

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identification:

Ms. Susan Muratori
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Surgical International Marketing
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Date Summary Prepared: May 23, 1997

2. Name of the Device:

Innosan Travelair® "S" Plus Portable Oxygen Concentrator

3. Predicate Device Information:

Innosan Travelair® "S" Portable Oxygen Concentrator, Code No. M407001853, K#963042.

4. Device Description:

The Innosan Travelair® "S" Plus Portable Oxygen Concentrator is a mobile oxygen concentrator intended for use in an automobile, with power from the automobile's battery and, for use with an AC power supply accessory. The Travelair® uses two molecular sieves to extract oxygen from ambient air; this is similar to most domestic 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 2.6 L/min in the demand mode. The unit has two large wheels, one small caster, and an adjustable handle to provide maneuverability. It has a hinged cover across the top panel to protect against the entry of fluids. An alarm warns of low oxygen concentration, excessive internal temperature and blocked

air inlet filter.

AC Power Supply Accessory Description:

The Innosan Travelair® "S" Plus Portable Oxygen Concentrator AC Power Supply Accessory, called the "Switching Power Supply for Travelair® "S" Plus Portable Oxygen Concentrator", is manufactured by an OEM vendor and packaged by Sim Italia s.r.l. specifically for the Travelair® Portable Oxygen Concentrator. The power supply has UL and TÜV certification. The code number for the power supply is 032228000. The AC power supply is housed in a plastic enclosure with approximate maximum dimensions of 10.5" x 6.25" x 4.73" high. The input power is supplied via a three-wire power cord connected to an input IEC-type receptacle. The output panel includes an ON-OFF switch and 6.5' input power cable that terminates in a connector intended for the Innosan Travelair® "S" Plus Portable Oxygen Concentrator. The input power requirements are 110/240 VAC, 50/60 Hz.

5. Intended Use:

The Innosan Travelair® "S" Plus Portable Oxygen Concentrator is a mobile oxygen concentrator for use in an automobile, with power from the automobile's battery or for use with a power supply accessory (off of a mains current - 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.

6. Comparison to Predicate Devices:

The Innosan Travelair® "S" Plus Portable Oxygen Concentrator, Code No. M407001853, is identical to our original 510(k) cleared device, K#963042, except for the addition of an AC power supply accessory.

The only difference between the Travelair® "S" device and the Travelair® "S" Plus device is that, in addition to the use of an automobile battery, it can now be line-powered with a standard power supply functioning off of a mains current (110 VAC 60 Hz/220 VAC/50 Hz).

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

Testing information demonstrating safety and effectiveness of the Innosan Travelair® "S" Plus Portable Oxygen Concentrator with an AC Power Supply Accessory in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted by CITECH:

- a. Input Voltage Variation
- b. Overcurrent Protection
- c. Controls Protection
- d. Connector Protective Incompatibility
- e. Mechanical Safety
- f. Mechanical Vibration and Shock Resistance (IEC-601-1 (1988))
- g. Fluid Spill Resistance (IEC-601-1, Clause 44.6)
- h. Extreme Operating and Storage Temperature/Humidity
- i. Surface Temperatures

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was CITECH's conclusion that the Travelair® sample tested met all relevant requirements of the aforementioned test.

In addition, the following testing was conducted by CITECH:

- a. Radiated and Conducted Electromagnetic Energy and Magnetic Field Testing on the Travelair® device. Testing was conducted per the DCRND Reviewer's Guideline, November 1993.
- b. Testing was also conducted per ASTM F1464-93, "Standard Specification for Oxygen Concentrators for Domiciliary Use".

Regarding the AC Power Supply:

The AC Power Supply Accessory for the Innosan Travelair® "S" Plus Portable Oxygen Concentrator was tested for compliance to electrical safety and environmental criteria when connected to a Travelair® Portable Oxygen

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Concentrator to simulate active operating conditions in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND. The following testing was conducted by CITECH:

- a. Overcurrent protection
- b. Electrical leakage current
- c. Mechanical shock resistance
- d. Extreme storage and operating environments
- e. Sinusoidal vibration
- f. Surface temperatures
- g. Spill resistance.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was CITECH's conclusions that the AC Power Supply sample tested met all relevant requirements of the aforementioned test.

In addition, the following testing was conducted by CITECH:

- a. Radiated and Conducted Electromagnetic Energy and Magnetic Field Testing on the AC Power Supply. Testing was conducted per the DCRND Reviewer's Guideline, November 1993.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

We have demonstrated that the Innosan Travelair® "S" Plus Portable Oxygen Concentrator with an AC Power Supply Accessory is identical to the predicate device presently on the market, with the addition of an AC Power Supply, based on electrical, mechanical and environmental results as well as ASTM F1464-93, "Standard Specification For Domiciliary Use". We also adhered to FDA's Reviewer Guidance for Oxygen Concentrators (1991).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

Ms. Susan D. Goldstein-Falk
SIM Italia s.r.l.
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 410
Great Neck, New York 11021

Re: K971947
Innosan Travelair "S" Plus
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: September 11, 1997
Received: September 15, 1997

Dear Ms. Goldstein-Falk:

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 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. 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 (Pre-market 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market 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 our 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/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

Enclosure

510(k) Number (if known): K971947

Device Name: Innosan Travelair(R) "S" Plus Portable Oxygen Concentrator,
Code No. M407001853 (with AC Power Supply Accessory)

Indications For Use:

The Innosan Travelair® "S" Plus Portable Oxygen Concentrator is a mobile oxygen concentrator for use in an automobile, with power from the automobile's battery or for use with a power supply accessory (off of a mains current - 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Pugh
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)