5 510(k) Summary

K062153

Non-Confidential Summary of Safety and Effectiveness

25-Jul-06

NOV 2 1 2006

Molecular Products Ltd.
Mill End
Thaxted, Essex CM6 2LT UK

Tel – 011-44-1371-830676
Fax – 011-44-1371-830998

Official Contact: Mandy Crudace, PhD, Technical Manager

Proprietary or Trade Name: POG

Common/Usual Name: Portable oxygen generator

Classification Name: Portable oxygen generator

Device: POG

Predicate Devices: OxySure Systems – OxySure – K052396

Device Description:

The Molecular Products' POG is a chemical based portable oxygen generator which generates 99% oxygen for 15 minutes at a flow rate of 6 lpm. It is a self-contained device with the oxygen delivered via a standard oxygen face mask or nasal cannula.

Indications for Use:

Indicated Use -- Intended to produce oxygen for emergency use.

Patient Population -- Any individual

Environment of Use -- Any environment

Contraindications -- None

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Device Attributes:

Over-the-counter (OTC)	Yes
Design	
Dry chemical based technology	Yes
Portable	Yes
Testing	
Test flow rate	6 Lpm
Duration	At least 15 minutes
% Oxygen	99%
External canister temperature	< 45°C

Differences Between Other Legally Marketed Predicate Devices

The POG is viewed as substantially equivalent to the following predicate device – OxySure – K052396.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Molecular Products Limited
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court, #102
Bonita Springs, Florida 34134

NOV 2 1 2006

Re: K062153
Trade/Device Name: POG Portable Oxygen Generator
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: October 11, 2006
Received: October 12, 2006

Dear Mr. Dryden:

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.

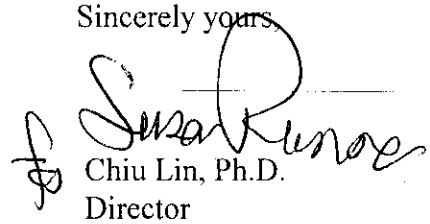
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for 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

4 Indications for Use Statement

510(k) Number: K062153 (To be assigned)

Device Name: POG

Indications for Use: The Portable Oxygen Generator (POG) is intended to produce oxygen for emergency use at 6 lpm for at least 15 minutes.

Prescription Use __ **or** **Over-the-counter use XX**
(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)

(Sign-Off)
...ion of Anesthesiology, General Hospital,
...on Control, Dental Devices
...Number: K062153