510(k) Summary

LIV (Linde Integrated Valve)

APR 17 2007

510(k) Number: K063354

Submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1.0 APPLICANT'S INFORMATION

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2.0 SUBMITTER'S INFORMATION

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3.0 DATE

October 31, 2006

4.0 DEVICE INFORMATION

Trade/Proprietary Name:	LIV (Linde Integrated Valve)
Common Name:	LIV (Linde Integrated Valve)
DEVICE NAME:	Cylinder, Compressed Gas, and Valve
Classification Panel:	Cardiovascular and Respiratory Devices
Classification Number:	868.2700
Product Nomenclature:	Regulator, Pressure, Gas Cylinder
Product Code(s):	CAN

Classification Number:	868.2610
Product Nomenclature:	Gauge, Gas Pressure, Cylinder/Pipeline
Product Code(s):	BXH
Classification Number:	unclassified
Product Nomenclature:	Cylinder, Compressed Gas, and Valve
Product Code(s):	ECX
Classification Number:	unclassified
Product Nomenclature:	Cylinder, Gas (Empty)
Product Code(s):	KGA

5.0 DEVICE CLASSIFICATION

Empty compressed gas cylinders and compressed gas cylinder with valve assemblies are unclassified devices, and reviewed by the Anesthesiology and Respiratory Devices Branch, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.

Gas cylinder pressure regulators and gas pressure gauges are Class I devices and exempted from pre-market notification.

6.0 PREDICATE DEVICE(s)

K033897 MEDICYL-E-Lite Portable Oxygen System

7.0 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 50psig 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.

8.0 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. For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx only. Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling.

9.0 TECHNOLOGICAL CHARACTERISTICS

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

Parameter	LIV (Linde Integrated Valve)	MEDICYL-E-Lite K033897
Valve/Regulator		
Flowrate Selector and Flow Outlet	yes	yes
Pressure Outlet	yes	no
Cylinder On/Off	yes	yes
Filling Port	active; w/ non-return valve	active; w/ non-return valve
Contents Gauge	active	non-active
Excess Flow Device	yes	yes
Residual Pressure Valve	yes	yes
Burst Disk	yes	yes
Single stage piston style	yes	yes
Guard		
Hand grip	2 grip	2 grip
Access Ports	yes	yes
Color	green	green
Cylinder		
Sizes	D, E	D, E
Materials/construction	Aluminum	Aluminum
MRI Compatibility	yes; tested up to 3.0T	yes; tested up to 3.0T

The manufacturer believes that the technological characteristics of theLIV (Linde Integrated Valve) is substantially similar to those of the predicate device.

10.0 PERFORMANCE DATA

The aluminum cylinders conform to the requirements of 21CFR49 § 178.46, Specification SAL seamless aluminum cylinders.

The LIV (Linde Integrated Valve) has been evaluated in accordance with the draft CDRH Magnetic Resonance Working Group document, A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems, dated February 7, 1997.

11.0 STATEMENT OF SUBSTANTIAL EQUIVALENCE

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
9200 Corporate Boulevard
Rockville MD 20850

Linde Gas Therapeutics
C/O Mr. James J. Rogers
General Manager
Coastal Consulting Group, Limited
P.O. Box 470218
Broadview Heights, Ohio 44147

APR 17 2007

Re: K063354
Trade/Device Name: LIV (Linde Integrated Valve)
Regulation Number: None
Regulation Name: Cylinder, Compressed Gas and Valve
Regulatory Class: Unclassified
Product Code: ECX
Dated: March 19, 2007
Received: March 20, 2007

Dear Mr. Rogers:

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 (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

510(k) Number (if known): _____

Device Name: LIV (Linde Integrated Valve

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Prescription Use ___X___ AND Over-the-Counter Use ___X___
(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)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

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