APR - 7 2009

510(K) Summary

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Device Information

Product Name: Portable Oxygen Unit SCA900

Common Name: Portable Oxygen Delivery System

Classification Name: Cylinder, Compressed Gas, and Valve

Product Code: CAN, KGA, ECX

Regulation Number: 868.2700

Device Class: Class I

General Description

The Portable Oxygen Unit SCA900 is a portable oxygen delivery system, consisting of a fully integrated cylinder, valve, regulator, nasal cannula and mask. The oxygen is delivered through the mask or nasal cannula with a range of user-selectable flow settings. This unit is suitable for use in all healthcare settings, including hospital and home healthcare.

Indication for Use

The Portable Oxygen Unit SCA900 is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults; a pressure regulator, flow meter and oxygen cylinder fully integrated into single unit. 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.

Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- Cyl-Fil Oxygen System (K061785) manufactured by Responsive Respiratory Inc.
- EZ-OX Plus (K053117) manufactured by Air Liquide Healthcare America.
- LIV (Linde Integrated Valve) (K063354) manufactured by Linde Gas Therapeutics.

Comparison to Predicate Devices

Testing and other comparisons have established that the subject of Portable Oxygen Unit SCA900 is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

San Cheong Company, Limited
C/o Mr. Jung Bae Bang
Kodent, Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

APR - 7 2009

Re: K080243
Trade/Device Name: Portable Oxygen Unit SCA900
Regulation Number: 21 CFR 868.2700
Regulation Name: Pressure Regulator
Regulatory Class: I
Product Code: CAN, ECX, KGA
Dated: April 3, 2009
Received: April 3, 2009

Dear Mr. Bang:

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,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K080243

Device Name: Portable Oxygen Unit SCA900

Indication for Use:

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Prescription Use ____X____ AND/OR Over-The-Counter ____X____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 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
nfection Control, Dental Devices

510(k) Number: K080243