



Food and Drug Administration  
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Silver Spring, MD 20993-0002

October 17, 2014

Aerogen Limited  
Mr. Martin Crehan  
Senior Regulatory Affairs Specialist  
IDA Business Park  
Dangan, Galway  
IRELAND

Re: K133360

Trade/Device Name: Aeroneb® Solo Nebulizer System / Aeroneb® Solo Adapter

Regulation Number: 21 CFR 868.5630

Regulation Name: Nebulizer

Regulatory Class: II

Product Code: CAF

Dated: October 3, 2014

Received: October 6, 2014

Dear Mr. Crehan:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

*Tejashri Purohit-Sheth, M.D.*

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Enclosure

## Indications for Use Statement

**510(k) Number (if known):** K133360

**Device Name:** Aeroneb<sup>®</sup> Solo Nebulizer System / Aeroneb<sup>®</sup> Solo Adapter

### Indications for Use:

*The Aeroneb<sup>®</sup> Solo Nebulizer System is a portable medical device for **single patient use** that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.*

*The Aeroneb<sup>®</sup> Solo Adapter is an accessory specific to the Aeroneb<sup>®</sup> Solo Nebulizer. It facilitates intermittent and continuous nebulization and optional supply of supplemental Oxygen to pediatric (29 days or older) and adult patients in hospital use environments via a mouthpiece or aerosol mask. If supplemental oxygen is used, for pediatric patients under 18 years of age, a maximum flow rate of 2 LPM should be used.*

**Note:** *The mouthpiece should not be used for children under 5 years of age.*

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## **510(k) Summary**

**Submitter's Name:** Aerogen Limited

**Submitter's Address:** IDA Business Park,  
Dangan,  
Galway, Ireland.

**Submitter's Telephone:** 00-353-91-540400 (Reception)  
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**Contact Person:** Martin Crehan  
Senior Regulatory Affairs Specialist

**Date Summary Prepared:** 17th October 2014

**Proposed New/Modified Device:** Aeroneb<sup>®</sup> Solo Adapter

**Trade Name:** Aeroneb<sup>®</sup> Solo Nebulizer System /Aeroneb<sup>®</sup> Solo Adapter

**Appropriate Panel/  
Classification Name:** Anesthesiology/ Nebulizer

**Regulation Number:** 21 CFR 868.5630

**Classification of the Device:** Class II

**Product Code:** CAF

### **Predicate (Cleared) Device(s):**

#### **Predicate**

**510(k) Number:** K070642

**Device:** Aeroneb<sup>®</sup> Solo Nebulizer System

**Date:** May 07, 2007.

**Manufacturer:** Aerogen.

**Description of the Proposed Device:**

The Aeroneb<sup>®</sup> Solo Adapter is designed to operate with the Aeroneb<sup>®</sup> Solo Nebulizer System, enabling efficient delivery of aerosol therapy to non-ventilated patients via an aerosol mask or mouthpiece. The device is composed of a valve controlled chamber with ports for connection of the Aeroneb<sup>®</sup> Solo Nebulizer via a mouthpiece or facemask. Air is drawn into the device and exhausted through distal and proximal valves respectively. The mouthpiece is interchangeable with a facemask (not supplied). The Aeroneb<sup>®</sup> Solo Adapter is equipped with an oxygen port for the delivery during aerosol therapy of supplementary oxygen via the Oxygen Tubing supplied. When using oxygen, the flow rate should be set between 1-6 LPM for adult use, and at a maximum rate of 2 LPM for pediatric patients less than 18 years of age.

Inclusion of a reference in the labeling (Instructions for Use); to the use of Nasal Cannula (not supplied with the device) as an alternate patient interface on/off ventilator when the Aeroneb<sup>®</sup> Solo Nebulizer is placed dry side of a humidifier.

**Intended Use of the Device:**

The Aeroneb<sup>®</sup> Solo Nebulizer System is a portable medical device for **single patient use** that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The Aeroneb<sup>®</sup> Solo Adapter is an accessory specific to the Aeroneb<sup>®</sup> Solo Nebulizer. It facilitates intermittent and continuous nebulization and optional supply of supplemental Oxygen to pediatric (29 days or older) and adult patients in hospital use environments via a mouthpiece or aerosol mask. If supplemental oxygen is used, for pediatric patients under 18 years of age, a maximum flow rate of 2 LPM should be used.

**Note:** The mouthpiece should not be used for children under 5 years of age.

**Technological Characteristics Compared to the Predicate Device(s):**

Only minor differences exist between the existing Aeroneb<sup>®</sup> Solo Nebulizer System and the modified system which do not affect the safety and effectiveness of the device.

The modified Aeroneb<sup>®</sup> Solo Nebulizer System is similar to the existing (unmodified) system in the following respects:

- No change to Solo nebulizer, Pro-X control module, Control module accessories or existing T piece accessories.
- No change to intended use, function or performance of the Aeroneb<sup>®</sup> Solo Nebulizer System.

The modified Aeroneb<sup>®</sup> Solo Nebulizer System is different to the existing (unmodified) system in the following respects:

- Addition of the Aeroneb<sup>®</sup> Solo Adapter, which is a non-sterile accessory.
- Inclusion of Tubing for optional supplemental Oxygen delivery.

In addition, the modified Aeroneb<sup>®</sup> Solo Nebulizer System including the Aeroneb<sup>®</sup> Solo Adapter is similar to the AeroEclipse<sup>®</sup> II BAN (additional predicate device) in the following respects:

- Intended Use / Target Patient Population / Anatomical Site.
- Patient Interface, Mode of Use, Care Setting for use, and some accessories that are provided (Facemask and Oxygen Tubing).
- Operational Mode; including Positioning, Medication Capacity, Feed / Loading, operation of Valves, MMAD values, provision of Supplementary Oxygen and cleaning.
- General materials of construction.

The modified Aeroneb<sup>®</sup> Solo Nebulizer System including Aeroneb<sup>®</sup> Solo Adapter is different to the AeroEclipse<sup>®</sup> II BAN (additional predicate device) in the following respects:

- The Aerosol Generator and Power Source;  
Vibrating Mesh / Electrical (Aeroneb<sup>®</sup> Solo) and Jet Nebulizer / Compressed Air (BAN).
- Physical Characteristics (Size / Weight), and the fact that the Aeroneb<sup>®</sup> Solo Nebulizer System includes the additional Aeroneb<sup>®</sup> Solo Adapter.

**Discussion of Non-Clinical Tests Performed to Determine Substantial Equivalence:**

**(a) Electromagnetic Compatibility/Electrical Safety**

Not applicable

**(b) Biocompatibility**

The materials used in the Aeroneb<sup>®</sup> Solo Nebulizer System remain unchanged. Biocompatibility testing per the requirements of ISO 10993-1 was conducted on the Aeroneb<sup>®</sup> Solo Adapter and associated Oxygen Tubing. The product categorization of the Aeroneb<sup>®</sup> Solo Adapter is defined as Externally Communicating tissue contact with limited contact duration, as per 10993 Part 1 and Blue Book Memorandum #G95-1: Use of International Standard ISO-10993, “Biological Evaluation of medical Devices part 1: Evaluation and Testing”.

Accordingly it was subjected to the following tests:

- Cytotoxicity Study Using the ISO Elution Method;
- ISO Systemic Toxicity Study in Mice;
- ISO Intracutaneous Study in Rabbits;
- ISO Maximization Sensitization Study.

This GLP testing was carried out at Aerogen Limited’s approved subcontract test supplier, NAMSA, Northwood, Ohio, USA. The GLP study reports showed acceptable results for the Aeroneb<sup>®</sup> Solo Adapter in each of the biocompatibility tests, and thus meet the requirements of ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-11.

**(c) Software**

Not applicable

**(d) Cleaning**

The Aeroneb<sup>®</sup> Solo Adapter device is a non-sterile disposable device, for single patient use, and therefore does not require cleaning. The IFU for the Aeroneb<sup>®</sup> Solo Adapter provides

direction to the user to rinse with sterile water, which is completed to maintain the functional performance of the device and in particular, the valves.

**(e) Simulated Life Testing**

Testing was completed for Valve Operating Pressure and Expected Life of the Aeroneb® Solo Adapter.

After 20 treatments (at a rate of four 3 ml doses per day over 5 days) the pressure within the device did not exceed +1.5 cm H2O when connected to a steady exhalation flow of 15 l/min or decrease below -1.5 cm H2O when connected to a steady inhalation flow of 15 l/min based on a 90 / 90% confidence / reliability.

The inlet or exhaust valve flaps did not dislodge after rinsing during intermittent therapy.

**(f) USP 661 Leachables Testing**

All drug contacting plastic materials in the Aeroneb® Solo Adapter and associated Oxygen Tubing were tested to determine the level of plastic leachables. The entire Aeroneb® Solo Adapter test Article was extracted at 50°C for 72 hours in 132mL of purified water. A control of purified water was similarly prepared without the test article. The test results demonstrated that all extractables were within the acceptable limits for drug contacting polymer based materials as per USP <661>. Under the conditions of the tests, no significant extractables originated from the test article.

In addition, an Exhaustive Extraction and Simulated Use Extraction were also carried out on the entire Aeroneb® Solo Adapter test Article, which demonstrated that the amounts of COPC that could potentially leach from the Aeroneb® Solo Adapter are not toxicologically significant, and will not elicit an adverse biological response in the patient population expected to use the device.

**(g) Aerosol Characterization**

The table below shows the results of aerosol performance testing using an 8 stage cascade impactor running at a continuous flow rate of 28.3 LPM. Indicated ranges correspond to confidence intervals with a confidence level of 95%.

Characteristic	Albuterol Sulphate (2mg/ml)	Budesonide (0.5mg/ml)	Ipratropium (0.25mg/ml)
Particle size (µm)	2.90 - 3.23	3.07 - 3.42	3.45 - 3.79
Geometric Standard Deviation (GSD)	2.09 - 2.35	1.80 - 1.93	1.92 - 2.14
Emitted Dose (% of fill)	97.23 - 99.30	97.61 - 98.64	94.12 - 97.84
Respirable Dose (0.5 – 5.0 µm) (% of fill)	67.66 - 73.50	71.78 - 76.69	62.32 - 66.90
Coarse particle Dose (>4.7 µm) (% of fill)	27.00 - 31.11	23.62 - 28.21	32.31 - 36.12
Fine particle Dose (<4.7 µm) (% of fill)	66.33 - 72.07	68.58 - 73.84	59.36 - 64.17
Ultra-fine Particle	5.91 - 9.93	1.85 - 4.19	2.36 - 4.51

<b>Dose (&lt;1.0 µm) (% of fill)</b>			
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**Conclusion:**

The Aeroneb<sup>®</sup> Solo Nebulizer System is approved for use in adult and pediatric (29 day or older) populations, and the Aeroneb<sup>®</sup> Solo Adapter will be used as an accessory for off vent use within these populations. Furthermore, Aerogen Limited has determined based on the review and results of testing detailed above; that the Aeroneb<sup>®</sup> Solo Nebulizer System with the Aeroneb<sup>®</sup> Solo Adapter, and the inclusion of a reference in the labeling (IFU) to the use of Nasal Cannula as an alternate patient interface on/off ventilator when the Aeroneb<sup>®</sup> Solo Nebulizer is placed dry side of a humidifier; is in our opinion, substantially equivalent to the existing predicate devices.