NOV 1 3 2003

Attachment #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: K032809

1. **Submitter's Identification:**

Respironics HealthScan, Inc.
41 Canfield Road
Cedar Grove, NJ 07009

Contact: Ms. Lauren R. Ziegler

Date Summary Prepared:

July 31, 2003

2. **Name of the Device:**

ProChamber ™ Valved Holding Chamber

3. **Predicate Device Information:**

K#992917, Aerochamber Plus™ Valved Holding Chamber, Trudell Medical International, London, Ontario, Canada

4. **Device Description:**

The device consists of an MDI Adapter, a Chamber, a Mouthpiece, a Duckbill Valve, an Exhaust Valve and a Silicone Cap. There are no electrical or electronic components.

5. **Intended Use:**

ProChamber™ Valved Holding Chamber is intended for use in combination with Metered Dose Inhalers (MDI's) to assist in respiratory drug delivery. All patients using MDI's, i.e., children and adults, may use ProChamber ™. Settings for use include the home, clinics and hospitals.

This device is intended for prescription use.

6. **Comparison to Predicate Devices:**

The subject (ProChamber™) and predicate device (AeroChamber Plus™ – K#992917) are indicated for the same intended use. The devices are of similar size and shape and performance characteristics are basically the same. The main difference is the valve design. The subject device and predicate devices share the following characteristics:

- Similar dimensions
- Portable
- Reproducible dose delivery
- Minimization of aerosol disposition in oropharynx
- Spray direction of aerosol plume is toward patient
- One-way valve
- Utilizes MDI's own actuator

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

The ProChamber ™ and the predicate device, the AeroChamber Plus™ , were tested for particle size distribution testing, as well as directly compared to and MDI alone without the spacer attached. A particle size comparison between the subject spacer and the attached MDI alone was tested, according to the methodology outlined in the FDA "Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators, 10/93". Testing documentation showed that particle size range and reproducibility compared to the predicate device, was acceptable.

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

Not applicable

9. **Conclusions:**

The subject device, the ProChamber™ Metered Dose Inhaler (MDI) Valved Holding Chamber, has a similar intended use and similar characteristics as the predicate device, the AeroChamber Plus™ Valved Holding Chamber. Moreover, non-clinical testing included in this submission demonstrated that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the subject device is substantially equivalent to the predicate device.

Exhibit B

510(k) Number (if known): K032809

Device Name ProChamber™ Valved Holding Chamber

Indications For Use:

ProChamber™ Valved Holding Chamber is intended for use in combination with Metered Dose Inhalers (MDI's) to assist in respiratory drug delivery. All patients using MDI's, i.e., children and adults, may use ProChamber ™. Settings for use include the home, clinics and hospitals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The Counter Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2003

Respironics Healthscan Inc.
C/O Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K032809
Trade/Device Name: ProChamber Valved Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: October 28, 2003
Received: October 29, 2003

Dear Mr. Mosenkis:

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.

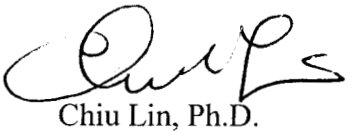
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

510(k) Number (if known): K032809

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This device is intended for prescription use.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032809

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Per 21 CFR 801.109) **(Optional Format 1-2-96)**