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AGA Linde Healthcare

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510(k) Summary
MEDICYL-E-Lite Portable Oxygen System
510(k) Number: K033897

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

1. APPLICANT'S INFORMATION:
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   PH: (216) 328-9801
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   Medical Establishment
   Registration No.: pending

2. SUBMITTER'S INFORMATION
   James Jochen Rogers
   General Manager
   Coastal Consulting Group, Ltd.
   P.O. Box 391117
   Solon, OH 44139
   PH/FX: 440.546.4936
   Mobile: 724.713.2298
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   Internet: http://www.immersive-reality.biz

3. Date: December 15, 2003

4. DEVICE INFORMATION
   Trade/Proprietary Name: MEDICYL-E-Lite Portable Oxygen delivery system
   Common Name: MEDICYL-E-Lite Portable Oxygen delivery system

   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

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Corporate Office (216) 642-6600
Customer Service (877) AGA-Medi [242-6334]
Fax (216) 901-5781

5. 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. PREDICATE DEVICE(s):
   - MEDICYL-E-Lite Portable Oxygen System
   - Praxair Grab n' Go Portable Medical Oxygen System

7. DEVICE DESCRIPTION:
The MEDICYL-E-Lite is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults. The device is MRI safe, MRI-compatible, 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.

The integrated system includes an aluminum cylinder, valve, regulator and flow meter. The device offers low flow settings that may be clinically appropriate for certain classes of patients.

8. INDICATIONS FOR USE:
The MEDICYL-E-Lite is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults. The device is MRI safe, MRI-compatible, 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. TECHNOLOGICAL CHARACTERISTICS:
A summary comparison of technological characteristics, including design and materials is provided in the table below:

Parameter	MEDICYL-E-Lite (MRI)	MEDICYL -E-Lite	Praxair Grab n' Go
Valve/Regulator			
Low Flow Settings	yes	yes	no
Flow Between Settings	no	no	no
Cylinder On/Off	yes	yes	no
Filling Port	active	active	active
Contents Gauge	non-active	non-active	active
Filters	3	3	1
Pressure Design	4350psi	4350psi	3000psi
Excess Flow Device	yes	yes	no

Parameter	MEDICYL-E-Lite (MRI)	MEDICYL -E-Lite	Praxair Grab n' Go
Single stage piston style	yes	yes	
Guard			
Hand grip	2 grip	2 grip	1 grip
Access Ports	yes	yes	no
Flow selector/hose barb/gauge aligned	yes	yes	no
Color	green	green	green
Height	6.75"	6.75"	8"
Cylinder			
Sizes	D, E	D, E	E
Weight (E)	900gr	900gr	1060gr
Materials/construction	Aluminum	Aluminum	Steel
MRI Compatibility			
MRI Safe	yes; tested up to 3.0T	no	no
MRI Compatible	yes; tested up to 3.0T	no	no

The manufacturer believes that the technological characteristics of the MEDICYL-E-Lite portable oxygen system is substantially similar to those of the predicate devices.

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

The MEDICYL-E-Lite portable oxygen delivery system 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. STATEMENT OF SUBSTANTIAL EQUIVALENCE:
Based upon the safety and performance testing and compliance with voluntary standards, the manufacturer believes that the MEDICYL-E-Lite portable oxygen delivery system is substantially equivalent to the predicate devices, 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

JUL 19 2004

AGA-Linde Healthcare, Incorporated
C/O Mr. James Jochen Rogers
General Manager
Coastal Consulting Group, Limited
P.O. Box 391117
Solon, Ohio 44139

Re: K033897
Trade/Device Name: Medicyl-E-Lite Portable Oxygen Delivery System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: ECX
Dated: May 15, 2004
Received: May 19, 2004

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 (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 (if known): K033897

Device Name: Medicyl-E-Lite Portable Oxygen Delivery System

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7/16/2004

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

510(k) Number: K033897

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND

Over-the-Counter Use X
(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)