).	**Equivalent**
Inspiratory Limb Resistance	2.1 cmH2O/L/s @ 60 L/min (HME) Max 6 cmH2O/L/s 2.0 cmH2O/L/s @ 60 L/min (HH) Max 7 cmH2O/L/s	Inspiratory/expiratory resistance: up to 5 cmH2O at: • 30 L/min for adult (20 to 22 mm) circuit size,	**Equivalent** ISO 80301-2-12:2020, section

Expiratory Limb Resistance	3.5 cmH2O/L/s @ 60 L/min (HME) Max 7 cmH2O/L/s 4.0 cmH2O/L/s @ 60 L/min (HH) Max 7 cmH2O/L/s	• 15 L/min for pediatric (14 to 16 mm) or pediatric/adult (19 mm) circuit size, and • 2.5 L/min for infant (9 to 13 mm) circuit size. Compliance: up to 4 ml/cmH2O	201.12.4.108(f) and 201.103(b) pressure drop measured at *patient- connection* port shall not exceed 6.0 cmH2O at 30 L/min, 15 L/min, and 2.5 l/min flowrates.
VBS (Patient Circuit) Compliance	< 4 mL/cmH2O (for passive HME) < 6 mL/cmH2O (for active heated humidification)	Not disclosed	Differences are ± 0.4 cmH2O from the predicate 5 cmH2O. Therefore, they are considered equivalent and do not raise different questions of safety and/or effectiveness.
Exhalation Control	• Dual Limb Circuit with Exhalation Valve connected to Exhalation Manifold. • Pneumatically Controlled Exhalation Valve. • Electronically Controlled PEEP.	• Active Exhalation Valve Line Connection for ActivePAP and Active Flow Circuits. • Dual Limb Active Exhalation Valve Connection (from patient). • Pneumatically Controlled Exhalation Valve. • Electronically Controlled PEEP.	**Equivalent**
Characteristic	**Subject Device: RESPOND® Ventilator**	**Predicate Device: Trilogy EVO Ventilator**	**Determination**
ENVIRONMENTAL & OPERATING CHARACTERISTICS			
Operating Relative Humidity	15 – 90% Noncondensing	5 – 93% Noncondensing	**Equivalent**
Operating Atmospheric Pressure	700 – 1060 hectopascals (hPa) 70 – 106 kilopascals (kPa)	620 – 930 hectopascals (hPa) 62 – 106 kilopascals (kPa)	**Equivalent** Differences in altitude range are minor and do not raise different questions of safety and/or effectiveness.
Operating Altitude	Up to 9,842 feet (3,000 meters)	-384 meters to 3954 meters (-1,261 – 12,971 feet)	**Equivalent** Differences in altitude range do not raise different questions of safety and/or effectiveness.
Operating Temperature	10°C – 30°C (50°F – 86°F)	0°C – 40°C (32°F – 104°F)	**Equivalent** Differences in temperatures range are minor and do not raise different questions of safety and/or effectiveness.
Store / Transport Temperature	-20°C – 50°C (-4°F – 122°F)	Storage: -25° C – 70°C (13°F – 158°F) Transient: -20°C – 50°C (-4°F – 122°F)	**Equivalent** Differences in temperatures range are minor and do not raise different questions of safety and/or effectiveness.
Store / Transport Relative Humidity	15 – 90% Noncondensing	5 – 93% Noncondensing	**Equivalent** Differences in RH range are unsignificant and do not raise different questions of safety and/or effectiveness.
Biocompatibility	Per ISO 10993-1:2018 – Long-term exposure Per ISO 18562-1:2017 – Permanent contact	Per ISO 10993-1:2018 – Long-term exposure Per ISO 18562-1:2017 – Permanent contact	**Equivalent**

Standards	IEC 60601-1:2020 Ed.3+A1:A2 IEC 60601-1-2 Edition 4.1 2020-09 IEC 60601-1-8 Edition 2.2 2020-07 IEC TR 60601-4-2 Edition 1.0 2016-05 ISO 80601-2-55 Second edition 2018-02	Similar	**Equivalent**

Substantial Equivalence Discussion

The table above compares the key features of the proposed subject device with the identified predicate device.

Though each of the devices' principles of operation, namely intended for patients that require mechanical ventilation are equivalent, there are minor differences. However, these differences do not raise new questions of safety or efficacy.

Indications for Use:
The indications for use are similar in that each device is to provide continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. However, the predicate device includes indications specific to oximetry capabilities, whereas RESPOND® does not offer oximetry.

This difference does not raise different or new questions of safety and/or effectiveness.

Environment for Use:
The subject device is indicated for use in hospital settings, whereas the predicate is indicated for use in not only the hospital but also the home and non-emergency transport settings.

This difference does not raise different or new questions of safety and/or effectiveness.

Patient Population:
The subject device is intended for pediatric and adult patients weighing at least 38 kg (84 lbs.); whereas the predicate device (Trilogy EVO) is intended for pediatric through adult patients weighing at least 2.5 kg. The subject device's patient population is a subset of the predicate's population.

This difference does not raise different or new questions of safety and/or effectiveness.

Ventilation Modes:
The technology of a blower powered positive pressure source with pressure and flow sensors to regulate flow and pressure are similar. The subject device provides the following ventilatory modes: PC, VC, PSV, SIMV-PC, SIMV-VS, PSV at 0 cmH2O, PSV with Apnea Backup Vent. Predicate offer an additional ventilation mode (AVAPS-AE), but this difference does not raise different or new questions of safety and/or effectiveness. Both ventilators meet the minimum requirements of ISO 80601-2-12 for performance specifications.

Alarms:
Both the subject device and predicate device offer a variety of high and medium priority alarms. Though the offered alarms may differ, both devices are compliant with the alarm's required per ISO 80601-2-12 and IEC 60601-1-8. Differences in alarms do not raise different questions of safety and/or effectiveness.

Conclusion on the Discussion of Differences:
In review of the comparative table and the noted differences, none of the differences raised different or new questions of safety or effectiveness.

Discussion of Testing Performed

Non-clinical Performance testing:

The subject device 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. The testing completed is summarized below:

- IEC 60601-1:2020
- IEC 60601-1-2:2020
- IEC 60601-1-8:2020
- ISO 80601-2-12:2020
- ISO 18562-1 – suite of biocompatibility tests
- Comparative waveform evaluation between the subject device and predicate demonstrated that the ventilatory performance is similar.

Additionally, the non-clinical performance testing included testing of a set of ventilation modes as described above, along with complete software verification and validation testing, as applicable. The data demonstrates that the subject device's technological characteristics are substantially equivalent with the predicate device.

Usability:
Summative usability tests were performed with a user group of respiratory therapists. The results demonstrated that the subject device meets the HF acceptance criteria.

Substantial Equivalence Conclusion
CorVent® Medical concludes that the RESPOND® Ventilator is substantially equivalent in Indications for Use, technology, design, performance, user base, user interface, and use context to the primary 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 or new concerns of safety when compared to the predicate. Therefore, the subject device is substantially equivalent to the predicate device.