K040220 JUN - 9 2004

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	eVent Medical Ltd..
DATE:	January 29, 2004
COMMON NAME:	Medical Air Compressor
PROPRIETARY NAME:	Independence™ Medical Air Compressor
CONTACT:	Robbie Walsh, VP Quality Assurance & Regulatory Affairs 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 868.6250 Portable Air Compressor.

PREDICATE DEVICES:

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

Predicate Device	510(k) Number	Classification
Drager Inc. Medical Air Compressor, Model 98	K982789	Class II, Portable Air Compressor per 21 CFR 868.6250

A Device Description:

The Independence™ Medical Air Compressor is a Class II device, "Portable Air Compressor", per 21 CFR Part 868.6250. This device is designated a Class I, Type B equipment per IEC 60601-1.

The Independence™ Medical Air Compressor is an air compressor for use in intensive care units or the recovery rooms of clinics, hospitals and hospital-type facilities which delivers filtered, oil-free and dehumidified compressed air to ventilators. Using the integrated backup function, the Independence™ Medical Air Compressor can be connected between an existing air supply network and a ventilator. If the compressed air from the air supply network fails, the Independence™ Medical Air Compressor automatically starts and supplies compressed air to the ventilator.

B Intended Use:

The Independence™ Medical Air Compressor is intended to provide compressed air to ventilators.

The device is intended for use in hospitals and 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

C Substantial Equivalence:

The intended use of the Independence™ Medical Air Compressor is the same as that for standard, currently marketed medical air compressors. The materials and design of this device are similar to those of the predicate device (Drager Inc. Medical Air Compressor, Model 98, K982789). The technical characteristics of the Independence™ Medical Air Compressor do not introduce new questions regarding safety or effectiveness. Furthermore, the labeling associated with the Independence™ Medical Air Compressor provides similar information as the predicate device.

Information provided in the 510(k) submission supports the determination of substantial equivalence. Performance testing was conducted per internal, company requirements while environmental and electromagnetic compatibility testing has been successfully completed in accordance with the requirements of the FDA's draft Reviewer Guidance for PreMarket Notification Submissions document (Nov '93). The Independence™ Compressor device is also compliant with various

voluntary and international standards including: IEC 60601-1:1990, IEC 60601-1-2:1993 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 Independence™ Medical Air Compressor 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

JUN - 9 2004

Mr. Robbie Walsh
Vice President, Regulatory Affairs & Quality Assurance
Event Medical, Ltd.
6A Liosban Business Park,
Tuam Road,
Galway, Ireland

Re: K040220
Trade/Device Name: Independence Medical Air Compressor
Regulation Number: 21 CFR 868.6250
Regulation Name: Compressor, Air, Portable
Regulatory Class: II
Product Code: BTI
Dated: May 14, 2004
Received: May 17, 2004

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.

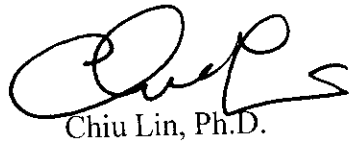
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.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: K040220

Device Name: Independence™ Medical Air Compressor

Indications for Use: The Independence™ Medical Air Compressor is indicated for use as a Medical Air Compressor providing compressed air to ventilators.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use _____ (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: K040220