

Section E: 510(k) Summary

[As required by 21 CFR 807.92]

Inspiration 5i/7i Ventilator System

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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OCT 29 2013

Registration Number: 3003638180

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Date Prepared: January 18, 2013

Device Trade Name: Inspiration 5i/7i Ventilator System

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
Hamilton G-5 Ventilator	K103803	Class II Continuous Ventilator per 21 CFR 868.5895

Device Description:

The Inspiration™ 7i / 5i Ventilator System provides continuous ventilation to patients requiring respiratory support by means of pressure-based and volume-based mandatory and spontaneous breaths. The device is identical to the cleared device, the Inspiration™ Ventilator System (K072950), with the following additions:

- a GUI change to deliver a GUI similar to that of the eVolution ventilator.
- Additional monitored and trended parameters.
- Additional waveforms and loops.
- Additional medium and high priority alarms.
- Additional patient setup and default setting criteria.
- Integration of SNMP fields for settings, monitored and trended data.
- Integration of Volumetric and Sidestream Capnography capability (7i model only)
 - The capnography addition will require specific adaptors and sensors to allow use of this feature.
- Integration of various maneuvers

Intended Use:

The Inspiration® 7i / 5i Ventilator System is intended for use with patients having body weights in the range of 0.3kg to 200kg and Tidal Volumes of 5ml to 2000ml. The Inspiration® Ventilator System is to be used by healthcare professionals in hospitals or healthcare facilities.

This product is intended for a wide range of patients from infant to adult and for a wide variety of clinical conditions.

The intended patient population includes infant through adult patients who require pressure-based or volume-based continuous respiratory support with tidal volumes as low as 5 ml and inspiratory pressures as low as 1 cm H₂O.

The device is intended for use in hospitals and hospital-type facilities, which provide respiratory care for patients requiring respiratory support.

The device is not to be used in the presence of flammable anesthetics.

The device is intended for sale by or on the order of a physician only. The device is intended for operation by trained and qualified personnel.

Summary of Performance Data and Substantial Equivalence:

The Inspiration 5i/7i ventilator has the same intended use as that for the eVent Inspiration Series Ventilators identified as cleared predicate device. The technical characteristics of the Inspiration 5i/7i 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	Predicate: Inspiration Ventilator System K072590	Inspiration 5i/7i Ventilator System
Description	<p>The Inspiration LS ventilator is an 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 colour LCD with real time graphic displays and digital monitoring capabilities, a touch screen for easy interaction, membrane keys and a dial for changing settings and operating parameters, a gas delivery engine with servo-controlled active inhalation and exhalation valves. The Inspiration Ventilator System is intended to provide continuous ventilation for patients requiring respiratory support.</p>	<p>The Inspiration 7i / 5i 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 neonatal through adult patients. It utilizes a flat panel colour LCD with real time graphic displays and digital monitoring capabilities, a touch screen for easy interaction, membrane keys and a dial for changing settings and operating parameters, a gas delivery engine with servo-controlled active inhalation and exhalation valves. The Inspiration Ventilator System is intended to provide continuous ventilation for patients requiring respiratory support.</p>
Indications for Use	<p>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.</p>	<p>The Inspiration® 7i / 5i Ventilator System is intended for use with patients having body weights in the range of 0.3kg to 200kg and Tidal Volumes of 5ml to 2000ml. The Inspiration® Ventilator System is to be used by healthcare professionals in hospitals or healthcare facilities. This product is intended for a wide range of patients from infant to adult and for a wide variety of clinical conditions. The intended patient population includes infant through adult patients who require pressure-based or volume-based continuous respiratory support with tidal volumes as low as 5 ml and inspiratory pressures as low as 1 cm H2O. The device is intended for use in</p>

Comparison Parameter	Predicate: Inspiration Ventilator System K072590	Inspiration 5i/7i Ventilator System
		hospitals and hospital-type facilities, which provide respiratory care for patients requiring respiratory support. The device is not to be used in the presence of flammable anesthetics. The device is intended for sale by or on the order of a physician only. The device is intended for operation by trained and qualified personnel.
Patient Types	Adult, Pediatric, Infant	Adult, Pediatric, Infant
Ventilation Modes		
Volume Modes	V-CMV, V-SIMV	V-CMV, V-SIMV
Pressure Modes	P-CMV, P-SIMV, SPAP, SPONT(CPAP + PS), NCPAP, NCPAP+, NIV	P-CMV, P-SIMV, SPAP, SPONT(CPAP + PS), NCPAP, NCPAP+, NIV
VTV Modes	PRVC-CMV, PRVC-SIMV, VS	PRVC-CMV, PRVC-SIMV, VS
Apnea backup	Volume, Pressure	Volume, Pressure
Settings/Controls		
Primary Settings	Patient Type, Rate, Tidal Volume, Inspiratory Pressure, Peak Flow, Inspiratory Pause, Inspiratory Time, PSV, PEEP, Flow Trigger, Pressure Trigger, Pressure High, Pressure Low, Time High, Time Low	Patient Type, Rate, Tidal Volume, Inspiratory Pressure, Peak Flow, Inspiratory Pause, Inspiratory Time, PSV, PEEP, Flow Trigger, Pressure Trigger, Pressure High, Pressure Low, Time High, Time Low
Advanced Settings	Bias Flow, PS Tmax, Exp Sens%, Rise Time, Advance Flow Control	Bias Flow, PS Tmax, Exp Sens%, Rise Time, Advance Flow Control
Monitoring	Inspiratory Tidal Volume, Expiratory Tidal Volume, Spontaneous Tidal Volume, Mandatory Tidal Volume, Vti/Kg, Vte/Kg, Rate, Rate Spont, Minute Ventilation (Ve), Spontaneous Minute Volume (Ve Spont), Ve/Kg, I:E, H:L, Ppeak, Ptrach, Pmean, Pplateau, PEEP, Auto PEEP, Pmin, Inspiratory Peak Flow (PF), Expiratory Peak Flow (PFe), Ti/Ttotal, Inspiratory Time, Expiratory Time, Static Compliance (Cstat), Cstat/kg, Dynamic Compliance (Cdyn), Cdyn/kg, Inspiratory Resistance	Inspiratory Tidal Volume, Expiratory Tidal Volume, Spontaneous Tidal Volume, Mandatory Tidal Volume, Rate, Rate Spont, Minute Ventilation (Ve), Spontaneous Minute Volume (Ve Spont), I:E, H:L, Ppeak, Pmean, Pplateau, PEEP, Auto PEEP, Inspiratory Peak Flow (PF), Expiratory Peak Flow (PFe), Ti/Ttotal, Inspiratory Time, Dynamic Compliance (Cdyn), Cdyn/kg, Inspiratory Resistance (Rinsp), Expiratory Resistance (Rexp), Leak, RSBI, O2, HeO2, Event History

Comparison Parameter	Predicate: Inspiration Ventilator System K072590	Inspiration 5i/7i Ventilator System
	(Rinsp), Expiratory Resistance (Rexp), Leak, RSBI, O2, HeO2, Event History, PO.1, PiMax, PO.1/PiMax, C20/C, WOBimp,	
Monitoring: Capnography	PetCO2, PeCO2, VCO2/min, VtiCO2, VteCO2, FetCO2, FeCO2, Vd ana, Vd alv, Vd/Vt/phy, Valv, Valv/min	Predicate: Hamilton G-5 Ventilator (K103803): PetCO2, PeCO2, VCO2/min, VtiCO2, VteCO2, FetCO2, FeCO2, Vd ana, Vd alv, Valv, Valv/min
Power/Physical/Environmental		
Type	Alternating Current (AC)	Alternating Current (AC)
Voltage Range	100 to 240 V	100 to 240 V
Frequency	50 – 60 Hz	50 – 60 Hz
Battery Type	Lead Acid (Optional battery pack = Lithium Ion)	Lead Acid (Optional battery pack = Lithium Ion)
Battery Time	1 Hour (1 hour per optional hot swappable battery) Hold 4-8 batteries	1 Hour (1 hour per optional hot swappable battery) Hold 4-8 batteries
Battery Capacity	Amp/hours	Amp/hours
Weight	53 lbs (24kg) without Cart 98 lbs (44.5kg) with Transport Cart	53 lbs (24kg) without Cart 98 lbs (44.5kg) with Transport Cart
Operating Temperature	10 to 40 ° C	10 to 40 ° C
Operating Humidity	10 to 80%	10 to 80%
Storage Temperature	-10 to 60 ° C	-10 to 60 ° C
Storage Humidity	5 to 95%	5 to 95%

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 Inspiration 5i/7i based on the determined Level of Concern.

The Inspiration 5i/7i 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. 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 Inspiration 5i/7i ventilator 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

October 29, 2013

eVent Medical, Limited
Mr. Rick Waters
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Re: K130178
Trade/Device Name: Inspiration 5i/7i Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 25, 2013
Received: September 27, 2013

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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

 Teleshri Purohit Sheth, M.D.
Clinical Deputy Director
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FOR

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Enclosure

