SEP 2 3 2005

K042991

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Section 3 Non-Confidential Summary of Safety and Effectiveness

Proprietary or Trade Name:	**I-*neb*** AAD System
Common / Usual Name:	Ultrasonic (vibrating mesh) Nebulizer
Classification Name:	Nebulizer, Direct Patient Interface
Official Contact:	Barbara Campbell Vice President, Corporate QA/RA Respironics Inc, Corporate Services 1010 Murry Ridge Lane Murrysville, PA 15668-8525
Predicate Devices	**Pro*dose*** AAD System, K030747 **Halo*lite*** AAD System K991685 **NeU04** K923024

Device Description

The **I-*neb*** AAD system is a portable, single patient use, reusable, ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication approved for use with the I-neb AAD System for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.

The **I-*neb*** AAD system consists of a hand-piece containing:-

- an ultrasonic horn *(to vibrate the mesh)*
- a pressure transducer, *(to monitor patient breathing)*
- a microprocessor *(to calculate aerosol pulse time based on breathing pattern)*
- a medication chamber *(to hold the medication)*
- a porous mesh (*to create aerosol and determine particle size).*
- a mouthpiece, which includes a bi-directional flap valve *(to guide aerosol to the patient)*
- a disc, which has a bi-directional, inductively coupled, Rf transponder *(to enable fine tuning operational parameters to be sent to the device).*

The **I-*neb*** AAD system incorporates the vibrating mesh technology developed and utilized in Omron's ultrasonic nebulizers, and the Adaptive Aerosol Delivery (AAD) technology developed and utilized by Profile's AAD system jet nebulizers.
The **I-*neb*** AAD system has been developed by Profile in collaboration with Omron Healthcare (Japan).

The vibrating mesh technology creates a low velocity aerosol by squeezing the liquid medication through 5-6,000 separate 3 micron holes during each vibration, creating thousands of droplets. The AAD technology is based on sensitive pressure transducers, microprocessors and firmware which together analyses a patient's breathing pattern and determines the appropriate aerosol pulse time to ensure that medication is only delivered during patient inspiration.
The length of each pulse of aerosol is calculated based on the measured inspiration time of the previous three breaths and the **I-*neb*** continues to monitor the breathing pattern throughout treatment in order to adapt to any changes in the breathing pattern. When the appropriate dose of medication has been delivered, the system indicates that the treatment is complete.

1. Intended use
The intended purpose of the I-neb AAD System is that is it is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication approved for use with the I-neb AAD System for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.

2. Environment of Use –
Home care, nursing home, sub-acute institutions or hospital.

3. Patient Population –
Patients requiring nebulized drug delivery, adults and children age 2 years upwards who can co-ordinate breathing into a mouthpiece..

Comparison to Other Legally Marketed Predicate Devices

The following comparison table details the primary attributes of the intended device and the legally marketed predicate devices. The most significant attributes have been listed.

Attribute **Use**	**Pro*dose*** K030747	**Halo*lite*** K991685	**NeU04** K923024	**I-*neb***
Small Volume Nebulizer	Yes	Yes	Yes	Yes
Intended to nebulize drugs	Yes	Yes	Yes	Yes
Jet Nebulizer	Yes	Yes	No	No
Ultrasonic Nebulizer	No	No	Yes	Yes
Synchronized Delivery of Nebulized drug	Yes	Yes	No	Yes
Drug Delivery on demand	Yes	Yes	No	Yes
Used in hospitals, home care, nursing home, sub-acute institutions	Yes	Yes	Yes	Yes

Single Patient reusable	Yes	Yes	Yes	Yes

Attribute **Design**	**Pro*dose*** K030747	**Halo*lite*** K991685	**NeU04** K923024	**I-*neb***
LCD Display	Yes	Yes	No	Yes
Software Driven	Yes	Yes	Yes	Yes
Mode of Operation	Breath Activated	Breath Activated	Constant Output	Breath Activated
Drug delivery triggered by	Patient Inhalation	Patient Inhalation	Constant Output	Patient Inhalation
Maximum Pulse time	5 Seconds	0.5 Seconds	N/A	5 Seconds
Used with Mouthpiece	Yes	Yes	No	Yes
Used with a Mask	No	No	Yes	No
Power Supply	Mains Only	Battery & Mains	Battery &/or Mains	Battery &/or Mains
RF Disc	Yes	No	No	Yes
Materials				
Materials in Contact with Patient	Polycarbonate	Polycarbonate	Rabalon	Polycarbonate
Packaging				
Provided clean, non-sterile	Yes	Yes	Yes	Yes
Performance Standards / Specifications Applicable under Section 514	No	No	No	No

Differences Between Other Legally Marketed Predicate Devices

The main differences between the intended device, **I-*neb*** AAD System, and the predicate device **Pro*dose*** AAD System are -

1. **I-*neb*** AAD system utilises a high frequency vibrating horn and porous mesh to generate aerosol, whereas the **Pro*dose*** AAD System utilises a pneumatic concentric jet and baffle system to generate aerosol.

2. The **I-*neb*** and **Pro*dose*** AAD Systems use the same user interface i.e. a disc containing a radio frequency transponder chip. In **Pro*dose*** this disc transmits a pre-set drug dose to the handset as well as other operational settings. In **I-*Nneb,*** the disc does not control the drug dose but does transmit other operational settings.

Note:- The same programmed disc can be used to operate both **I-*neb*** and **Pro*dose***

3. The dose of drug delivered by the **I-*neb*** AAD system is controlled by the medication chamber volume rather than a programmed value in the disc.

4. The **I-*neb*** AAD system is a portable, battery powered device. The **Pro*dose*** AAD System is a mains powered device that should not be used outside.

Note:- The **I-*neb*** AAD system can be operated via a mains power supply as an alternative to using battery power.

5. The **Pro*dose*** handpiece is powered by an internally created DC supply from the 115v mains power supply unit. The **I-*neb*** handpiece has an internal 3.8-volt Lithium rechargeable battery.

6. The firmware in the **I-*neb*** AAD system also unlimited treatments from a single disc, whereas the **Pro*dose*** AAD System firmware only permitted the number of treatments programmed onto the disc (maximum 256).

There are no other differences between the **I-*neb*** device and the predicate **Pro*dose*** device, which would be significant to patient safety or effectiveness.

The main differences between the new device, **I-*neb*** AAD System and the predicate device **Halo*lite*** AAD System are -

1. The **I-*neb*** AAD System provides a user-friendly LCD graphic display to show visual information such as "treatment completed", "message codes" "battery power level" and "pause mode" compared with the flashing LED lights used in **Halo*lite*** AAD System for visual feedback.

2. The **I-*neb*** AAD System user interface is a micro-processor disc. This permits the **I-*neb*** device to be supplied with information stored in the disc rather than relying on users

selecting the correctly colored buttons on the front of **Halo*lite***. The disc also prevents multiple doses being delivered by inappropriate button pressing as the **I-*neb*** device needs to be restarted to deliver further doses.

3. The **I-*neb*** handpiece is powered by an internal rechargeable 3.8 volt Lithium battery. The **Halo*lite*** handpiece has an internal single use 9 volt battery.

4. The **I-*neb*** AAD System is able to supply longer aerosol pulses (up to 5 seconds) into long inhalation cycles, shortening treatment times for patients with these types of breathing patterns.

There are no other differences between the **I-*neb*** device and the predicate **Halo*lite*** device, which would be significant to patient safety or effectiveness.

The main differences between the intended device, **I-*neb*** AAD System, and the predicate device **NeU04** are -

1. **I-*neb*** AAD system contains a pressure transducer, microprocessor and device firmware as the main elements of the AAD technology which the **NeU04** does not.

2. The **I-*neb*** AAD system utilizes a Platinum porous mesh to create aerosol, whereas the **NeU04** utilises a Ceramic porous mesh to create aerosol. The liquid medication passes through the Titanium ultrasonic horn / Stainless Steel pump in **NeU04** but sits between the Titanium horn and mesh in the **I-*neb*** AAD system.

3. The **I-*neb*** AAD system ultrasonic horn operates at 180 kHz whereas the **Ne04** operates at 65 kHz.

4. The **I-*neb*** handpiece is powered by an internal rechargeable 3.8 volt Lithium battery. The **NeU04** handpiece uses 4 x 1.5v single use (AA) batteries.

5. The **I-*neb*** AAD system utilizes a polycarbonate mouthpiece, whereas the **NeU04** utilises a Rabalon elastomer mask for patient contact.

There are no other differences between the **I-*neb*** device and the predicate **NeU04** device, which would be significant to patient safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2005

Profile Therapeutics PLC
C/O Ms. Barbara Campbell
Respironics, Incorporated
Corporate Services
1010 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8525

Re: K042991
Trade/Device Name: I-neb AAD System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: August 22, 2005
Received: September 14, 2005

Dear Ms. Campbell:

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,

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

RESPIRONICS
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Section 2 Indications for use

Indications for Use

510(k) Number: K 042991 (~~To be assigned~~)

Device Name: I-*neb* AAD System

Intended Use: The intended purpose of the I-neb AAD System is that is it is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication approved for use with the I-neb AAD System for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.

Prescription Use X **or** **Over-the-counter use** __
(Per CFR 801.109)

(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: K042991