NOV 19 1998

K982243

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Submitted By:

Canogen International, Ltd.
P.O. Box 766
Syosset, New York 11791
Tel: (516) 228-6600
Fax: (516) 228-6664

Contact Person: Steven R. Broder at address above

B. Device Trade Name: Canogen Portable Oxygen Generator, Model 615
Common Name: Portable Oxygen Generator
Classification Name: Portable Oxygen Generator

C. Predicate Device: Jet Research Center, Model 415 Oxygen Canister and Dispenser Model 3445-c, 510(k) #K780020

D. Device Description:

The Canogen Portable Oxygen Generator, Model 615 provides an average of 6.5 liters a minute for a minimum of 15 minutes, through a chemical reaction. The Canogen Portable Oxygen Generator, Model 615 consists of three parts. The first part is a reaction vessel in which the chemical reaction takes place. The reaction vessel may be reused. The second part is the cartridge containing the chemicals required to generate the oxygen produced by this device. The third part of the generator consists of the plastic tubing and gas mask which are attached to the outlet of the generator.

E. Indications for Use:

The Canogen Portable Oxygen Generator, Model 615 is intended to produce oxygen for emergency use.

F. Technological Comparison:

The Canogen Portable Oxygen Generator, Model 615 and the Model 415 Oxygen Canister are designed to generate oxygen. Both devices are provided in

kit form with the necessary containers, chemicals and accessories to provide oxygen for emergency use (with the exception of tap water for the Portable Oxygen Generator). As with the Jet Research Model 415, the chemicals used in the Canogen Portable Oxygen Generator are packaged in cartridges which are inserted into the reaction vessel to contain the reaction and port the gas to the face mask tubing.

II. Testing

Bench test runs were conducted while using flow gauges, temperature sensors, data logger and pressure gauges to monitor performance characteristics during each run. The cartridge was inserted into the reaction vessel. The gas generated by the reaction was ported through plastic tubing to the flow sensor and manual flow gauges. For each test run the data acquisition system was used to log the flow rate, and temperatures.

The Canogen Portable Oxygen Generator, Model 615 was determined to produce humidified oxygen at a purity of greater than 99% for a minimum of fifteen (15) minutes at an average flow rate of six and a half (6.5) liters per minute.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1998

Ms. Melissa Mahall
Canogen International Ltd.
c/o Bio-Reg Associates, Inc.
14900 Sweitzer Lane, Suite 200
Laurel, MD 20707

Re: K982243
Canogen Portable Oxygen Generator, Model 615
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: October 7, 1998
Received: October 13, 1998

Dear Ms. Mahall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

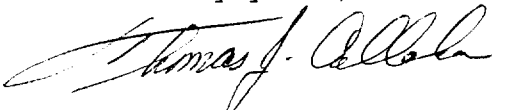
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set

forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Canogen Portable Oxygen Generator, Model 615

Sponsor Name: Canogen International Ltd.

Indications for Use

The Canogen Portable Oxygen Generator, Model 615 is intended to produce oxygen for emergency use.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982243

Prescription Use ☐
Over-The-Counter Use ☑