K102454

510(k) Summary
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26-Sep-11

OCT 25 2011

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Official Contact: Clare Fripp, Quality and Regulatory Affairs Manager

Proprietary or Trade Name: I-neb AAD Systems with TIM and
I-neb Insight AAD System

Common/Usual Name: Nebulizer (direct patient interface)

Classification Name: Nebulizer
CAF – 868.5630

Predicate Devices:
K062263 – Omron U-22
K870027 – Salter 8900 nebulzier
K072019 – Activaero - AKITA² APIXNEB
K042991 – Profile - I-neb AAD
K052491 – Profile - I-neb Insight

Device Description:
The I-neb AAD System is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication (except pentamidine) for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.

The I-neb Insight AAD System is an accessory for use with the I-neb AAD system and controls monitoring software that provides feedback to the patient recording treatment events, including treatment times and compliance data which is also available to the clinician.

The I-neb AAD system with TIM incorporates a modification of the predicate I-neb AAD system with (tidal breathing mode (TBM)), K042991. While the I-neb Insight incorporates updated software to accommodate the added TIM feature, it is a modification of the predicate I-neb Insight AAD System, K052941.

Indications for Use:
The I-neb AAD system with TIM is a nebulizer system designed to aerosolize liquid medication for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.

The I-neb Insight AAD System is monitoring software that provides feedback to the patient recording treatment events, including treatment times and compliance data which is also available to the clinician. It is an accessory to an accessory for use with the I-neb AAD system.

Patient Population:
The I-neb AAD system with TIM is intended for patients > 3 years and older who can coordinate breathing.

Environment of Use:
Home care, nursing home, sub-acute institution, or hospital environment.

Contraindications:
None

Performance Testing:
We performed comparative bench testing to demonstrate that the I-neb AAD System with TIM is equivalent to the predicates I-neb AAD System (K042991) in TBM mode, and Omron U22 (K062263), and Salter 8900 (K870027). The comparative testing demonstrates that the proposed device is substantially equivalent to the predicate devices.

Previous testing of the I-neb AAD system (K042991) included IEC 60601 and electrical safety, EMC, EMI and mechanical and environmental testing. As the proposed device is a modification of the predicate I-neb AAD with TBM (K042991) and I-neb AAD with Insight (K052491) and no modification to the basic hardware was performed, thus repeating these tests was not required to demonstrate safety.

Particle characterization via Cascade Impactor was performed with 3 drugs. This testing was performed at flow rates of 15 lpm and 30 lpm to simulate the intended patient population.

Comparative dosing was performed. This testing demonstrated that the TBM and the TIM modes as well as to the predicates Omron U22 (K062263) and Salter 8900 (K870027) were equivalent.

Substantial Equivalence:
The I-neb AAD System with TIM is viewed as substantially equivalent to the predicate devices because:

Indications –
As a general purpose nebulizer, identical to predicate – Omron U-22 (K062263), Salter 8900 (K870027) and Activaero AKITA² APIXNEB (K072019)

Technology –
Identical vibrating mesh nebulizer technology to predicates – K042991 – I-neb AAD and K062263 – Omron U-22

Identical breath triggered nebulization technology to predicate - K042991 – I-neb AAD System and K072019 Activaero AKITA² APIXNEB

Materials –
The materials in the gas and fluid pathway are identical to predicate device - K042991 – I-neb AAD System.

Environment of Use –
Identical to predicate – K062263 – Omron U-22, K072019 - Activaero AKITA² APIXNEB and K042991 – I-neb AAD.

Patient Population –
Equivalent to predicates –K062263 – Omron U-22, K042991 – I-neb AAD System and K072019 Activaero AKITA² APIXNEB.

The **I-neb Insight** AAD System is viewed as substantially equivalent to the predicate devices because:

Indications –
Identical to predicate – K052491 – I-neb Insight AAD System

Technology –
Identical technology to predicate – K052491 – I-neb Insight AAD system

Summary of Specific Particle Characterization and Dose testing

- Comparison of particle characterization testing included the evaluation of
  - MMAD, GSD, Respirable Fraction (%) – the predicates and the proposed device were found to be substantially equivalent.
- Comparative Dose for the I-neb AAD system in TBM vs. TIM mode and to the predicates Omron U22 (K062263) and Salter 8900 (K870027) was performed.
  - Parameters measured and compared included – gravimetric dose, Filter dose and Treatment time
  - Results – the predicates and the proposed device were substantially equivalent.

Attribute	Omron U22 nebulizer K062263	Salter 8900 K870027	Activaero AKITA² APIXNEB K072019	Profile I-neb AAD K042991	Proposed I-neb AAD with TIM
Indications for use	General purpose use	General purpose use	General purpose use	Specific to a drug	General Purpose use
Patient population	Adult and pediatric	Adult and Pediatric	3 and older who can coordinate breathing	2 and older who can coordinate breathing	3 and older who can coordinate breathing
Nebulizer technology	Vibrating Mesh	Jet / venturi	Vibrating Mesh	Vibrating Mesh	Vibrating Mesh
Accessory mouthpiece	Yes	Yes	N/A	Yes	Yes
Software driven	Yes	No	Yes	Yes	Yes
Mode of Operation	Continuous	Continuous	Breathe activated	Breathe activated	Breathe activated
Synchronized delivery of nebulized drug	No	No	Yes Inhalation only	Yes Inhalation only	Yes Inhalation only
Drug delivery on demand	No	No	Yes	Yes	Yes
Drug delivery triggered by	N/A	N/A	Patient inhalation Pressure signal	Patient inhalation Pressure signal	Patient inhalation Pressure signal
Drug delivery pulse range (seconds)	N/A	N/A	1 to 7 sec	0.5 to 5 sec	Up to 7 sec
Delivers medication	Continuously	Continuously	Up to the last 1 second of the inhalation cycle	Between 50 to 80% of the inhalation cycle	Up to the last 1 second of the inhalation cycle
Method of guiding patient for Controlled inhalation	None	None	Auxiliary flow is provided from a compressor set at 15 Lpm	Use of a flap valve in the mouthpiece in which the patient entrains room air which mixes with the nebulized medication. Approximate flow rate is not controlled in TBM mode	Use of a restrictive flap valve in the mouthpiece to control breathing. Vibration felt by the patient to indicate target time. The patient entrained room air which mixes with the nebulized medication. Approximate flow rate is 15 Lpm for TIM mode
Method of providing pre-set parameters for nebulizer performance	None	None	Yes Smart Card	Yes RF disc	Yes RF disc
Accessory for monitoring and recording patient data for review by the clinician	N/A	N/A	N/A	Yes	Yes

I-neb Insight with TIM

Results	**Profile** **I-neb Insight** **(K052491)**	**Proposed** **I-neb AAD with TIM**
Indications for Use (all have except pentamidine)	Will be used with patients for whom doctors have prescribed medication for nebulization	Will be used with patients for whom doctors have prescribed medication for nebulization
Accessory to I-neb AAD system with the indications of monitoring and providing patient feedback	The I-neb Insight is monitoring software that provides feedback to the patient recording treatment events, including treatment times and compliance data which is also available to the clinician	The I-neb Insight is monitoring software that provides feedback to the patient recording treatment events, including treatment times and compliance data which is also available to the clinician

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Respironics Respiratory Drug Delivery (UK) Limited
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

OCT 2 5 2011

Re: K102454
Trade/Device Name: I-neb AAD Systems with TIM and
I-neb Insight AAD System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: October 6, 2011
Received: October 7, 2011

Dear Mr. Dryden:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K102454

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I-neb Insight AAD system

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The I-neb AAD system with TIM is intended for patients 3 years and older who can coordinate breathing.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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