italia s.r.l.
SURGICAL INTERNATIONAL MARKETING

K963042

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EXHIBIT #2
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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: K963042

1. **Submitter's Identification:**

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Date Summary Prepared: July 25, 1996

2. **Name of the Device:**

Innosan Travelair® "S" Portable Oxygen Concentrator

3. **Predicate Device Information:**

a) OxLife Traveler L3, K#933081; K#955549
b) Chad Therapeutics Oxymatic™ Electronic Oxygen Conserver, K#952650

4. **Device Description:**

The Travelair® is a mobile oxygen concentrator intended for use in an automobile, with power from the automobile's battery. 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, blocked air inlet filter, and loss of power.

® TRADE MARK

5. **Intended Use:**

The Innosan Travelair® "S" Portable Oxygen Concentrator is a mobile oxygen concentrator for use in an automobile, with power from the automobile's battery, 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 Travelair® does not employ rechargeable batteries; only an automobile battery. It is not line-powered. The Travelair® is an oxygen concentrator which is mechanically similar to the predicate devices, with the addition of the demand valve which allows oxygen to flow only when the patient breathes. This conserving feature is similar to the CHAD Oxymatic device

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" Portable Oxygen Concentrator 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".

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

We have demonstrated that the Innosan Travelair® "S" Portable Oxygen Concentrator is as safe and effective as predicate devices presently on the market, 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).