DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 10, 2015

Aerogen Limited
Martin Crehan
Senior Regulatory Affairs Specialist
Galway Business Park, Dangan
Galway, Ireland

Re: K143719
Trade/Device Name: Aerogen USB Controller System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 2, 2015
Received: June 5, 2015

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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Clinical Deputy Director
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Erin I. Keith, M.S.
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Enclosure

5 Indications for Use Statement

510(k) Number (if known): K143719

Device Name:

Aerogen USB Controller System

Indications for Use:

The Aerogen USB Controller System includes the Aeroneb® Professional and Aeroneb® Solo Nebulizers, which are intended to aerosolize physician-prescribed medications for inhalation to patients on and off ventilation or other positive pressure breathing assistance in the hospital environment, and on vent only in the homecare environment.

*The Aeroneb® Professional Nebulizer is intended for **multiple patient use in hospital environment** and **single patient use in home environment**. Aeroneb® Solo Nebulizer is for **single patient use**. Both nebulizers are for pediatric (29 days or older) and adult patients.*

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (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)

510(k) Summary

Submitter's Name:	Aerogen Limited
Submitter's Address:	Galway Business Park, Dangan, Galway, Ireland.
Submitter's Telephone:	00-353-91-540400 (Reception) 00-353-91-540459 (Martin Crehan)
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Contact Person:	Martin Crehan Senior Regulatory Affairs Specialist
Date Summary Prepared:	July 10, 2015
Proposed New/Modified Device:	Aerogen USB Controller System
Trade Name:	Aerogen USB Controller System
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:	K133360
Device:	Aeroneb® Solo Nebulizer System / Aeroneb® Solo Adapter,
Clearance Date:	October 17, 2014
Predicate 510(k) Number:	K120939
Device:	Aeroneb Pro
Clearance Date:	April 26, 2012
Manufacturer:	Aerogen Limited

Description of the Proposed Device:

The Aerogen USB Controller System includes the previously cleared Aeroneb® Professional and Solo Nebulizers. The Aeroneb® Professional Nebulizer was cleared as part of K021175, and Aeroneb® Solo Nebulizer was cleared as part of K070642. The Aerogen USB Controller is an alternative controller to the existing Aeroneb® Pro and Aeroneb® Pro-X Controllers. The power source for the Aerogen USB Controller is the Aerogen USB AC/DC Adapter.

The Aerogen USB Controller System utilises the following components:

- Aeroneb® Pro or Solo Nebulizers
- Aerogen USB Controller
- T-Piece
- AC/DC Adapter and Clips

The Aerogen USB Controller can be used to power the Aeroneb® Pro and Solo nebulizers in both the hospital and homecare environments. For homecare use, it is operated on vent only.
The Aerogen USB Controller provides two modes of operation; a 30 minute and a 6 hour nebulization cycle. The particular mode to be used depends on the accompanying nebulizer. The Aeroneb Pro® nebulizer can be used in the 30 minute intermittent mode only, whereas the Aeroneb® Solo nebulizer can be used in both the 30 minute intermittent and 6 hour modes.

Intended Use of the Device:

The Aerogen USB Controller System includes the Aeroneb® Professional and Aeroneb® Solo Nebulizers, which are intended to aerosolize physician-prescribed medications for inhalation to patients on and off ventilation or other positive pressure breathing assistance in the hospital environment, and on vent only in the homecare environment.

The Aeroneb® Professional Nebulizer is intended for ***multiple patient use in hospital environment*** *and* ***single patient use in home environment****. Aeroneb® Solo Nebulizer is for* ***single patient use****. Both nebulizers are for pediatric (29 days or older) and adult patients.*

Technological Characteristics Compared to the Predicate Device(s):

There is no change to the existing Aeroneb® Solo or Aeroneb® Professional Nebulizers. This 510(k) submission introduces an alternative controller for powering the Aeroneb® Solo or Aeroneb® Professional Nebulizers, and extends their use to the home environment.

- The Pro-X Controller powers the Aeroneb® Solo Nebulizer for hospital use.
- The Pro Controller powers the Aeroneb® Professional Nebulizer for hospital use.
- The USB Controller powers both the Aeroneb® Solo Nebulizer and Aeroneb® Professional Nebulizer for hospital and home use.

The table below compares the Aerogen USB Controller with the existing Aerogen Nebulizer Controllers.

Component	15 Minutes	30 Minutes	6 Hours	Continuous	Power Source
Aerogen USB Controller	N/A	√	√	N/A	5V USB AC/DC Adapter
Aerogen Pro-X Controller	N/A	√	N/A	√	9V AC/DC Adapter / Battery
Aerogen Pro Controller	√	√	N/A	N/A	9V AC/DC Adapter / Battery

Aerogen Controller Comparison - Modes of Operation / Power Source(s)

The Aerogen USB Controller System includes existing Aeroneb® Solo and Aeroneb Professional Nebulizers:

- There is no change to the nebulizers, in their general materials of construction and packaging, or in their form, function or performance characteristics.
- There is no change in nebulizer Operational Mode or principles; including Positioning, Medication Capacity and Feed / Loading.
- The nebulizers continue to be used in the same manner in critical, acute and sub-acute care settings [Hospital]; with no change in the administered anatomical site or in the target patient population.
- The nebulizers are powered by the same principle, via a separate type Controller; which controls the relevant indicator lights and this facet of operation remains unchanged.
- The Indication for Use has been expanded to incorporate the Homecare environment in a limited capacity; the on-vent mode only. The introduction to this environment setting does not impact the classification of the Aeroneb® Pro and/or Solo Nebulizers.

The Aerogen USB Controller System also includes the Aerogen USB Controller. The functionality of the Aerogen USB Controller will be similar to the Pro-X Controller, with 30 minute intermittent and 6 hour modes.

Only minor differences exist between the existing Aerogen Pro and Aerogen Pro-X Controllers and the Aerogen USB Controller. The differences are as highlighted below:

- The controller types are physically different in form. The physical characteristics of the Controllers differ, with the Aerogen USB Controller being smaller in size and lighter in weight, and the length of the associated cable(s) differing to that of the existing Pro-X Controller (K133360) / Pro Controller (K120939).

- The Aerogen Pro and Pro-X Controllers are both powered from a 9V AC/DC Adapter, and can also be powered from an internal rechargeable battery. The Aerogen USB Controller is powered from a USB AC/DC Adapter only. Note: All the AC/DC Adapters are 60601 approved.

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

(a) Electromagnetic Compatibility/Electrical Safety

The Aerogen USB Controller System was subjected to the full suite of required electrical safety testing. This testing was successfully performed on behalf of Aerogen Limited by TUV Rheinland, and a CB Test Certificate and associated Test Listing Report were provided at the end of the process attesting to this fact.

The applicable standards used to demonstrate compliance for Electrical Safety and Electromagnetic Compatibility are as listed below:

FDA Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
19-4	AAMI ANSI	ES60601-1:2005/(R)2012 and A1:2012	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
19-1	IEC	60601-1-2 Edition 3: 2007-03	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

(b) Biocompatibility

- All the materials of construction used in the Aeroneb® Pro and Solo Nebulizer Systems remain unaltered.
- The Aerogen USB Controller is the electrical power source used to drive the nebulizers, and does not come into contact with the aerosol being inhaled by the patient. Therefore it does not fall under the scope of a "*medical device*"; per Clause 3.1 of ISO 10993-1:2009 and no additional or new biocompatibility testing is required, per Attachment C of the draft FDA Guidance issued on April 23, 2013.

(c) Software

- A Software Level of Concern Assessment for the Aerogen USB Controller was performed with reference to the 2005 FDA Guidance and documented; wherein the Level of Concern was identified as ***Moderate***.
- In addition the Software Safety Classification was determined using the FDA Consensus Standard; IEC 62304:2006, and it was identified as ***Class B***.
- Finally for each software lifecycle phase; the associated activities, tasks and deliverables were defined, in conjunction with their specific requirements.
  The acceptance criteria for each deliverable were reviewed and it was confirmed that they had been successfully achieved in all instances.

(d) Cleaning / Sterilisation

- The USB Controller is sold non-sterile, and does not require cleaning.

- In relation to the constituent nebulizers, please note the following:
  - Aeroneb® Solo Nebulizer:
    This nebulizer is for single patient use only, and the nebulizer or any of its associated or constituent components do not require to be cleaned, disinfected or sterilized.

  - Aeroneb® Pro Nebulizer:
    This nebulizer is intended for multiple patient uses in the hospital environment and single patient use in the home environment, and it can be cleaned including boiling (in the home environment) and cleaned, disinfected and autoclaved (if so required) in the hospital environment, as documented in the Instruction Manual.

(e) Design Verification and Validation Testing

All applicable design verification and validation tests were identified, conducted and successfully completed on the Aerogen USB Controller and the associated nebulizers. This testing demonstrated that the Aerogen USB Controller System met all the required design inputs.

In addition and in order to demonstrate substantial equivalence of the Aerogen USB Controller to the previously cleared Aeroneb Pro and Pro-X Controllers, cascade impaction testing was performed; using an Aeroneb Pro nebulizer and an Aeroneb Solo nebulizer with a USB Controller and one drug - Salbutamol Sulphate (Albuterol).
This testing was performed using the 8 stage Andersen Cascade Impactor (ACI).
The acceptance criteria were that both the tested nebulizers met the Specification Range of 1 to 5 µm for MMAD Droplet Size, and this was successfully achieved.
In addition, a range of associated aerosol characteristics were assessed and demonstrated to be acceptable.
Based on the test results obtained for MMAD, and the additional assessed aerosol characteristics; the combination of the Aerogen USB Controller with the Aeroneb Pro and Solo nebulizers: provide results which meet the acceptance criteria for the nebulizers, and which are substantially equivalent to the previously cleared Aeroneb Pro and Pro-X Controllers.

Conclusion:

With the introduction of the Aerogen USB Controller System, the respective nebulizers will continue to be ‘controlled’ in exactly the same manner with no impact on safety and / or effectiveness.

Furthermore, Aerogen Limited has determined based on the review and results of testing detailed above; that the introduction of the Aerogen USB Controller System; is substantially equivalent to the existing predicate device.