DEC 20 2005

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 Part 807.92.

The assigned 510(k) number is: K053203

1. **Submitter's Identification:**

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

Contact: Lauren R. Ziegler, Senior Manager, Quality, Regulatory and Clinical Affairs
Date Summary Prepared: October 3, 2005

2. **Name of the Device:**
MyNeb Nebulizer, Model RDD100
Common Name or Classification Name (21 CFR Part 807.87) of Device:
Nebulizer, 21 CFR Part 868.5630

3. **Predicate Device Information:**

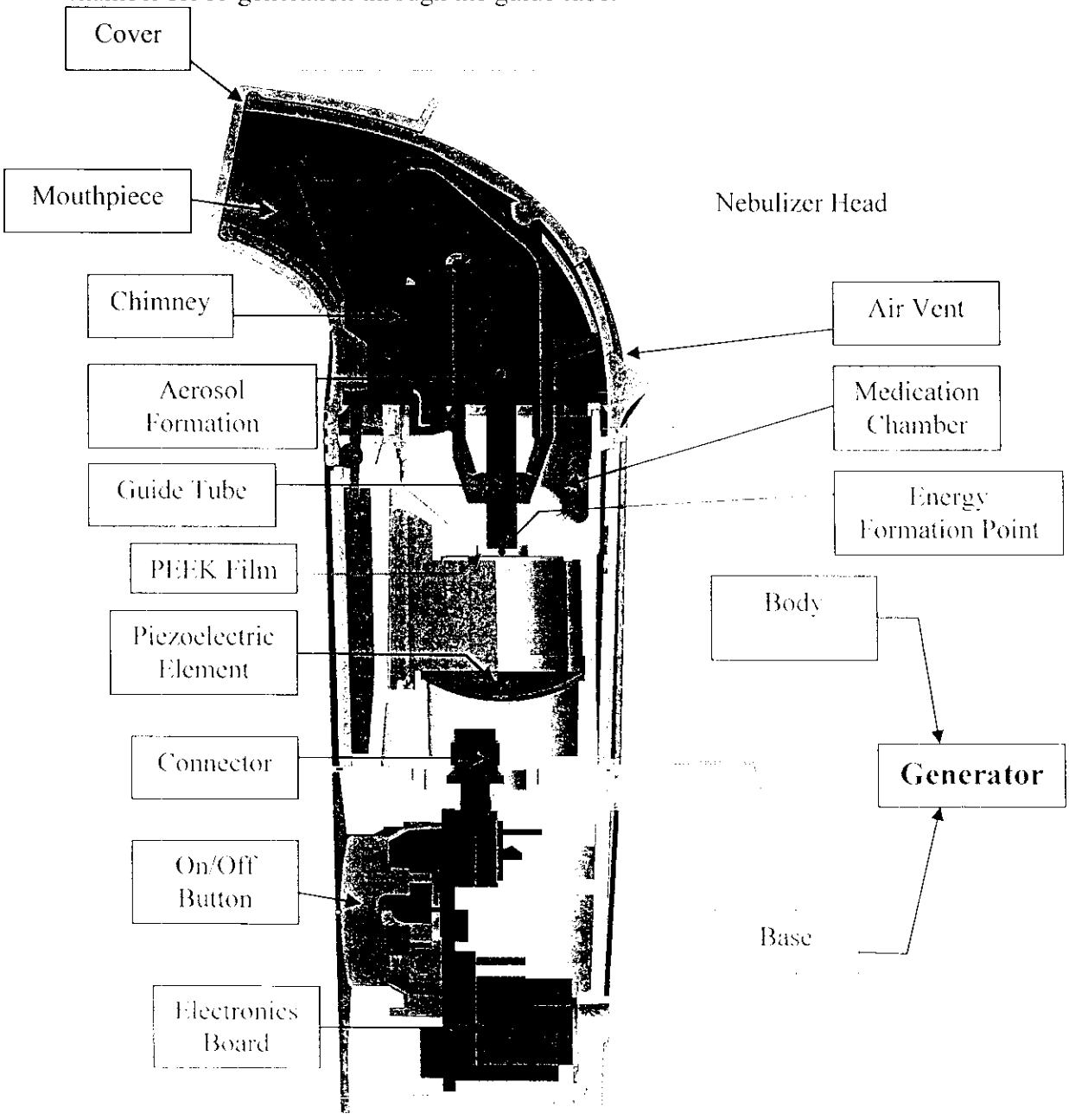
MABISMist II., K990506, Pari Trek with LC+, K960675 and K935540

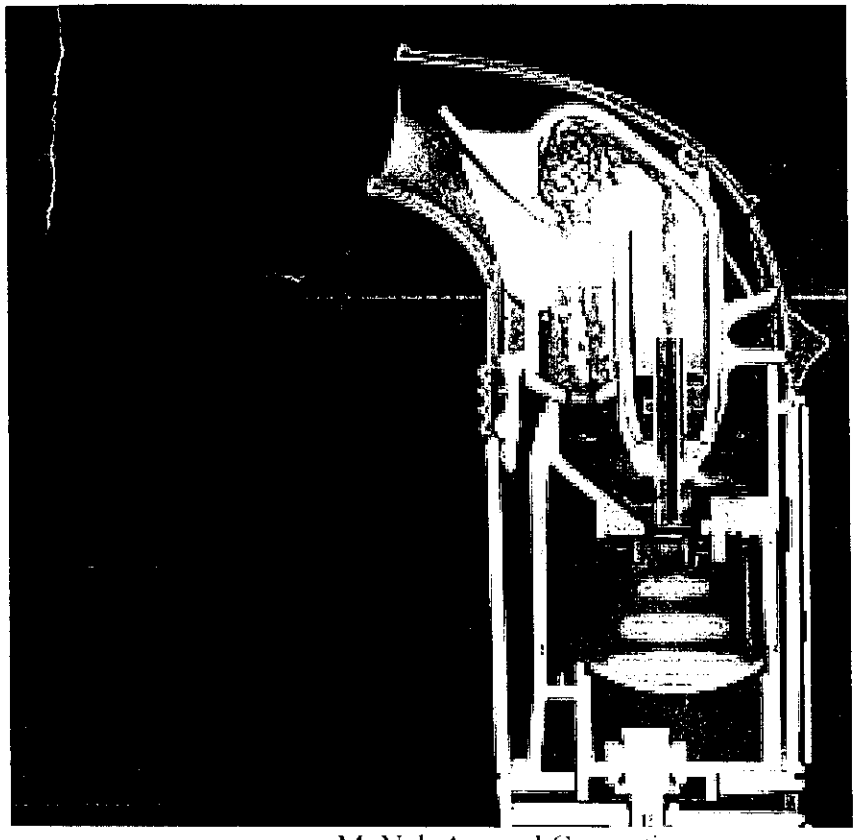
4. **Device Description:**

This AC (adaptor with DC converter) or battery-pack powered nebulizer is housed in a plastic case. Dimensions are 4.96"(H) x 2.80" (W) x 1.46"(L) and weighs 4 ounces. It consists of a piezoelectric element driven by a microprocessor with dedicated software. The batteries are rechargeable via an AC power supply (100-240 VAC, 50-60 Hz). The external battery pack is made up of 2 lithium polymer cells.

The following is the method of aerosol generation:
Step 1: Ultrasonic energy is created and focused by a concave piezoelectric element, located within the generator, to a point at the base of the medication chamber that is located at the top of the generator.

Step 2: The focused ultrasonic energy forms a liquid fountain that is driven up through the guide tube inside the nebulizer head. Upon exiting the tube, the energized liquid fountain generates cavitation of aerosol particles and the liquid medication is converted into an aerosol.
Step 3: The forces associated with the fountain generate an air draft whereby air is drawn into the nebulizer head via the air vents. The aerosolized medicine is carried by this air draft, through the nebulizer's chimney and out through the nebulizer's mouthpiece opening.
Step 4: Non aerosolized liquid medication returns back into the medication chamber for re-generation through the guide tube.





MyNeb Aerosol Generation

5. **Intended Use:**

MyNeb is an AC or battery-pack powered nebulizer designed to convert liquid medication into aerosol for inhalation by the patient.

6. **Comparison to Predicate Devices:**

The subject (MyNeb) and predicate devices (MABISMist II, K990506; Pari Trek with LC+, K960675 and K935540) are indicated for the same intended use, are electrically powered, meet Environmental Safety and EMC requirements, and have similar compressor operating pressure and flow ranges. The MABISMist II, like the MyNeb, utilizes a piezoelectric element to achieve energy generation. Performance characteristics are basically the same, and all three units are lightweight.

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

When used as intended, MyNeb 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 MyNeb nebulizer 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. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

We have demonstrated that the MyNeb Nebulizer, Model RDD100 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

DEC 2 0 2005

Intertek Testing Services
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K053203
Trade/Device Name: MyNeb Nebulizer, Model RDD100
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: December 14, 2005
Received: December 15, 2005

Dear Mr. Lehtonen:

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.

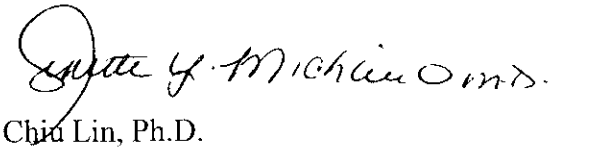
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/industry/support/index.html.

Sincerely yours,



Chin Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Exhibit B

Indications for Use

510(k) Number (if known): K053203

Device Name:
MyNeb Nebulizer, Model RDD100

Indications for Use:
MyNeb is an AC or battery-pack powered nebulizer designed to convert liquid medication into aerosol for inhalation by the patient.

Prescription Use__X___		**Over –The-Counter Use_____**
(Per 21 CFR 801 Subpart D)	**OR**	**(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K053203