1.1 510 (K) SUMMARY: LINDE GAS THERAPEUTICS HELONTIX VENT K072926

Preparer/Contact	Ann-Cathrin Jareman Director Regulatory Affairs AGA AB Linde Gas Therapeutics SE-181 81 Lidingö Sweden Tel: +468 731 1031 Mobile: +4670 250 0874 Email: ann.cathrin.jareman@linde-gas.com
Manufacturer	Linde Gas GmbH Wolfholzgasse 28 2345 Brunn am Gerbirge AUSTRIA

Date summary was prepared:	October 1, 2007
Name(s) of the device:	Helontix Vent
Identification of predicate device(s):	Puritan Bennett 840 Ventilator System K970460 GE Datex-Ohmeda Aptaér Heliox Delivery system, K041524 Maquet Critical Care AB, Servo-i Ventilator system NIV option, K041223

1.2 ESTABLISHMENT REGISTRATION NUMBER

Will be applied for with submission and review of this 510(k)

1.3 ADDRESS OF MANUFACTURING SITE:

Manufacturing Location:	Linde Gas GmbH Wolfholzgasse 28 2345 Brunn am Gerbirge AUSTRIA

1.4 OFFICIAL CORRESPONDENT

Ann-Cathrin Jareman
Director Regulatory Affairs

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1.5 CLASSIFICATION

21 CFR 868.5895
Regulation Name: 868.5895 Continuous ventilator
Regulatory Class: Class II
Product Code: CBK

1.6 CLASSIFICATION NAME

Ventilator, continuous, facility use

1.7 COMMON OR USUAL NAMES

Continuous Ventilator

1.8 PROPRIETARY NAME

Linde Therapeutics Helontix Vent

1.9 INTENDED USE

The Helontix Vent is designed to deliver helium/oxygen mixtures to spontaneously breathing patients via a facemask with or without pressure support. The system is designed for facility use and should only be used under the orders of a clinician.

The Helontix Vent delivery system is not intended as a life support device and is not intended for intubated patients.

1.10 PREDICATE DEVICES

Puritan Bennet 840 Ventilator System K970460

GE Datex-Ohmeda Aptaér Heliox Delivery system, K041524

Maquet Critical Care Servo-I Ventilator system NIV option, K041223

1.11 DESCRIPTION OF THE DEVICE:

The Helontix vent is a stand alone assembly to deliver heliox or oxygen. To accomplish this, the Helontix vent consists of a device with a built in battery and a trolley with mounted oxygen and Heliox gas cylinders. When connected to O2 and Heliox (79%He, 21%O2) the Helontix vent delivers a mixture of oxygen and helium in the required fraction to the patient who can breathe over a mask that is connected to the device via a hose system. The Helontix vent interacts with the user via a user interface, i.e. a display, diodes, speaker, several keys and a control wheel. The device informs the user on the screen about set values, monitored values, alarms, ventilation modes and the navigation through the menus while the user can choose the ventilation mode, set values, silence alarms and navigate through menus by using keys and control wheel. The Helontix vent is device designed for Non-invasive Positive Pressure Ventilations (NPPV) for spontaneous breathing patients. The inspiration flow can be either triggered by the patient with a surplus support of pressure (pressure support mode, PSM, 3-30mbar@peak flow 160SLPM) or alternatively a constant flow from 5-60 SLPM without a pressure support (constant flow mode, CFM) can be selected. The breathing circuit, mask and filter used are purchased previously cleared devices.

1.12 5 10(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Proprietary Name: Linde Gas Therapeutics Helontix Vent

Common name: Ventilator, Continuous

Classification: Anesthesiology, 73 CBK, 21 CFR 868.5895

The 5 10(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Linde Gas Therapeutics Helontix Vent is substantially equivalent to the following currently marketed device:

GE Datex-Ohmeda Aptaér Heliox Delivery System **K041524**

The GE Datex-Ohmeda Aptaér Heliox delivery system is designed to deliver heliox from a source gas cylinder to spontaneously breathing patients via a sealed facemask using pressure support. A built in nebulizer, the Aerogen Aoroneb Pro (K021175) is provided for adding nebulized medication to the delivered heliox. The system is designed for facility use and should only be used under the orders of a clinician.

The Aptaér Heliox Delivery system is not intended as a life support device and is not intended for intubated patients.

Puritan-Bennett 840 ventilator system **K970460**

The 840 ventilator system is used to provide continuous ventilation to patient's requiring respiratory support. This device is used for a wide range of patients from infants to adult and for a wide variety of clinical conditions.

Maquet Critical Care Servo-i Ventilator system NIV option **K041223**

The Servo-i Ventilator System is intended for treatment and monitoring of patients in the range of neonates, infants and adults with respiratory failure or respiratory insufficiency.
Servo-i is a ventilator system with advanced functionality. It may be used only by professional health care providers who have sufficient experience in ventilator treatment.

The Helontix Vent is not intended as a life support device and is not intended for intubated patients. The intended use is:

> The Helontix Vent is designed to deliver helium/oxygen mixtures to spontaneously breathing patients via a facemask with or without pressure support. The system is designed for facility use and should only be used under the orders of a clinician.
>
> The Helontix Vent delivery system is not intended as a life support device and is not intended for intubated patients.

The Helontix Vent was designed to comply with the applicable portions of the following voluntary standards;

Standard	**year**	
UL 60601-1	2003	Medical electrical equipment - General requirements for safety
EN/IEC 60601-1:	1996	Medical electrical equipment - General requirements for safety
EN/IEC 60601-1-2:	2002	Electromagnetic compatibility- requirements and tests
EN/IEC 60601-1-4:	2001	Safety requirements for programmable systems
EN 60601-2-12/ ASTM F100	2001	Particular requirements for the safety of lung ventilators – Critical care ventilators
EN 60601-1-8	2006	Electrical Alarm signals
EN 980:	2003	Graphical symbols
EN ISO 21647:	2004	Medical electrical equipment -Respiratory gas monitors
EN 739:/ ISO 5359	2002	Low-pressure hose assemblies for use with medical gases
EN 14971:	2003	Medical devices – Application of risk management to medical devices
EN 60601-1-6:	2005	Usability
ISO 5356-1	2004	Conical connectors
Draft Reviewer Guidance for Ventilators	1995	Draft reviewer guidance for ventilators

For software control, the Helontix Vent is a major concern device even though it is not life supporting because of outcomes that could potentially occur prior to mitigation. The submissions contains full software information regarding the Level of Concern Analysis, Risk Analysis, Software Development, Software Requirements and Design, Verification and Validation testing, and Traceability. EMC, Electrical, Environmental and full performance

testing is also provided in support of the submission. Positive results from extensive testing demonstrate that the Linde Helontix Vent is substantially equivalent to the predicate devices.

The Linde Helontix Vent and the currently marketed device are substantially equivalent in design concepts, technologies and materials. The Linde Helontix Vent has been validated through rigorous testing that, in part, supports the compliance of Helontix Delivery System to the standards listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

Ms. Ann-Cathrin Jareman
Head of Global Regulatory Affairs
Linde Gas Therapeutics
AGA AB
SE-181 81 Lindingö
SWEDEN

Re: K072926
Trade/Device Name: Linde Therapeutics Helontix Vent
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: October 3, 2008
Received: October 8, 2008

Dear Ms. Jareman:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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 Statement

510(k) Number (if known): K072926

Device Name: Linde Therapeutics Helontix Vent

Indications for Use:

The Helontix Vent is designed to deliver helium/oxygen mixtures to spontaneously breathing patients via a facemask with or without pressure support. The system is designed for facility use and should only be used under the orders of a clinician.

The Helontix Vent delivery system is not intended as a life support device and is not intended for intubated patients.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K 072926

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

510(k) Number: _____