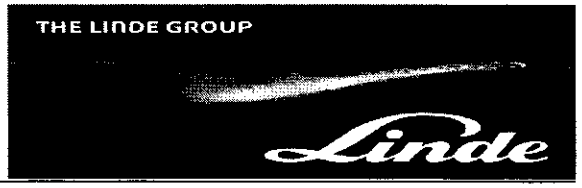
K101792



Traditional 510(k) Notification

MAR 18 2011

Section 6 - 510(k) Summary

Contact Persons for this submission:

MICHAEL C. PIACENZA

Medical and FDA Compliance Manager
Linde North America, Inc.
575 Mountain Avenue, Murray Hill, NJ 07974, USA
Office: 908-508-2729
Fax: 908-771-1203
Mobile: 908-720-0200

Date prepared: June 25, 2010

Trade Names
LIV (Linde Integrated Valve)

1. LIV Portable Oxygen System - with a 2000 psi service pressure rating
2. LIV Portable Oxygen System - with a 3000 psi service pressure rating

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Portable Oxygen Delivery System	unclassified		

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
LIV	K063354
Medicyl-E-lite	K033897

Device Description:

The Linde Integrated Valve® ("LIV") is a portable oxygen delivery system, consisting of a fully integrated cylinder, valve, regulator, flow meter, and shock-absorbing guard. A range of user-selectable flow settings is available, including low flows that may be clinically appropriate for certain classes of patients. An additional DISS-1240 connection provides standard 50 psig oxygen delivery, while an optional bed hanger allows the LIV to be readily attached to a bed. The LIV is suitable for use in all healthcare settings including, but not limited to, hospital, outpatient, imaging center, ambulatory, and home healthcare.

Intended Use of the Device:

The LIV is an integrated portable oxygen delivery system intended to provide supplemental oxygen to pediatrics and adults.. The device is MR-conditional (per ASTM standard 2503-05), and intended for use during MR imaging for MRI systems up to 3.0T. Rx only. Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling

Comparison to Predicate Devices:

A summary comparison of technological characteristics, including design and materials is provided in the table below:

Parameter	Medicyl-E-lite (K033897)	LIV (Linde Integrated Valve)
Flow selector and flow outlet	yes	yes
Fixed pressure outlet	no	yes
Cylinder On/Off	yes	yes (with optional open close indication)
Contents Gauge	non-active	Active
Excess Flow Device	No	No
MR Compatibility	yes; tested up to 3.0T	yes; tested up to 3.0T
Cylinder Sizes	D,E	D,E
Cylinder materials construction	Aluminium	Aluminium
Guard colour	green	green
Guard hand grip	2 grips	2 grips

Based on the Medicyl-E-lite - K033897, the new LIV valves have been revised to comply with ISO 10524-3 (valid standard for Medical Valve Integrated Pressure Regulator - ratified April 2006). The modified devices also have the same intended use and indications for use as the aforementioned predicate device. Linde believes that the technological characteristics of the LIV (Linde Integrated Valve) is substantially similar to those of the predicate device.

Non-Clinical Performance Summary:

In terms of operating and safety specification the device conforms to applicable standards including

1. ISO 10524-3:2005 Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves
2. ISO 15996:2005 Gas cylinders -- Residual pressure valves -- General requirements and type testing
3. BS EN 1789:2007 Medical vehicles and their equipment. Road ambulances
4. ISO 9227:2006 Corrosion tests in artificial atmospheres -- Salt spray tests
5. DOT 49 CFR 178.46. Specification SAL seamless aluminum cylinder (Aluminium cylinders)
6. CE marking; Council Directive 93/42/EEC of 14.June 1993, concerning medical devices.
7. ISO 11117:2008 Gas cylinders-valve protection caps and valve guards for industrial and medical gas cylinder- Design, construction and tests

Conclusion:

Based upon the safety and performance testing and compliance with voluntary standards, the manufacturer believes that the LIV (Linde Integrated Valve) is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Michael Piacenza
Medical and FDA Compliance Manager
Linde Gas North America LLC
575 Mountain Avenue
Murray Hill, New Jersey 07974

MAR 18 2011

Re: K101792
Trade/Device Name: Linde Integrated Valve - LIV
Regulatory Class: II
Product Code: ECX
Dated: February 4, 2011
Received: February 7, 2011

Dear Mr. Piacenza:

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,

for

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

Enclosure

Section 5 - Indications for Use Statement

510(k) Number: k101792

Device Name: Linde Integrated Valve - LIV

Indications for Use:

The LIV is an integrated portable oxygen delivery system intended to provide supplemental oxygen to pediatrics and adults.. The device is MR-conditional (per ASTM standard 2503-05), and intended for use during MR imaging for MRI systems up to 3.0T. Rx only. Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling.

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: k101792