K113743

Section C: 510(k) Summary

[As required by 21 CFR 807.92]

DEC 18 2012

eVolution 3e Ventilator

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter: eVent Medical, Ltd.
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Date Prepared: June 10, 2010

Device Trade Name: eVolution 3e Ventilator

Common Name: Continuous Ventilator

Device Class: Class II
per 21 CFR 868.5895

Product Code: 73 CBK

Predicate Device: The predicate devices are:

Table 1 - Predicate Devices

Manufacturer/Product	510(k)	Classification
eVent Medical Inspiration™ Ventilator System	K072590	Class II Continuous Ventilator per 21 CFR 868.5895

Device Description:

The eVolution 3e Ventilator utilizes dual valve technology and three hot wire flow sensors for precise breath delivery and lower work of breathing. The eVolution 3e is an electrically powered microprocessor-controlled software-driven ventilator with an electrically controlled exhalation valve. The eVolution 3e is available in two configurations; one version of The eVolution 3e utilizes an integrated high performance internal gas source (blower) and the second version of the eVolution 3e utilizes outside compressed air source and does not utilize a blower.

Intended Use:

The eVolution 3e ventilator is intended for and designed to provide continuous and or intermittent mechanical ventilation to patients requiring ventilatory support through invasive or non-invasive interfaces and is suitable for use in the ICU, sub acute, long-term acute care, rehabilitation, and emergency room venues.

This product is intended for a wide range of patients from pediatric to adult having body weights in the range of 5 kg (11 lb) or more who require pressure-based or volume-based continuous respiratory support, as prescribed by an attending physician.

The eVolution 3e ventilator system is a class IIb medical device to be used by trained and qualified healthcare professionals in hospitals or healthcare facilities and intended for sale by or on the order of a physician only.

Summary of Performance Data and Substantial Equivalence:

The eVolution 3e Ventilator has the same intended use as that for the eVent Inspiration Series Ventilators identified as cleared predicate device. The technical characteristics of the eVolution 3e Ventilator do not introduce new questions regarding safety or effectiveness associated with critical care ventilators.

The following table provides a comparison to the predicate device:

Comparison Parameter	**Inspiration Ventilator System K072590**	**eVolution Ventilator System**
Description	The Inspiration® ventilator is a fifth generation, electrically powered, microprocessor and servo controlled, software-driven ventilator. It has a dynamic range of breathing gas delivery that provides for infant through adult patients. It utilizes a flat panel color LCD with real time graphic displays and digital monitoring capabilities, a touch screen for easy interaction, membrane keys and a dial for changing	The eVolution® 3e ventilator is a fifth generation, electrically powered, microprocessor and servo controlled, software-driven ventilator. It has a dynamic range of breathing gas delivery that provides for pediatric through adult patients. It utilizes a flat panel color LCD with real time graphic displays and digital monitoring capabilities, a touch screen for easy interaction, membrane keys

Comparison Parameter	Inspiration Ventilator System K072590	eVolution Ventilator System
	settings and operating parameters, a gas delivery engine with servo-controlled active inhalation and exhalation valves as well as an integrated internal compressor. The Inspiration Ventilator System is intended to provide continuous ventilation for patients requiring respiratory support.	and a dial for changing settings and operating parameters, a gas delivery engine with servo-controlled active inhalation and exhalation valves, three hot wire flow sensors for precise breath delivery and lower work of breathing. The eVolution 3e Ventilator System is intended to provide continuous ventilation for patients requiring respiratory support.
Indications for Use	The Inspiration Ventilator is indicated for use with a wide range of patients from infant through adult, requiring respiratory support for a wide range of clinical conditions in hospital, hospital-type facilities and intra-hospital transport.	The eVolution 3e ventilator is intended for and designed to provide continuous and or intermittent mechanical ventilation to patients requiring ventilatory support through invasive or non-invasive interfaces and is suitable for use in the ICU, sub acute, long-term acute care, rehabilitation, and emergency room venues. This product is intended for a wide range of patients from pediatric to adult having body weights in the range of 5 kg (11 lb) or more who require pressure-based or volume-based continuous respiratory support, as prescribed by an attending physician. The eVolution 3e ventilator system is a class IIb medical device to be used by trained and qualified healthcare professionals in hospitals or healthcare facilities and intended for sale by or on the

Comparison Parameter	Inspiration Ventilator System K072590	eVolution Ventilator System
		order of a physician only.
Patient Types	Adult, Pediatric, Infant	Adult, Pediatric
Acuity Level	High/Level 3; Mid/Level 2; Low/Level 1	High/Level 3; Mid/Level 2; Low/Level 1
Ventilation Modes		
Volume Controlled	VC-CMV; VC-SIMV	VC-CMV; VC-SIMV
Mixed Modes	PRVC-CMV; PRVC-SIMV; VS	PRVC-CMV; PRVC-SIMV; VS
Pressure-Controlled	PC-CMV; PV-SIMV	PC-CMV; PV-SIMV
Spontaneous	PS; VC; SPAP; NCPAP+	PS; VC; SPAP
Apnea backup	V-CMV; V-SIMV; P-CMV; P-SIMV; PRVC-CMV; PRVC-SIMV; SPAP; OFF	V-CMV; V-SIMV; P-CMV; P-SIMV; PRVC-CMV; PRVC-SIMV; SPAP; OFF
Ventilation Application		
Non Invasive (NIV)	All ventilation modes; Leakage Comp; Alarm Setting Adaptable	All ventilation modes; Leakage Comp; Alarm Setting Adaptable
Leakage Compensation	Auto Leak Compensation; Automatic Flow Trigger Adjust to Leak; Expiratory Criteria Adaptation; Leak Monitoring	Auto Leak Compensation; Automatic Flow Trigger Adjust to Leak; Expiratory Criteria Adaptation; Leak Monitoring
BTPS Compensation	Selection Humidifier; Selection HME	Selection Humidifier; Selection HME
Automatic Weaning System	Auto Control; Algorithm Based System; Control (CMV) Modes Only	Auto Control; Algorithm Based System; Control (CMV) Modes Only
Settings/Controls		
Patient Options	New Patient; Previous Patient	New Patient; Previous Patient
Ideal Body Weight Calculator	Patient Height; Gender; IBW	Patient Height; Gender; Frame Size IBW
Humidification Selection	Humidifier; HME; None	Humidifier; HME; None
Gas Type	Air; Heliox	Air
Patient Info	Patient ID; Room/Bed ID	Not Available

Comparison Parameter	Inspiration Ventilator System K072590	eVolution Ventilator System
O2 (FiO2)	21 – 100%	21 – 100%
Rate (Respiratory Rate)	1 to 150 b/min	1 - 120 b/min
Vt (Inspiratory Tidal Volume)	5 to 2000 ml	50 - 2000 ml
Ti (Inspiratory Time)	0.1 to 10 sec	0.2 - 5.0 sec
Flow (Inspiratory Peak Flow)	1 to 120 l/min (mandatory)	5 to 120 l/min (mandatory)
PEEP	0 to 50 cmH2O	0 to 40 cmH2O
Pcontrol (Inspiratory Pressure)	2 to 80 cmH2O	2 to 80 cmH2O
Psupport (Pressure Support)	0 to 80 cmH2O	0 to 60 cmH2O
Trigger Type	Flow Trigger; Pressure Trigger	Flow Trigger; Pressure Trigger
Ftrig	0.2 – 25.0 l/min	0.5 – 20.0 l/min
Ptrig (Pressure trigger setting level)	0.5 – 20.0 cmH2O	0.5 – 20.0 cmH2O
Esens (exhalation sensitivity)	10 to 80% of peak flow	10 to 80% of peak flow
Rise Time (pressure slope / ramp)	1, 5, 10	1, 5, 10
Flow Pattern	Decelerating; Decelerating 50%; Square; NIV; Pause	Decelerating; Decelerating 50%; Square; NIV; Pause
Auto Control	Auto; Auto Time; Leak Comp; Base Flow	Auto; Auto Time; Leak Comp; Base Flow
SPAP Settings	Cycle; Phigh; Plow; Thigh; Tlow; Psup high; Psup low	Cycle; Phigh; Plow; Thigh; Tlow; Psup high; Psup low
SPAP Type	Time Only; Cycle + Time; Cycle + Ratio; H:L	Time Only; Cycle + Time; Cycle + Ratio; H:L
Functions/Special Features	100% Oxygen Delivery; +20% Infant Oxygen Delivery; Manual Breath; Alarm Silence; Alarm Pause; Standby mode; Prox. Flow Sensor On/Off; Oxygen Sensor On/Off; Audio Level Control; Screen Clicks On / Off; Screen Brightness Control	100% Oxygen Delivery; Manual Breath; Alarm Silence; Alarm Pause; Standby mode; Low Flow O2 Inlet Pressure On/Off; Oxygen Sensor On/Off; Audio Level Control; Screen Clicks On / Off; Screen Brightness Control
Maneuvers	Insp. Hold; Exp. Hold	Insp. Hold; Exp. Hold
Nebulizer (Smart Nebulizer)	Nebulizer On / Off; Nebulizer Time; Interval On / Off; Interval Time	Nebulizer On / Off; Nebulizer Time; Interval On / Off; Interval Time
Sigh (Smart Sigh)	Sigh On / Off; Sigh %; Sigh	Sigh On / Off; Sigh %; Sigh

Comparison Parameter	Inspiration Ventilator System K072590	eVolution Ventilator System
	Frequency; Sigh Multiples	Frequency; Sigh Multiples
Monitored Parameters		
Pressure (monitors)	Ppeak (peak inspiratory pressure); Pmean (mean airway pressure); PEEP; Pplateau (Plateau pressure); Auto PEEP	Ppeak (peak inspiratory pressure); Pmean (mean airway pressure); PEEP; Pplateau (Plateau pressure); Auto PEEP
Volume (monitors)	Vti (Insp. tidal volume) Vte (exp. tidal volume) Ve (exp. minute volume) Ve Spont (exp. minute volume spontaneous) Vi (insp. minute volume) Vi Spont (insp. minute volume spontaneous) Vti/kg Vte/kg Ve/kg Leak PF (peak flow) PFe (exp. peak flow)	Vti (Insp. tidal volume) Vte (exp. tidal volume) Ve (exp. minute volume) Ve Spont (exp. minute volume spontaneous) Vi (insp. minute volume) Vi Spont (insp. minute volume spontaneous) Leak PF (peak flow) PFe (exp. peak flow)
Breathing Frequency (monitors)	Rate (breath rate total) Rate Spont. (breath rate spontaneous) Insp. Time Exp. Time I:E Ratio H:L Ratio Spont %1 hr Spont %8 hr	Rate (breath rate total) Rate Spont. (breath rate spontaneous) Insp. Time Exp. Time I:E Ratio H:L Ratio Spont %1 hr Spont %8 hr
Gas Concentration (monitors)	O2 (FiO2) HeO2 (Heliox %)	O2 (FiO2)
Respiratory Mechanics (monitors)	Rinsp (insp. resistance) Rexp (exp.p resistance) Cstat (static compliance) Cdyn (dynamic compliance) Cstat/kg Cdyn/kg RSBI (rate / VT ratio) C20/C (Cdyn20% / Cdyn ratio)	Rinsp (insp. resistance) Rexp (exp.p resistance) Cstat (static compliance) RSBI (rate / VT ratio)

Comparison Parameter	Inspiration Ventilator System K072590	eVolution Ventilator System
Other calculated values	Ti/Ttot (Ti / by total cycle time)	Ti/Ttot (Ti / by total cycle time)
Trended Parameters		
Pressure (trends)	Ppeak (peak inspiratory pressure) Pmean (mean airway pressure) PEEP Pplateau (Plateau pressure) Auto PEEP	Ppeak (peak inspiratory pressure) Pmean (mean airway pressure) PEEP Pplateau (Plateau pressure)
Volume (trends)	Vti (Insp. tidal volume) Vte (exp. tidal volume) Ve (exp. minute volume) Ve Spont (exp. minute volume spontaneous) Vi (insp. minute volume) Vi Spont (insp. minute volume spontaneous) Vti/kg Vte/kg Ve/kg Leak PF (peak flow) PFe (exp. peak flow)	Vti (Insp. tidal volume) Vte (exp. tidal volume) Ve (exp. minute volume) Ve Spont (exp. minute volume spontaneous) Vi (insp. minute volume) Vi Spont (insp. minute volume spontaneous) Leak PF (peak flow) PFe (exp. peak flow)
Breathing Frequency (trends)	Rate (breath rate total) Rate Spont (breath rate spontaneous) Insp. Time Exp. Time	Rate (breath rate total) Rate Spont (breath rate spontaneous) Insp. Time Exp. Time
Gas Concentration (trends)	O2 (FiO2) HeO2 (Heliox %)	O2 (FiO2)
Respiratory Mechanics (trends)	Rinsp (insp. resistance) Rexp (exp. resistance) Cstat (static compliance) Cdyn (dynamic compliance) Cstat/kg Cdyn/kg RSBI (rate / VT ratio)	Rinsp (insp. resistance) Rexp (exp. resistance) Cstat (static compliance) RSBI (rate / VT ratio)
Other calculated values (trends)	Ti/Ttot (insp time / by total cycle time)	Ti/Ttot (insp time / by total cycle time)
Alarm Settings / Controls		

Comparison Parameter	Inspiration Ventilator System K072590	eVolution Ventilator System
Alarm Settings	High Minute Volume (Ve high) Low Minute Volume (Ve low) High Tidal Volume (Vte high) Low Tidal Volume (Vte low) Vti Limit High (Insp. Tidal volume alarm) High Respiratory Rate (Rate high) Low Respiratory Rate (Rate low) High Peak Pressure (Ppeak high) Low Peak Pressure (Ppeak low) High Mean Airway Pressure (Pmean high) Low Mean Airway Pressure (Pmean low) High leak rate (High leak) Apnea Time AUTO SET (Auto adjusts all alarms)	High Minute Volume (Ve high) Low Minute Volume (Ve low) High Tidal Volume (Vte high) Low Tidal Volume (Vte low) Vti Limit High (Insp. Tidal volume alarm) High Respiratory Rate (Rate high) Low Respiratory Rate (Rate low) High Peak Pressure (Ppeak high) Low Peak Pressure (Ppeak low) High PEEP Pressure (PEEP high) Low PEEP Pressure (PEEP low) High leak rate (High leak) Apnea Time AUTO SET (Auto adjusts all alarms)
Oxygen (FiO2) Alarms	High Oxygen (automatic 7% above set FiO2) Low Oxygen (automatic 7% below set FiO2)	High Oxygen (automatic 7% above set FiO2) Low Oxygen (automatic 7% below set FiO2)
Equipment Alarms	Gas Supply Failure Power Failure Ventilator Inoperative Low Internal Battery Low External Battery Self Diagnostics	Gas Supply Failure Power Failure Ventilator Inoperative Low Internal Battery Low External Battery Self Diagnostics
Gas Supply Management	High Pressure Air Inlet Internal Compressed Gas Source High Pressure Oxygen Inlet	High Pressure Air Inlet (HP Model Only) Blower (Blower Model Only) Source High Pressure Oxygen Inlet Oxygen via low pressure inlet
Human Interface		
Graphic Settings	1, 2, 3 , 4 graphs displayed	1, 2, 3 , 4 graphs displayed

Comparison Parameter	Inspiration Ventilator System K072590	eVolution Ventilator System
	Pressure Flow Volume Flow / Volume Pressure / Volume Dynamic Auto Scaling Manual Scaling Freeze / Unfreeze X / Y Axes cursor scroll	Pressure Flow Volume Flow / Volume Pressure / Volume Dynamic Auto Scaling Manual Scaling Freeze / Unfreeze X / Y Axes cursor scroll
Connectivity	Nurse call Ethernet RS232 Remote monitoring Other Outputs: SNMP	Nurse call Ethernet RS232
Power Management		
Type	Alternating Current (AC)	Alternating Current (AC)
Voltage range	100 - 240 VAC	100 - 240 VAC
Frequency	50 - 60 Hz	47 - 63 Hz
Battery Type	Lead Acid	Lithium Ion
Battery time	> 120 min	> 120 min
Battery capacity	Amp/hours	Amp/hours
Stand By	> 360 min	> 360 min
Physical / Environmental		
Operating temperature	10 to 40 ° C	5 – 40 °C
Operating humidity	10% - 80%	15% - 95%
Storage temperature	-10 ° C to 60 ° C	-10 ° C to 60 ° C
Storage humidity	5% - 95%	5% - 95%
Operating Altitude	Up to 11,600 ft (3,536 m) above sea level	Up to 9,999 ft (3,048m) above sea level

The design and development process at eVent Medical, Ltd. requires adherence to internal procedures written to comply with the Design Control requirements of the Quality System Regulations defined in 21 CFR 820.30.

FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, dated May 29, 1998, was used to define the software design and development activities required for the software developed for the eVolution 3e based on the determined Level of Concern.

The eVolution Ventilator System has been tested and shown to be compliant with the following standards documents:

1. IEC 60601-1: 1995, Medical Electrical Equipment, Part 1: General Requirements for Safety

2. IEC 60601-1-2:2004, Medical Electrical Equipment – Part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility-Requirements and tests
3. IEC 60601-2-12:2001, Medical Electrical Equipment. Particular requirements for the safety of lung ventilators. Critical care ventilators.
4. EPA Method TO-15, Determination of Volatile Organic Compounds (VOCs) In Air Collected in Specially Prepared Canisters and Analyzed by Gas Chromatography/Mass Spectrometry (GC/MS)
5. ASTM F1100-90 Standard Specification for Ventilators Intended for Use in Critical Care.

Performance was conducted using ASTM F1100-90 Standard Specification for Ventilators Intended for Use in Critical Care to demonstrate the durability that the predicate ventilator met and to which compliance has been routinely accepted as requisite to any substantial equivalence claim.

Conclusion:

eVent Medical Ltd. hereby presents data as part of the 510(k) process to support the eVolution 3e Ventilator safety and effectiveness for its stated intended use and presents data claiming substantial equivalence to the identified predicates currently marketed and previously cleared by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2012

Mr. Rick Waters
Vice President, Regulatory Affairs and Quality Assurance
eVent Medical, Limited
971 Calle Amanecer, Suite 101
SAN CLEMENTE CA 92673

Re: K113743
Trade/Device Name: eVolution 3e Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 5, 2012
Received: December 14, 2012

Dear Mr. Waters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section B: Indications for Use Statement

510(k) Number: K113743

Device Name: eVolution 3e Ventilator

Indications for Use:

The eVolution 3e ventilator is intended for and designed to provide continuous and or intermittent mechanical ventilation to patients requiring ventilatory support through invasive or non-invasive interfaces and is suitable for use in the ICU, sub acute, long-term acute care, rehabilitation, and emergency room venues.

This product is intended for a wide range of patients from pediatric to adult having body weights in the range of 5 kg (11 lb) or more who require pressure-based or volume-based continuous respiratory support, as prescribed by an attending physician.

The eVolution 3e ventilator system is a class IIb medical device to be used by trained and qualified healthcare professionals in hospitals or healthcare facilities and intended for sale by or on the order of a physician only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal

Albert E. Moyal
2012.12.17
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113743