JUL 12 2005

K051550

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	eVent Medical Ltd..
DATE:	June 10, 2005
COMMON NAME:	Continuous Ventilator
PROPRIETARY NAME:	Inspiration™ Ventilator System
CONTACT:	Robbie Walsh, VP Regulatory Affairs and Quality Assurance eVent Medical Ltd. 6A Lisoban Business Park Tuam Road Galway, Ireland. Tel: + 353 91 764472 Fax: + 353 91 764379
CLASSIFICATION:	Class II per 21 CFR 868.5895 Continuous Ventilator

PREDICATE DEVICES:

eVent Medical Ltd.. is claiming substantial equivalence to the following two predicate medical devices:

Predicate Device	510(k) Number	Classification
eVent Medical Ltd.. Inspiration™ Ventilator	K030341	Class II, Continuous Ventilator per 21 CFR 868.5895
Siemens – Elma AB. Servo*i* Ventilator	K010925	Class II, Continuous Ventilator per 21 CFR 868.5895

A Device Description:

The Inspiration™ 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, with the addition of the capability to

set tidal volumes in volume targeted modes down to 5 ml, while 10 ml is the lower limit on the cleared device.

This modification is implemented on the Inspiration™ Ventilator through additional functionality in software only. The existing modalities, pneumatic design, breath delivery control algorithms, electrical circuitry and user interface mechanism have remained unchanged from the cleared Inspiration™ ventilator device.

B Intended Use:

The device intended use is the same as that of the cleared device, the Inspiration™ Ventilator system and is re-stated below.

Purpose and Function of the Device:

The Inspiration™ Ventilator System is intended to provide continuous ventilation for patients requiring respiratory support. This product is intended for a wide range of patients from infant to adult and for a wide variety of clinical conditions.

Intended Patient Population:

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 H_2O.

Intended Environment of Use:

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

The device may be used for intra-hospital transport within a hospital or hospital-type facility. The device is not intended for transport between hospitals or hospital-type facilities.

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

Indication for Use:

The Inspiration™ Ventilator System with Smart Positive Airway Pressure (SPAP) and Volume Targeted Ventilation (VTV) options 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.

C Substantial Equivalence

The intended use of the Inspiration™ Ventilator is the same as that for standard, currently marketed critical care ventilators. The materials and design of this device are similar to those of the predicate devices. The technical characteristics of the Inspiration™ Ventilator System do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the Inspiration™ Ventilator System provides similar information as the predicate devices.

Information provided in the 510(k) submission supports the determination of substantial equivalence. Software design and development, (including verification and validation testing, test and software quality procedures) was conducted using FDA's Guidance for the Content of Premarket Submissions for Software contained in medical devices, dated May 11 2005, as a guidance and per internal company requirements. The Inspiration™ Ventilator device design and testing are also compliant with various voluntary, international standards including: EN60601-1:1990, EN 60601-1-2:1993, CAN/CSA C22.2 No. 601-1M90:1994, UL 2601-1:1994, EN 794-1 and 93/42/EEC Medical Device Directive.

The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

In summary eVent Medical Ltd. has demonstrated the Inspiration™ Ventilator System to be safe and effective. This device is considered to be substantially equivalent to currently marketed devices which have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Mr. Robbie Walsh,
VP Regulatory Affairs and Quality Assurance
eVent Medical Limited
6A Lisoban Business Park
Tuam Road
Galway, Ireland

Re: K051550
Trade/Device Name: Inspiration™ Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: June 10, 2005
Received: June 14, 2005

Dear Mr. Walsh:

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.

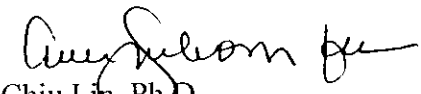
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Inspiration™ Ventilator

Indications for Use: The Inspiration™ Ventilator System with Smart Positive Airway Pressure (SPAP) and Volume Targeted Ventilation (VTV) options 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.

Prescription Use __X___ AND/OR Over-The-Counter-Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051550