OCT 1 3 2004

EXHIBIT #1

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: **K042655**.

1. **Submitter's Identification:**

Respironics New Jersey, Inc.
41 Canfield Road
Cedar Grove, NJ 07009

Contact: Ms. Lauren R. Ziegler, Senior Manager, Technical Services
Phone: 973-571-2608; Fax: 973-857-9521

Date Summary Prepared: September 8, 2004

2. **Name of the Device:**
Inspiration Elite Nebulizer Compressor, with Nebulizer, Model HS456
Common Name or Classification Name (21 CFR Part 807.87) of Device:
Nebulizer Compressor, 21 CFR Part 868.6250, Portable Air Compressor

3. **Predicate Device Information:**

InvaCare Envoy Jr., K# 992643

4. **Device Description:**

This line-powered piston compressor is housed in a plastic cabinet (case). Dimensions are 7.5" (L) x 7.49" (W) x 4.18" (H) and weighs 3.3 lbs. It consists of a motor-driven piston compressor and a switch; it contains no microprocessors or other electronic components. It operates from 115 VAC, 60 Hz. It is supplied with tubing, an instruction manual, and a Sidestream (510(k) cleared) nebulizer. The Inspiration Elite, Model HS456 is not be used without the nebulizer.

In use, the compressor is placed on a flat surface and the nebulizer tubing is connected to the hose barb. The unit is then turned on. Inlet air to the compressor passes through a replaceable filter.

5. **Intended Use:**

This nebulizer compressor is an AC-powered air compressor nebulizer system intended to provide a source of compressed air for medical purposed for use in home health care. It is to be used with a pneumatic nebulizer to produce aerosol particles of medication for respiratory therapy for both children and adults.

6. **Comparison to Predicate Devices:**

The subject (Inspiration Elite) and predicate device (InvaCare Envoy Jr., K#992643) are indicated for the same intended use, are AC-powered, meet Environmental Safety and EMC requirements, and have similar compressor operating pressure and flow ranges. Performance characteristics are basically the same, and both units are lightweight.

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

The Inspiration Elite conforms or will conform to the electromagnetic compatibility, mechanical/environmental, and electrical testing recommendations, described in the *Reviewer Guidance for Premarket Notification Submissions* (November 1993). Testing information demonstrating safety and effectiveness of the Inspiration Elite Nebulizer Compressor, with Nebulizer, Model HS456 in the intended environment of use is or will be 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.

8. Functional Comparison Chart

FUNCTION	INSPIRATION ELITE	ENVOY JR.
Model	HS456	1001RC
Dimension	4.2" x 7.5" x 7.5"	4.1"x 7.0"x 7.0"
Weight	3.3 lbs	3.5 lbs
Electrical requirements	115VAC/60Hz	115VAC/60Hz
Avg. Power consumption	89 -90 watts*	88 -89 watts*
Avg. Flow Rate @ 10-15 psig	7.6 -6.8 Lpm*	7.6 -6.8 Lpm*
Power Indication	No	No
Intensity Control	No	No
Intensity Indication	No	No
Turn ON/OFF switch	Yes (switch)	Yes (switch)

*Reference Exhibit #2 (Rietschle Thomas Compressor Comparison Data Table dated 8/10/04)

9. Discussion of Clinical Tests Performed:

Not Applicable

10. Conclusions:

We have demonstrated that the Inspiration Elite Nebulizer Compressor, with Nebulizer, Model HS456 is as safe and effective as predicate devices presently on the market, based on electrical, mechanical, environmental and EMC testing results outlined in the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions". We also adhered to FDA's DCRND "Reviewer Guidance for Home Use Respiratory Devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 3 2004

Respironics New Jersey, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue SE
Grand Rapids, Michigan 49548

Re: K042655
Trade/Device Name: Inspiration Elite Nebulizer Compressor with Nebulizer, Model HS456
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF, BTI
Dated: October 6, 2004
Received: October 7, 2004

Dear Mr. Devine:

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/dsma/dsmamain.html

Sincerely yours,

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

Exhibit B

Indications for Use

510(k) Number (if known): K042655

Device Name:
Inspiration Nebulizer Compressor, with Nebulizer, Model HS456

Indications for Use:
This nebulizer compressor is an AC-powered air compressor nebulizer system intended to provide a source of compressed air for medical purposed for use in home health care. It is to be used with a pneumatic nebulizer to produce aerosol particles of medication for respiratory therapy for both children and adults.

Prescription Use__X___
(Per 21 CFR 801 Subpart D)

OR

Over –The-Counter Use_____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiolo[illegible]eneral Hospital,
Infection Control, Dental [illegible]vices

510(k) Number K042655