

Appendix B: Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories

Updated: May 29, 2020

To be added to **Appendix B** (below), ventilators, ventilator tubing connectors, and ventilator accessories must be determined to meet the applicable conditions and criteria for safety, performance and labeling set forth in [Section II](#), [Section IV](#), and [Appendix A](#). FDA will add a ventilator, ventilator tubing connector, and ventilator accessory to the list of authorized products in **Appendix B** (below) upon submission of a request from a sponsor as described in the Scope of Authorization Section of the [Letter of Authorization](#) (Section II) and pursuant to the Conditions of Authorization (Section IV) in this EUA and based on FDA's review and concurrence.

Ventilators

Manufacturer	Product Name	Device Description	Intended Use	Date of Authorization
Beijing Aeonmed Co., Ltd	VG70 ventilator	Critical Care Ventilator	Mechanical ventilation of patients in ICU	March 25, 2020
Shenzen Mindray Bio-medical Electronics	Mindray SV300/SV600/SV800 ventilators	Critical Care Ventilator	This product is intended to provide ventilation assistance and breathing support for adult, pediatric and infant patients	March 28, 2020
Vyair Medical, Inc.	LTV2 model 2200 and LTV model 2150	Critical Care Ventilator	LTV2 model 2200 and 2150 ventilators are intended to provide continuous or intermittent ventilatory 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 O2. The Model 2150 operates with low pressure.	March 28, 2020
RESMED	Stellar 150	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	The Stellar 150 is intended to provide ventilation for non-dependent, spontaneously breathing adult and pediatric patients (30 lb/13 kg and above) with respiratory insufficiency, or respiratory failure, with or without obstructive sleep apnea. The device is for noninvasive use, or invasive use (with the use of the ResMed Leak Valve). The iVAPS mode with optional AutoEPAP is intended for patients weighing more than 66lb (30kg). Operation of the device includes both stationary, such as in hospital or home, or mobile, such as wheelchair usage	March 30, 2020

RESMED	Lumis 150 VPAP ST	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	<p>The ResMed Lumis 150 VPAP ST devices are indicated to provide non-invasive ventilation for patients weighing more than 30 lbs (13 kg), or more than 66 lbs (30kg) in iVAPS mode, with respiratory insufficiency or obstructive sleep apnea (OSA). They are intended for home and hospital use.</p> <p>The ResMed Lumis 150 VPAP ST devices can be used with an attachable humidifier that is intended for single patient use in the home environment and re-use in a hospital/institutional environment.</p>	March 30, 2020 Amended April 17, 2020
RESMED	GA ST	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	<p>The GA non-invasive ventilator is an assist ventilator and is intended to augment patient breathing. It is intended solely for spontaneously breathing individuals who require mechanical ventilation: patients with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional settings under the direction of a physician.</p> <p>The ventilator is intended to support patients weighing 20 kg (44 lb) or greater.</p> <p>The ventilator is intended to be used by qualified medical professionals, such as physicians, nurses, and respiratory therapists.</p>	March 31, 2020
RESMED	Flexo Bi-Level ST	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	<p>Flexo Bi-level positive airway pressure therapy device is used to provide non-invasive ventilatory support of mechanical ventilation for: Patients who are independent and spontaneously breathing, Patients with respiratory insufficiency and sleeping breathing disorders. It can provide both a stable continuous positive airway pressure and a bi-level positive airway pressure. It is not a life support ventilator. It is intended to be used in the home or professional medical environment.</p> <p>The therapeutic pressure is prescribed by a physician according to patients' condition.</p>	March 31, 2020
RESMED	AirCurve ST	Ventilator, Continuous, Minimal	AirCurve ST device has indications for use that include respiratory insufficiency.	March 31, 2020 Amended

		Ventilatory Support, Facility Use	The AirCurve ST device is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (30kg). It is intended for home and hospital use.	April 17, 2020
Amsino	YUWELL® YH-730 Bi-level PAP and YH-830 Bi-level PAP	Ventilator, Non-Continuous	The Bi-level device is indicated for treatment of sleep apnea hypopnea syndrome in patients weighing more than 66lb (30kg). It is intended both for home use and hospital use. The water tank is intended for single patient use in the home environment and re-use in a hospital/institutional environment.	March 31, 2020
Inovytac	Ventway Sparrow	Ventilator, Continuous	The Ventway Sparrow ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg (11 lb), who require the following types of ventilatory support: SIMV - VC (PS), CPAP. The Ventway Sparrow lung ventilator is intended for emergency use and during transportation. It may be used for invasive or non-invasive ventilation presets. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.	March 31, 2020
Philips Respironics	VX850 Ventilator	Critical Care Ventilator	The VX850 ventilator is intended to provide continuous or intermittent respiratory support and monitoring of pediatric and adult patients. The VX850 is intended to be used in a hospital or other institutional healthcare environment and is intended for intra-facility transport. The VX850 ventilator is intended for use by qualified, trained personnel under direction of a physician. The VX850 is intended for use with pediatric (infants) ages 2 months to 2 years and weighing 5 kg or greater, up to and including adult patients.	April 1, 2020
BMC Medical CO., LTD	Luna G3 BPAP 25A- LG3700	Ventilator, Continuous, Minimal Ventilatory	The G3 B25A BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation	April 2, 2020

		Support, Facility Use	for patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. These devices are intended for adult patients by prescription in the home or hospital/institutional environment.	
BMC Medical Co., Ltd.	Y-30T	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	BPAP System (Y-30T Model) is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. Y-30T device is intended for adult patient by prescription in the home or hospital/institutional environment. This device is not intended for life support. The optional Heated Humidifier used with the Y-30T device together is indicated for taking humidifying and heating air from the device.	April 2, 2020
Dragerwerk AG & CO. KGaA	Evita V800 and Evita V600	Critical Care Ventilator	The intensive care Ventilator Evita is intended for the Ventilation of adults, adolescents, children, infants and neonates. This device provides mandatory Ventilation modes and Ventilation modes for supporting spontaneous breathing as well as Ventilation monitoring	April 2, 2020
Dragerwerk AG & CO. KGaA	Babylog VN800 and VN600	Critical Care Ventilator	The intensive care ventilator Babylog is intended for the ventilation of neonates from 0.4 kg (0.88 lb) up to 10 kg (22 lb), and pediatric patients from 5 kg (11 lb) up to 20 kg (44lb) bodyweight. This device provides mandatory ventilation modes and ventilation modes for supporting spontaneous breathing as well as ventilation monitoring.	April 3, 2020
GE Healthcare	pNeuton Model A-E Ventilator	Ventilator, Continuous, Facility Use	The pNeuton Ventilator is intended for continuous mechanical ventilation of patients in the following patient populations and use locations: Patient population - adult / pediatric patients 23 Kg and greater who require the following general types of ventilatory support: <ul style="list-style-type: none"> • positive pressure ventilation delivered invasively (via an ET tube) or non-invasively (via a mask) •CMV and IMV modes of ventilation •with or without PEEP / CPAP •with oxygen or a mixture of air and 	April 3, 2020

			<p>oxygen</p> <p>The ventilator is suitable for use in:</p> <ul style="list-style-type: none"> •Hospitals and alternate care units to meet the needs for mechanical ventilation •Pre-hospital transport applications including accident scene, emergency rescue vehicles •Hospital ICU transport applications including emergency, radiology, surgery and post anesthesia/recovery •Air transport via helicopter or fixed wing 	
Covidien LLC	Puritan Bennett 560 Ventilator System	Ventilator, Continuous,	<p>The Puritan Bennett 560 Ventilator is indicated for the continuous or intermittent mechanical ventilatory support of patients weighing at least 11 lb (5 kg) who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a doctor. It is essential to read, understand, and follow these instructions before using the Puritan Bennett 560 Ventilator.</p> <p>Specifically, the ventilator is applicable for adult and pediatric patients who require the following general types of invasive or non-invasive ventilatory support, as prescribed by an attending doctor:</p> <ul style="list-style-type: none"> •Positive Pressure ventilation •Assist/Control, SIMV, or CPAP modes of ventilation •Breath types including Volume Control, Pressure Control, and Pressure Support <p>The ventilator is suitable for use in institutional, home, and portable settings. It is not intended for use in Emergency Medical Service (EMS) such as an emergency transport.</p>	April 5, 2020
CoLabs	COVID Ventor	Emergency Ventilator	<p>The COVID Ventor system is an emergency use ventilator used to provide adult patients with emergency ventilatory support when no alternative FDA-approved ventilators are available. The COVID Ventor System consists of the reusable Ventor Console (Console) and the single use, disposable Ventor-Specific Breathing</p>	April 6, 2020

			Circuit (Breathing Circuit). The COVID Venter is able to provide Pressure Controlled, Pressure Supported, and Volume Controlled long-term ventilatory support in emergency situations	
MEKICS Co., Ltd	MTV1000 ventilator	Ventilator, Continuous	MTV1000 ventilator is designed for use on patient population sizes from pediatric through adult who require respiratory support or mechanical ventilation and weigh a minimum of 5.0 kg. It is suitable for service in hospitals to provide continuous positive pressure ventilatory support using medical oxygen and compressed medical air from internal air sources to deliver oxygen concentrations of 21 % to 100 %. Ventilatory support can be delivered invasively or noninvasive.	April 6, 2020
Drägerwerk AG & Co. KGaA	Atlan A350 and Atlan A350 XL	Gas-Machine, Anesthesia	This device is intended for use in anesthetizing adults, pediatric patients, and neonates. The device can be used for mechanical ventilation, manual ventilation, pressure-supported spontaneous breathing, and spontaneous breathing. The device is equipped with the following basic functions: <ul style="list-style-type: none"> – Ventilation monitoring – Inspiratory O2 measurement – Device monitoring – Anesthetic gas receiving system The following options are additionally available: <ul style="list-style-type: none"> – Patient-gas measurement module for O2, CO2, N2O, and anesthetic gases – O2 insufflation Anesthesia is achieved through a mixture of pure oxygen and Air (medical compressed air) or pure oxygen and nitrous oxide, with the addition of volatile anesthetic agents. Ventilation is accomplished on the patient through a laryngeal mask, a breathing mask, or an endotracheal tube. The integrated breathing system can be used with partial rebreathing (low-flow or minimum-flow).	April 7, 2020
VenTec Life Systems	V+Pro Emergency Ventilator	Ventilator, Continuous	VOCSN Unified Respiratory System is intended to provide continuous or intermittent ventilatory support for	April 7, 2020

			<p>the care of individuals who require mechanical ventilation. It may be used in invasive and non-invasive applications. 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.</p>	
<p>AMBULANCE TECH.CO., LTD</p>	<p>Models 6000S, T5, T7</p>	<p>Emergency Transport Ventilator</p>	<p>Model 6000S - The 6000S ventilator is intended to provide continuous ventilation for patients who require invasive or noninvasive respiratory support and weigh more than 15KG (Infants, children, adults). The 6000S ventilator offers IPPV (Intermittent Positive Pressure Ventilation Mode), AC (Assisted Control Ventilation Mode), CPR auxiliary modes, etc. The 6000S ventilator can display the monitoring pressure waveform and interface parameters (Pmax, Pmean) in real time. The 6000S Ventilator is intended for use in emergency treatment outside the hospital and in-hospital transportation, and it runs under the central oxygen supply of the hospital or an oxygen cylinder pressure greater than 2.7Bar.</p> <p>Model T5 - The T5 ventilator is intended to provide continuous ventilation for patients who require invasive or noninvasive respiratory support (Infants, children, adults), with a tidal volume greater than 50ml. The T5 ventilator offers capacity control (IPPV, VAC, VSIMV), pressure control (PCV, PAC, PSIMV), noninvasive breathing (CPAP) modes, etc. It also has CPR auxiliary function and ETCO2 detection function. The T5 ventilator can display pressure waveform, ETCO2 waveform and parameters (pressure, tidal volume, ETCO2) in real time. The T5 ventilator is intended for use in out-of-hospital emergency treatment (first aid treatment on the ground, at sea, and in the air) and in-hospital transportation run under the central oxygen supply of the hospital or an oxygen cylinder pressure greater than 2.7Bar.</p>	<p>April 8, 2020</p>

			<p>Model T7 - The T7 ventilator is intended to provide continuous ventilation for patients with weight greater than 2kg (infants, children, adults) who require invasive or noninvasive respiratory support, with a tidal volume greater than 20ml. The T7 ventilator offers volume control (IPPV, VAC, VSIMV), pressure control (PCV, PAC, PSIMV), non-invasive (CPAP, CPAP + PSV, BiPPV, APRV), advanced ventilation (PRVC, PRVC + PSV, APRV + PSV), resuscitation mode (CPR, RSA, HFNC), etc.; and has functions such as ETCO2, ring chart, respiratory mechanics and trend chart. The T7 ventilator can display pressure waveform, flow waveform, tidal volume waveform, ETCO2 waveform and interface parameters (pressure, tidal volume, ETCO2, FIO2) in real time. The T5 ventilator is intended for use in out-of-hospital emergency treatment (first aid treatment on the ground, at sea, and in the air) and in-hospital transportation run under the central oxygen supply of the hospital or an oxygen cylinder pressure greater than 2.7Bar.</p>	
Philips Respironics	E30 ventilator	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	<p>The Philips Respironics E30 ventilator is intended to provide invasive and non-invasive ventilatory support for individuals with Respiratory Insufficiency. It is specifically for the care of adult and pediatric patients >7 years of age and >18kgs. It is intended to be used in the hospital or other institutional healthcare environments, as well as spaces converted for the care of large numbers of COVID-19 patients (e.g. convention centers, university dormitories, motels). The Philips Respironics E30 ventilator is intended for use by qualified, trained personnel under the direction of a physician.</p>	April 8, 2020
Incoba LLC	Apogee	Oxygen Conserver	<p>The Apogee gas conserver is intended as a delivery device for medical grade oxygen from high-</p>	April 8, 2020

			<p>pressure oxygen cylinders. This is an ambulatory device which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder. The Apogee is intended to be used in the hospital, healthcare facilities, or home care environments.</p> <p>The Apogee Device shall be used by trained professionals either in a doctor's office or clinical setting initially. However, once recommended by the physician or healthcare provider the device can be prescribed for use within a home environment for subsequent treatments.</p> <p>The Apogee Device essential performance is to provide short puffs of air during operation as noted on the display for nasal output L or R. In the event air is not delivered use the bypass adaptor and return the device to Dynaris for immediate replacement.</p> <p>The Apogee unit is a regulated device and carries warnings and cautions regarding safe use of this product. Failure to read this manual and adhere to the warnings and caution stated within the manual can affect device performance and potentially harm to the user.</p> <p>The Apogee Device and its accessories do not contain any natural rubber latex-containing components.</p>	
SecondBreath LLC	Pneumatic Resuscitator device	Emergency Resuscitator	<p>The SecondBreath LLC Pneumatic Resuscitator is an electric pneumatic ventilator. This system uses compressed air to drive a pneumatic cylinder equipped with a plunger to compress an AMBU bag and provides the patient with positive inspiratory pressure. This device is intended only for use for transport or emergency resuscitation unless there are no other ventilation modalities available due to emergency resource limitations. The user can set tidal volume (TV), inspiratory to</p>	April 13, 2020

			expiratory (I:E) ratio, respiratory rate, expiratory pause, and inspired oxygen (FiO2) at a constant 1.0 rate. Pure oxygen can be delivered through the AMBU bag. The device can only be operated in volume control (VC) continuous mandatory ventilation mode. Continuous end-tidal carbon dioxide monitoring is required for safe use of this device since there are no alarms for TV not met/exceeded. Additionally, power supply needs to be monitored as there is a loss of power alarm but no backup power supply to provide ventilation.	
University of Minnesota Medical School and Boston Scientific Corporation	Coventor Adult Manual Resuscitator Compressor	Emergency Resuscitator	This device is intended for compression of an adult manual resuscitator device intended for pulmonary resuscitation of adult patients for whom no other appropriate means of mechanical ventilation exists due to resource limitations from pandemic conditions in the region of use.	April 14, 2020
Umbulizer	UMV-001 EUA	Emergency Resuscitator	The Umbulizer UMV-001 is intended to provide ventilatory support to adults when Positive Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The Umbulizer series is appropriate for adults that weigh at least 45 kg (approximately 99 lbs). It is intended to be used in a pre-hospital, field hospital, and transport environments, as well as hospital settings where sufficient standard ventilators are not available.	April 14, 2020
Hillrom	MetaNeb 4	Intermittent Positive Pressure Breathing Device	The MetaNeb 4 System is indicated for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and also has the ability to provide supplemental oxygen when used with compressed oxygen. Patient Population – 5 years old and above whom can follow verbal instructions. Environment of Use – Hospitals, sub-acute and nursing facilities, physician offices, clinics, and home settings.	April 16, 2020
Spiro Devices LLC	Spiro Wave	Emergency Resuscitator	The Spiro Wave is an automated manual resuscitator that has been designed specifically to meet AAMI guidelines for emergency use resuscitators and provide respiratory	April 17, 2020

			<p>support for adult patients in acute respiratory failure. It does not replace standard mechanical ventilation but acts as a bridge to standard mechanical ventilation by increasing the functionality of existing manual resuscitator bags.</p> <p>The Spiro Wave is compatible with existing manual resuscitator bags, and clinicians can control key ventilatory parameters.</p> <p>The Spiro Wave is designed to provide basic ventilator functionality to a single adult patient, in an emergency situation when there are no other options available to the patient.</p>	
RESMED	AirCurve 10 ST-A	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	<p>The AirCurve 10 ST-A is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) with respiratory insufficiency or obstructive sleep apnea (OSA). The iVAPS mode is indicated for patients weighing more than 66lbs (30 kg).</p> <p>The AirCurve 10 ST-A is intended for home and hospital use.</p> <p>The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.</p>	April 17, 2020
PVA	PREVENT	Emergency Resuscitator	<p>PREVENT is indicated for emergency resuscitation with appropriate critical care monitoring on adult patients weighing at least 66 pounds that require mechanical respiratory support where standard ventilators are not available during the National Emergency.</p>	April 17, 2020
3B Medical Inc	Luna G3 B30VT	Ventilator, Continuous, Minimal Ventilatory Support	<p>The G3 B30VT BPAP is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. These devices are intended for adult patients by prescription in the home or hospital/institutional environment.</p>	April 20, 2020
Resvent	iBreeze PAP	Ventilator, Continuous, Minimal Ventilatory	<p>The iBreeze PAP system delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea (OSA) in spontaneously</p>	April 20, 2020

		Support, Facility Use	breathing patients weighting over 30kg (66lbs) for use in the home, hospital, or institutional environment.	
Virgin Orbit	Virgin Orbit Resuscitator	Emergency Resuscitator	This emergency use resuscitator is for use with appropriate critical care monitoring on adults (>18 years of age) requiring mechanical ventilation during declaration of National Emergency where ventilator need has surpassed ventilator supply and no other ventilatory support devices are available.	April 22, 2020 Amended April 23, 2020
Amsino International Inc's	YUWELL YH-725 BiPAP	Ventilator, Non-Continuous	The YH-725 Bi-level device is indicated for treatment of sleep apnea hypopnea syndrome in patients weighing more than 66lb (30kg). It is intended both for home use and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.	April 23, 2020
AutoMedX Inc.	SAVe II Series Ventilator	Powered Emergency Ventilator	The SAVe II series are intended to provide ventilatory support for adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF) or other situations where mechanical ventilation is needed. The SAVe II series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, outpatient environments, hospitals, ICU's, transport environments or any other healthcare environment requiring the use of ventilator.	April 24, 2020
SLS Medical Technology Corp. Ltd.	CP101/CP101S Series	Ventilator, Non-Continuous	This CPAP (Continuous Positive Airway Pressure) product can provide a continuous and positive airway in patients with respiratory insufficiency. This product provides 4~20 cmH2O of positive airway pressure and is equipped Oxygen Inlet to allow multiple Oxygen sources i.e. Oxygen generator. It is intended to be used under prescription of a physician.	April 24, 2020
Zhejiang LifeMed Technology Co., Ltd.	LA Series Ventilators LA20C, LA20A, LA20B, LA25B, LA25B	Ventilator, Non-Continuous	The LifeMed LA Series Ventilator is a ventilator indicated for the treatment of respiratory insufficiency in patients weighing more than 30kg (66 lbs). It is intended for hospital use. The built-in humidifier is intended for repeated use by the same	April 24, 2020

			patient.	
Resvent Medical Technology CO., Ltd's	iBreeze 30STA device	Ventilator, Non-Continuous	The iBreeze 30STA PAP system delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea (OSA) in spontaneously breathing patients weighing over 30kg (66lbs), it is for use in the home, hospital, or institutional environment.	April 27, 2020
Shenzhen Yamind Medical Tech	CPAP Devices: DM28-20C-G; Auto CPAP Devices: DM28-20A-W, DM28-20A-WP; BiPAP Devices: DM28-20S-G, DM28-20SA-G, DM28-20ST-G, DM28-25S-B, DM28- 25SA-BP, DM28-25ST-BP, DM28-30ST-B, DM28-30ST-BP, DM28-30STA-BP	Ventilator, Non-Continuous	The subject device provides noninvasive ventilation for patients with obstructive sleep apnea. It is indicated for adult patients weighing more than 30kg and can be used in homes and hospitals. It is not intended for life support, or for central sleep apnea. It may be used to improve the oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing.	April 28, 2020
NASA Jet Propulsion Laboratory	VITAL ventilator	Emergency Ventilator	The VITAL ventilator is intended to provide continuous ventilatory support for adult (body weight ≥ 50 kg) patients who require mechanical ventilation. VITAL provides patients with emergency ventilatory support when no alternative standard ventilators are available. The VITAL ventilator is a restricted medical device intended for use by qualified healthcare provider who understands the functionality of the device operating under the direction of a physician.	April 30, 2020
Venti-Now	Venti-Now Resuscitator Model JM-P2020A	Emergency Resuscitator	The Venti-Now resuscitator is indicated for continuous or intermediate mechanical support of adult patients who require mechanical ventilation. The resuscitator is a restricted medical device intended for use by qualified,	April 30, 2020

			<p>trained personnel under the direction of a Physician for COVID-19/Emergency use when no FDA-cleared ventilators are available. It is essential to read, understand, and follow these instructions before using the Venti-Now resuscitator.</p> <p>The Venti-Now resuscitator is a volumetric device that compresses a disposable BVM bag to create the positive pressure airflow to the patient. As such its use is applicable for use where a BVM unit is in use today. In addition, the unit has means to control Tidal volume, Inhalation/Exhalation rates, and bpm that make it suitable for a broader range of target patients than manually pumped BVM bags.</p>	
Wilcox Industries Corp	Wilcox PATRIOT SAVR	Emergency Ventilator	<p>PATRIOT SAVR is indicated for emergency continuous or intermittent mechanical support of adult patients when their ventilatory status cannot be maintained by high flow oxygen by nasal cannula, and a FDA cleared ventilator is not available.</p> <p>Target Patients The SAVR is applicable for adult patients who require the general types of invasive or non-invasive ventilatory support, as prescribed by an attending doctor:</p> <ul style="list-style-type: none"> • Positive Pressure ventilation • Assist/Control, SIMV modes of ventilation <p>The SAVR provides multiple alarms states but minimal monitoring capability, and thus the level of patient criticality should be considered before use. It is not indicated for Level 3 Critical Care patients.</p> <p>Target Environments The ventilator is suitable for use in</p>	May 1, 2020

			<p>institutional and portable settings.</p> <p>Target Operators This ventilator must be used only under the responsibility and on the prescription of a doctor. The ventilator may be operated by the following caregivers:</p> <ul style="list-style-type: none"> • Respiratory therapists • Doctors • Nurses 	
<p>Elemaster S.p.A. Tecnologie Elettroniche</p>	<p>Mechanical Ventilator Milano (MVM)</p>	<p>Emergency Ventilator</p>	<p>The MVM is a pressure-regulated mechanical ventilator designed for adult patients to provide emergency ventilatory support when no alternative standard ventilators are available.</p> <p>The device should be used by:</p> <ul style="list-style-type: none"> • healthcare professionals responsible for the treatment of a patient on ventilation support equipment, and • staff who will be performing routine maintenance on the device. <p>The MVM is intended to provide ventilation support for intensive therapy during the COVID-19 pandemic for patients who require mechanical ventilation and weigh more than 40 kg (88 lbs).</p>	<p>May 1, 2020</p>
<p>BMC Medical CO., LTD., China</p>	<p>Luna G3 BPAP S/T- LG3800-G3 B30VT</p>	<p>Ventilator, Continuous, Minimal Ventilatory Support</p>	<p>The ventilator is intended to provide continuous ventilatory support for adult patients who require mechanical ventilation. The ventilator is a restricted medical device intended for use in hospitals and hospital-type facilities, which provide respiratory care for patients requiring respiratory support.</p>	<p>May 2, 2020</p>
<p>ZIBO ZHONGXUN MEDICAL EQUIPMENT CO. LTD</p>	<p>ZXH-550</p>	<p>Emergency Ventilator</p>	<p>The ventilator is intended to provide continuous ventilatory support for adult patients who require mechanical ventilation. The ventilator is a</p>	<p>May 2, 2020</p>

			restricted medical device intended for use in hospitals and hospital-type facilities, which provide respiratory care for patients requiring respiratory support.	
JIUXIN MEDICAL	JIXI H-100	Emergency Ventilator	The ventilator is intended to provide continuous ventilatory support for adult patients who require mechanical ventilation. The ventilator is a restricted medical device intended for use in hospitals and hospital-type facilities, which provide respiratory care for patients requiring respiratory support.	May 2, 2020
Vayu Global Health Innovations	Vayu bubble Continuous Positive Airway Pressure Circuit (“Vayu bCPAP”)	Continuous Positive Airway Pressure Circuit	The Vayu bCPAP system is intended to provide continuous positive airway pressure in the hospital environment to spontaneously breathing neonates and infants, up to 5 kg in weight, that require respiratory support due to conditions associated with prematurity, such as Respiratory Distress Syndrome, or other conditions where the physician desires and prescribes CPAP.	May 5, 2020
Hunan Beyond Medical Technology Co., Ltd	BEYOND C20A CPAP	Ventilator, Continuous, Minimal Ventilatory Support	The C20A CPAP is designed for delivery of positive airway pressure to provide non-invasive ventilation for adult patients with respiratory insufficiency or obstructive sleep apnea (OSA) in home or hospital environment.	May 6, 2020
Hunan Beyond Medical Technology Co., Ltd	BEYOND B30P BiPAP	Ventilator, Continuous, Minimal Ventilatory Support	The B-30P BiPAP is designed for delivery of positive airway pressure to provide non-invasive ventilation for adult patients with respiratory insufficiency or obstructive sleep apnea (OSA) in home or hospital environment. The device is to be used only under the prescription of a licensed health care professional.	May 6, 2020
Guangzhou Hypnus	Hypnus ST730	Ventilator, Continuous,	The device is indicated to provide non-invasive positive airway	May 6, 2020

Healthcare Co., Ltd.		Minimal Ventilatory Support	pressure to spontaneously breathing patients weighing over 30kg with Obstructive Sleep Apnea (OSA) or respiratory insufficiency. This device is intended for hospital and home use. It is not intended for patients dependent on mechanical ventilation.	
AutoMedX Inc.	SAVe II+ (M50016, M50017)	Powered Emergency Ventilator	The SAVe II series are intended to provide ventilatory support for adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF) or other situations where mechanical ventilation is needed. The SAVe II series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, outpatient environments, hospitals, ICU's, transport environments or any other healthcare environment requiring the use of a ventilator.	May 7, 2020
Taiyuan Shanghai Medical	Fabius Plus / Fabius Plus XL	Gas Machine, Anesthesia	<p>Fabius plus is an inhalation anesthesia workstation for use in operating, induction and recovery rooms. It may be used with O₂, N₂O, and AIR supplied by a medical gas pipeline system or by externally mounted gas cylinders.</p> <p>Fabius plus is equipped with a compact breathing system, providing fresh-gas decoupling, PEEP, and pressure limitation. The following ventilation options are available:</p> <ul style="list-style-type: none"> – Volume Controlled Ventilation – Pressure Controlled Ventilation (Optional) – Pressure Support (Optional) – SIMV/PS (Optional) – Manual Ventilation – Spontaneous Breathing <p>Fabius plus is equipped with an electrically driven and electronically controlled ventilator and monitors for airway pressure (P),</p>	May 8, 2020

			volume (V), and inspiratory oxygen concentration (FiO2).	
Somnetics International, Inc.	Transcend 3 BiPAP	Ventilator, Non-Continuous	The Transcend 3 BiPAP is intended for the therapy of adults weighing over 66 pounds (30 kg) with mild to moderate respiratory distress. The device delivers positive airway pressure (PAP), specifically positive end-expiratory pressure (PEEP) with ventilatory support, to provide ventilation assistance and breathing support. The device is intended for use in healthcare settings.	May 8, 2020
Lanick Med Systems LLC	Lyra x1 and Lyra x2 Ventilators	Ventilator, Continuous, Facility Use	<p>The LYRA x1 ventilator is a mechanical ventilator designed to provide invasive and noninvasive, continuous or intermittent, respiratory support for pediatric and adult patients.</p> <p>Intended areas of use:</p> <ul style="list-style-type: none"> • In the intensive care ward or in the recovery room. • During transfer of-ventilated patients within the hospital. <p>The LYRA x1 ventilator is intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.</p> <p>The LYRA x2 ventilator is a mechanical ventilator designed to provide invasive and noninvasive, continuous or intermittent, respiratory support for pediatric and adult patients.</p> <p>Intended areas of use:</p> <ul style="list-style-type: none"> • In the intensive care ward or in the recovery room • During transfer of ventilated patients within the hospital. <p>The LYRA x2 ventilator is intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.</p>	May 12, 2020

CMI Health	Beijing Aeonmed Shangrila510S	Emergency Transport Ventilator	The Shangrila510S is an emergency transport ventilator intended to be used to provide ventilatory support in the emergency rooms of hospitals, transfer after operations, field and occasions where first aid or transfer is needed for care of adult ,pediatric patients weighting at least 3.5 kg who require mechanical ventilation.	May 15, 2020
SysMed (China) Co., Ltd	VM series- DPAP20 Plus, DPAP25 Plus, DPAP25 Pro, DPAP30 Pro	Ventilator, Continuous, Minimal Ventilatory Support	The device delivers positive pressure therapy for the treatment of Obstructive Sleep Apnea or respiratory insufficiency in spontaneously breathing adults weighing over 30kg (66 lbs). It is for use in the home or hospital/institutional environment.	May 18, 2020
SysMed (China) Co., Ltd	Resware BI 20 S, Resware BI Auto S, Resware BI 25 S/T, Resware BI 30 S/T, ZiZ Auto, Aurora Bi-Level S, Aurora Bi-Level S/T, Aurora Bi-Level Auto S	Ventilator, Continuous, Minimal Ventilatory Support	The Resware, ZiZmer, and Aurora CPAP products provide positive pressure therapy for the treatment of obstructive sleep apnea or respiratory insufficiency in spontaneously breathing adults weighing over 30 kg (66 lbs). This product can be used in the home as well as in clinical/hospital environments.	May 20, 2020
Guangzhou Hypnus Healthcare Co., Ltd	BA825W, BA825, ST830W and ST830	Ventilator, Continuous, Minimal Ventilatory Support	Hypnus Positive Airway Pressure Device 8 Series are indicated to provide non-invasive positive airway pressure to spontaneously breathing patients weighing over 30kg with Obstructive Sleep Apnea (OSA), and BPAP-T mode and BPAP-ST mode can be used for respiratory insufficiency. This device is intended for hospital and home use. It is not intended for patients dependent on mechanical ventilation.	May 22, 2020
Origin Medical Devices Inc.	Panther 5 Model P5DLVENT	Ventilator, Continuous, Facility Use	The PANTHER 5 ventilator is intended to provide continuous ventilation to adult patients requiring respiratory support. The device is intended for facility use under clinical supervision.	May 22, 2020

Ventilator Tubing Connectors

Manufacturer	Product Name	Device Description	Intended Use	Date of Authorization
Prisma Health	Ventilation Expansion Splitter (VESper)	VESper allows multiple patients to be treated by a single ventilator	A single ventilator fitted with the Vent Splitter can be used for multiple patients for ventilatory support during the COVID-19 pandemic when individual ventilators are not available or preemptively to increase the potential of single-use ventilators permitting mechanical ventilation for multiple patients simultaneously	March 25, 2020
Vent Multiplexor LLC	Vent Multiplexor	Dual Patient Circuit Connector	The Vent Multiplexor is intended to provide temporary rescue mechanical ventilation for dual patient ventilation until an additional ventilator is available to resume single mechanical ventilation or as soon as respiratory recovery is attained in either patient.	April 15, 2020
MakeMedical	VentMI	Dual Patient Circuit Connector	A single ventilator fitted with the VentMI Ventilator Splitter can be used for two adult patients with the same pathology for ventilatory support for up to fourteen (14) days during the COVID-19 pandemic when individual ventilators are not available.	April 19, 2020
Northwell Health, Inc.	Northwell 3D Printed BiPAP Adapter	Ventilator Tubing Connector	The Northwell Health 3D Printed BiPAP Adapter (“Adapter”) is intended for use as an exhalation port that enables invasive use of a bilevel positive airway pressure (BiPAP) machine with a pressure control ventilation (PCV) option as a pressure-controlled ventilator.	April 29, 2020
Formlabs Inc.	Formlabs 3D Printed BiPAP Adapter	Ventilator Tubing Connector	The Formlabs 3D Printed BiPAP Adapter (“Adapter”) is intended for use as an exhalation port that enables invasive use of	April 29, 2020

			a BiPAP with a pressure control ventilation (PCV) option as a pressure-controlled ventilator.	
Covidien LLC	DAR Adult Dual Patient Breathing Circuit 301P14429	Dual Patient Circuit Connector	The Adult Dual Breathing Circuit can be used for two patients for ventilatory support during the COVID-19 pandemic when individual ventilators are not available to increase the potential of single-use ventilators permitting mechanical ventilation for two patients simultaneously.	May 5, 2020
Safe Flight Instrument Corporation	Safe Flight 9100-3 Quad Vent	Patient Circuit Connector	The intended use of the Safe Flight 9100-3 Quad/Vent ventilator splitter is to enable a single ventilator to be shared between multiple patients for ventilatory support. Is intended to provide temporary rescue mechanical ventilation for multi-patient ventilation only when single mechanical ventilation is not possible due to shortage.	May 7, 2020
Safe Flight Instrument Corporation	Safe Flight 9100-1 Quad Vent	Patient Circuit Connector	The intended use of the Safe Flight 9100-1 Quad/Vent ventilator splitter is to enable a single ventilator to be shared between multiple patients for ventilatory support. Is intended to provide temporary rescue mechanical ventilation for multi-patient ventilation only when single mechanical ventilation is not possible due to shortage.	May 7, 2020
Stryker Instruments	Flow Control Valve	Patient Circuit Connector	The Flow Control Valve is intended for use on patients suffering from acute respiratory failure. During the COVID-19 pandemic, when the number of patients requiring	May 8, 2020

			<p>ventilation exceeds the number of ventilators, the Flow Control Valve enables a single ventilator to be used to provide ventilator support to two patients. The Flow Control Valve is used to regulate the flow once the breathing circuit has already been split by a T-piece. This device is only intended to be used in the setting of an acute shortage of ventilators, as a lifesaving measure to provide acute ventilatory support in times of scarcity when other standard single ventilators are not available. The Flow Control Valve is only suitable for use with ventilators that have separate inspiratory and expiratory ports, such as Critical Care Ventilators and Anesthesia machines.</p>	
Valhalla Medical Supply, LLC	Single-Use Emergency Ventilator 2-Way Manifold	Dual Patient Circuit Connector	<p>The Single-Use Emergency Ventilator 2-Way Manifold (vent splitter) is intended to allow a single ventilator to be used simultaneously to provide ventilatory support of two adult patients with similar lung compliances and respiratory needs during the COVID-19 pandemic when individual ventilators are not available.</p>	5/13/2020
Bloom Energy	Ventilator Sharing and Monitoring System	Patient Circuit Connector	<p>The Ventilator Sharing and Monitoring System allows a single critical care ventilator to be used for up to four adult patients for</p>	May 29, 2020

			ventilator support during the COVID-19 pandemic when individual ventilators are not available.	
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Ventilator Accessories

Manufacturer	Product Name	Device Description	Intended Use	Date of Authorization
SMD Manufacturing, LLC	ReddyPort Mini NIV Access Elbow	Elbow Connector for Mask	The ReddyPort Mini NIV Access Elbow is intended to provide an interface for application of CPAP or bi-level therapy. The elbow is for single patient use in the hospital/institutional environment. The elbow is to be used on patients 7 years or older (>40lbs/18.2kg) for whom CPAP or bi-level therapy has been prescribed	April 13, 2020
3B Medical, Inc.	3B Hi-Flow H80	Respiratory Humidifier	H-80 series humidifier is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This device is for patients by prescription in the home or hospital/institutional environment. The device is only allowed to be used after the physician provides guidance for the patient and targeted setting of the device; the physician should ensure that the patient understands all functions and methods of operation of the device.	April 14, 2020
Janisys	Janisys CPAP Flow Generator	Positive End Expiratory Pressure Breathing Attachment	The Janisys CPAP Flow Generator, when used in conjunction with a PEEP valve, is used to provide CPAP to a spontaneously breathing adult in hospital settings. The DD-3 variable-flow model is intended to provide 28%-100% FIO2 and the DD-4	April 28, 2020

			fixed-flow model is intended to provide 28%-33% FIO2.	
Vincent Medical Manufacturing Co., Ltd.	O2FLO High Flow Respiratory Humidifier (VUN-001)	Respiratory Humidifier	The O2FLO High Flow Heated Respiratory Humidifier (VUN-001) is intended to deliver warmed and humidified respiratory gases to spontaneously breathing patients with a flow rate from 2LPM to 60LPM and is capable of providing high flow therapy. The device can be used in the emergency room, outpatient department, inpatient department and other diagnostic and treatment rooms.	May 20, 2020