APR 2 5 2003

Attachment #15

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K030233.

1. Submitter's Identification:

Sim Italia S.r.l.
Via Gramsci, 9
40018 S. Pietro in Casale (B0)
Italy

Date Summary Prepared:

January 21, 2003

2. Name of the Device:

TravelSome Standard Portable Oxygen Concentrator

3. Predicate Device Information:

1. Innosan Travelair® "S" Portable Oxygen Concentrator, Model NO. M 407001853 (with AC Power Supply Accessory), K#971947, Sim Italia S.r.l., Italy.

2. Innosan Travelair® "S" Portable Oxygen Concentrator, K#963042, Sim Italia s.r,l., Italy.

4. Device Description:

The TraveSome® Standard Portable Oxygen Concentrator is a mobile oxygen concentrator intended for use in an automobile, with power from the automobile's battery and, for use off standard house current through the unit's incorporated power supply. The TravelSome uses two molecular sieves to extract oxygen from ambient air, which is similar to most 510(k) cleared oxygen concentrators. The unit provides two switch-selectable operating modes, continuous and demand, with a nonadjustable flow of approximately 1.2 L/min continuous and approximately 3.0 L/min in the demand mode. The unit has a detachable trolley with two wheels and a telescoping handle to provide maneuverability. It has a

hinged cover across the top panel to protect against the entry of fluids, and a soft plastic textile cover which further protects the unit against the entry of fluids, and a soft plastic textile cover which further protects the unit against blows and splashes. An alarm warns of low oxygen concentration, lack of current, excessive internal temperature and blocked air inlet filter. The incorporated AC power supply, called the "Switching Power Supply for TravelSome Standard Portable Oxygen Concentrator", is manufactured by an OEM vendor and incorporated into the TravelSome Standard unit by Sim Italia S.r.l., the manufacturer of the TravelSome Standard unit. The power has UL and TUV certification. The code number for the power supply is PM 200. The input power requirements are 110/220 VAC, 50/60 Hz.

5. **Intended Use:**

The TravelSome Standard Portable Oxygen Concentrator is a mobile oxygen concentrator for use in an automobile, with power from the automobile's battery or for use from house current through the unit's incorporated power supply (110 VAC, 60 Hz or 220 VAC, 50 Hz) when the patient is away from their primary home oxygen source, intended to provide a patient with supplemental oxygen. This device delivers oxygen to patients by physical means, using a molecular sieve bed oxygen concentrator and is designed to conserve the use of oxygen during such delivery.

Indications For Use:

The TravelSome Standard Portable Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders for use in the home, or during travel by car.

6. **Comparison to Predicate Devices:**

In comparison to our previous 510(k) cleared devices, the modifications are as follows:

1) Internal power supply.
2) Sieve bed material.
3) Alarm
4) Electronic pressure sensor
5) "Demand" flow of 3 lpm.
6) Trolley and handle.
7) Cover

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

There are no substantial changes to the unit other than those indicated in the enclosed information.

Test bench testing is the same as that used on the current predicate device.

8. **Discussion of Clinical Tests Performed:**

There are no substantial changes to the technical specifications and current function of the unit. Therefore no clinical tests were deemed necessary.

9. **Conclusions:**

The unit is substantially the same as the predicate device, with only an increased flow due to unit modifications as herein described, to the benefit of the user; power loss alarm, and increased portability/safety with the new trolley and insulated cover.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2003

Sim Italia s.r.l.
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K030233
Trade/Device Name: TravelSome Standard Portable Oxygen Concentrator
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: March 31, 2003
Received: April 2, 2003

Dear Ms. Goldstein-Falk:

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment #14

510(k) Number (if known): K030233

Device Name TravelSome Standard Portable Oxygen Concentrator

Indications For Use:

The TravelSome Standard Portable Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders for use in the home, or during travel by car.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use only /

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

510(k) Number: K030233