May 10, 2024

Aerogen Ltd.
% Paul Dryden
Consultant
Aerogen Ltd. c/o ProMedic LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K232507
Trade/Device Name: Aerogen®Solo Nebulizer System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: April 16, 2024
Received: April 16, 2024

Dear Paul 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K232507

Device Name
Aerogen® Solo Nebulizer System and Aerogen® USB Controller System

Indications for Use *(Describe)*
The Aerogen® Solo Nebulizer System includes the Aerogen® Solo Nebulizer, which is intended to aerosolize physician-prescribed medications for inhalation to patients on and off ventilation or other positive pressure breathing assistance in the hospital environment.

Aerogen® Solo Nebulizer is for single-patient use. The Aerogen Solo nebulizer is for pediatric (29 days or older) and adult patients.

The Aerogen® USB Controller System includes the Aerogen® Solo Nebulizer, which is 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.

Aerogen® Solo Nebulizer is for single patient use. The Aerogen Solo nebulizer is for pediatric (29 days or older) and adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**Date Prepared:** 10-May-24

**Sponsor:**
Aerogen Ltd
Galway Business Park,
Dangan, Galway, Ireland.
Tel - + 353-91-540400

**Sponsor Contact:** Thelma Marley
Senior Manager of Global Strategic Regulatory Affairs

**Submission Correspondent:** Paul Dryden
ProMedic, LLC

**Proprietary or Trade Name:** Aerogen® Solo Nebulizer System
**Common/Usual Name:** Nebulizer
**Classification CFR:** 868.5630
**Product Code:** CAF
**Classification Name:** Nebulizer

**Primary Predicate Device:** K133360 - Aeroneb® Solo Nebulizer System / Aeroneb® Solo
**Proprietary or Trade Name:** Adapter
**Common/Usual Name:** Nebulizer
**Classification CFR:** 868.5630
**Product Code:** CAF
**Classification Name:** Nebulizer

**Reference Device:**
**Proprietary or Trade Name:** K143719 – Aerogen® USB Controller System
**Common/Usual Name:** Nebulizer
**Classification CFR:** 868.5630
**Product Code:** CAF
**Classification Name:** Nebulizer

**Device Description:**
The Aerogen® Solo Nebulizer System consists of the Aerogen® Solo Nebulizer, which has the proposed modification outlined in these 510(k) applications, and the Aerogen® Pro-X Controller (K133360 for both components and system) or the Aerogen Solo Nebulizer can also be used alternatively with the reference device - Aerogen® USB Controller (K143719).

The Aerogen® Solo Nebulizer is intended to aerosolize physician-prescribed medications for inhalation which are approved for use with a general-purpose nebulizer. It is intended for use on and off mechanical ventilation or other positive pressure breathing assistance and is intended for both intermittent and continuous nebulization.

The Aerogen® Solo Nebulizer is designed to operate in-line with standard ventilator circuits and mechanical ventilators. It operates without changing patient ventilator parameters and can be refilled without interrupting ventilation.

This submission is for a modification of the attachment process of the Aperture Plate (AP) to the Oscillator washer, both are components of the core for the Aerogen® Solo Nebulizer. The current method of attachment of the Aperture Plate to the Oscillator washer is by means of Brazing, a metal fusion process, where a copper/gold filler washer is melted in the brazing process to form the bond. The piezo is then attached using a heat cured epoxy adhesive.

**Indications for Use:**
The Aerogen® Solo Nebulizer System includes the Aerogen® Solo Nebulizer, which is intended to aerosolize physician-prescribed medications for inhalation to patients on and off ventilation or other positive pressure breathing assistance in the hospital environment.

Aerogen® Solo Nebulizer is for single-patient use. The Aerogen Solo nebulizer is for pediatric (29 days or older) and adult patients.

The Aerogen® USB Controller System includes the Aerogen® Solo Nebulizer, which is 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.

Aerogen® Solo Nebulizer is for single patient use. The Aerogen Solo nebulizer is for pediatric (29 days or older) and adult patients.

**Predicate and Reference**
We have selected a primary predicate and reference device which cover the 2 different controllers which both utilize the Aerogen® Solo nebulizer. Therefore the modified Aerogen® Solo nebulizer will still be used with each controller model thus the rationale for including both.

We present a comparison of the proposed device and a Solo nebulizer predicate in Table 1 and then discuss the table and any differences. Table 2 presents the comparative particle characterization performance of the predicate vs. the modified nebulizer.

## Table 1 – Substantial Equivalence Comparative Table

| Features | Primary Predicate Aerogen Solo Nebulizer K133360 (Reference noted K143719) | Proposed Aerogen Solo Nebulizer | Comparison |
|---|---|---|---|
| **Indications for use** | The Aerogen® Solo Nebulizer System includes the Aerogen® Solo Nebulizer, which is intended to aerosolize physician-prescribed medications for inhalation to patients on and off ventilation or other positive pressure breathing assistance in the hospital environment.<br><br>Aerogen® Solo Nebulizer is for single-patient use. The Aerogen Solo nebulizer is for pediatric (29 days or older) and adult patients.<br><br>The Aerogen® USB Controller System includes the Aerogen® Solo Nebulizer, which is 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.<br><br>Aerogen® Solo Nebulizer is for single patient use. The Aerogen Solo nebulizer is for pediatric (29 days or older) and adult patients. | The Aerogen® Solo Nebulizer System includes the Aerogen® Solo Nebulizer, which is intended to aerosolize physician-prescribed medications for inhalation to patients on and off ventilation or other positive pressure breathing assistance in the hospital environment.<br><br>Aerogen® Solo Nebulizer is for single-patient use. The Aerogen Solo nebulizer is for pediatric (29 days or older) and adult patients.<br><br>The Aerogen® USB Controller System includes the Aerogen® Solo Nebulizer, which is 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.<br><br>Aerogen® Solo Nebulizer is for single patient use. The Aerogen Solo nebulizer is for pediatric (29 days or older) and adult patients. | Similar to the primary predicate. No change to the indications for use<br><br>The Indications for Use provided are similar to the intended use and information provided elsewhere in the Labeling for the predicate K133360 and reference K143719. |
| **Patient Population** | The device may be used with pediatric (29 days or older) and adult patients | The device may be used with pediatric (29 days or older) and adult patients | Similar, no change to patient population |
| **Environment of Use** | Predicate:<br>The Aerogen® Solo System consists of the Aerogen® Solo nebulizer and the Aerogen® Pro-X Controller. It is intended for hospital use only. | Predicate:<br>The Aerogen® Solo System consists of the Aerogen® Solo nebulizer and the Aerogen® Pro-X Controller. It is intended for hospital use only. | Similar, no change to environment of use |

| | Reference:<br>The Aerogen® USB Controller System with the Aerogen® Solo Nebulizer is intended for use in the hospital environment and on vent only in the homecare environment. | Reference:<br>The Aerogen® USB Controller System with the Aerogen® Solo Nebulizer is intended for use in the hospital environment and on vent only in the homecare environment. | |
|---|---|---|---|
| **Features** | **Primary Predicate Aerogen Solo Nebulizer K133360 (Reference noted K143719)** | **Proposed Aerogen Solo Nebulizer** | **Comparison** |
| **Principle of Operation and rate** | Vibrating mesh<br>Approximately 128 kHz | Vibrating mesh<br>Approximately 128 kHz | Similar, no change |
| **Aerosolization** | Continuous during inhalation and exhalation | Continuous during inhalation and exhalation | Similar, no change |
| **Compressed gas source** | N/A | N/A | Similar |
| **Reservoir volume** | Maximum 6 ml | Maximum 6 ml | Similar, no change |
| **Flow rate** | ≥ 0.2ml/min | ≥ 0.2ml/min | |
| **Duration of Use** | The Aerogen Solo Nebulizer<br>• Intermittent use for a maximum of 28 days (4 treatments per day.)<br>• For continuous use the life of the Aerogen Solo nebulizer and the Continuous Nebulization Tube Set have been validated for use for a maximum of 7 days. | The Aerogen Solo Nebulizer<br>• Intermittent use for a maximum of 28 days (4 treatments per day.)<br>• For continuous use the life of the Aerogen Solo nebulizer and the Continuous Nebulization Tube Set have been validated for use for a maximum of 7 days. | Similar devices, no change to Duration of Use |
| **Nebulizer components cleanable** | No | No | Similar, no change |
| **Software driven** | No | No | |
| **Power source** | Pro-X controller<br>USB Controller | Pro-X controller<br>USB Controller | Same device, no change to power source |
| **Power consumption** | The power consumption of the Aerogen® Solo nebulizer is ≤2.0 watts. | The power consumption of the Aerogen® Solo nebulizer is ≤2.0 watts. | Same device, no change to power consumption |
| **Weight** | Nebulizer Weight: 13.5g (0.5oz) nebulizer and plug | Nebulizer Weight: 13.5g (0.5oz) nebulizer and plug | Same device, no change to the Aerogen Solo Nebulizer weight |
| **Nebulizer Dimensions (mm)** | 67 mm H x 48 mm W x 25 mm D 2.6” H x 1.88” W x 1.1” D | 67 mm H x 48 mm W x 25 mm D 2.6” H x 1.88” W x 1.1” D | No change to Nebulizer dimensions |
| **Operating Conditions** | **Aerogen® Solo Nebulizer System:** | **Aerogen® Solo Nebulizer System:** | No change to operating conditions |

| | | | |
|---|---|---|---|
| | Maintains specified performance at circuit pressures up to 90cm H20 and temperatures from 5°C (41°F) up to 45°C (113°F).<br>Atmospheric Pressure: 450 to 1100 mbars<br>Humidity: 15% to 95% relative humidity<br>Noise level: < 35 dB measured at 0.3 m distance<br><br>**Reference: Aerogen USB Controller System:**<br>Maintains specified performance at circuit pressures up to 90cm H20 and temperatures from 5°C (41°F) up to 40°C (104°F).<br>Atmospheric Pressure: 700 to 1060 mbar<br>Humidity: 15% to 93% relative humidity<br>Noise level: < 35 dB measured at 1m distance | Maintains specified performance at circuit pressures up to 90cm H20 and temperatures from 5°C (41°F) up to 45°C (113°F).<br>Atmospheric Pressure: 450 to 1100 mbars<br>Humidity: 15% to 95% relative humidity<br>Noise level: < 35 dB measured at 0.3 m distance<br><br>**Reference: Aerogen USB Controller System:**<br>Maintains specified performance at circuit pressures up to 90cm H20 and temperatures from 5°C (41°F) up to 40°C (104°F).<br>Atmospheric Pressure: 700 to 1060 mbar<br>Humidity: 15% to 93% relative humidity<br>Noise level: < 35 dB measured at 1m distance | |
| **Features** | **Primary Predicate Aerogen Solo Nebulizer K133360 (Reference noted K143719)** | **Proposed Aerogen Solo Nebulizer** | **Comparison** |
| **Storage Conditions** | **Aerogen Solo Nebulizer System:**<br>**Transient Temperature Range:** -20 to +60°C (-4 to +140°F)<br>**Atmospheric Pressure**: 450 to 1100mbars<br>**Humidity:** 15 to 95% relative humidity<br><br>**Aerogen USB Controller Nebulizer System:**<br>Transient Temperature Range: -25 to +70 °C (-13 to +158 °F)<br>Atmospheric Pressure: 450 to 1060 mbars<br>Humidity: Up to 93% relative humidity. | **Aerogen Solo Nebulizer System:**<br>**Transient Temperature Range:** -20 to +60°C (-4 to +140°F)<br>**Atmospheric Pressure**: 450 to 1100mbars<br>**Humidity:** 15 to 95% relative humidity<br><br>**Aerogen USB Controller Nebulizer System:**<br>Transient Temperature Range: -25 to +70 °C (-13 to +158 °F)<br>Atmospheric Pressure: 450 to 1060 mbars<br>Humidity: Up to 93% relative humidity. | No change to storage conditions |
| **Aging** | Not done | Post-aging and degradation testing | Similar – additional testing of post-aging for performance |
| **User interface** | The medical device (Aerogen® Solo Nebulizer) interfaces with the patient through inhalation of the aerosolized medications which are approved for inhalation. The aerosolized medications can be administered through the Aerogen® Solo Nebulizer through a ventilator circuit or patient interface i.e., a mouthpiece or | The medical device (Aerogen® Solo Nebulizer) interfaces with the patient through inhalation of the aerosolized medications which are approved for inhalation. The aerosolized medications can be administered through the Aerogen® Solo Nebulizer through a ventilator circuit or patient interface i.e., a mouthpiece or face mask. The | No Change to the User Interface |

| | | | |
|---|---|---|---|
| | face mask. The modification to the Aerogen® Solo Nebulizer described in this application does not change the interaction with the patient or other medical devices. | modification to the Aerogen® Solo Nebulizer described in this application does not change the interaction with the patient or other medical devices. | |
| **Features** | **Primary Predicate Aerogen Solo Nebulizer K133360 (Reference noted K143719)** | **Proposed Aerogen Solo Nebulizer** | **Comparison** |
| **Standards** | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-6<br>IEC 62366<br>IEC 60601-1-11<br>ISO 13544-1 | ISO 27427 supersedes ISO 13544-1.<br>Biocompatibility<br>ISO 10993-5<br>ISO 10993-10<br>ISO 10993-17<br>ISO 10993-18<br>ISO 10993-23<br>ISO 18562-2<br>ISO 18562-3<br>ISO 18562-4<br>EMC and Safety<br>IEC 60601 series remains unchanged | Similar and testing performed and is considered similar. |
| **Materials per ISO 10993** | External Communicating<br>(Indirect gas pathway)<br>Tissue / Bone / Dentin communicating.<br>Duration of Use – Long-term (permanent) duration (>30 days) | External Communicating<br>(Indirect gas pathway)<br>Tissue / Bone / Dentin communicating.<br>Duration of Use – Long-term (permanent) duration (>30 days) | The materials are similar except for the new adhesive which was evaluated under ISO 10993-1 testing. |

Non-clinical Performance Testing included:

- Comparative Particle Characterization testing via Cascade Impactor
    - Flow rate of 28 LPM to the predicate which was tested with 3 drugs via Anderson Cascade Impactor at 28.3 Lpm with the modified FAB device with one drug class also at 28.3 Lpm with an Anderson Cascade Impactor.
- Performance of the modified FAB with 3 drug classes at 15 Lpm with the NGI test device.
- Aerosol Performance – Inter- and Intra-sample variability
- Performance of post-aging and degradation

**Comparative Particle Characterization Performance**

**Table 2** present summaries of the comparative test results of aerosol performance testing using a cascade impactor, running at a continuous flow rate of 15 LPM or 28.3 LPM. Indicated ranges correspond to confidence intervals with a confidence level of 95%.

## Table 2 – Comparative Aerosol Performance

| Features | Primary Predicate Aerogen Solo Nebulizer K133360 | Proposed Modified Nebulizer | Proposed Modified Nebulizer | Comparison |
|---|---|---|---|---|
| | Particle Characterization per Cascade Impactor @ 28 lpm | Particle Characterization per Cascade Impactor @ 28 lpm | Particle Characterization per NGI @ 15 lpm | |
| **Total Dose (ug)** | Albuterol: N/A<br>Ipratropium: N/A<br>Budesonide: N/A | Albuterol: N/A | Albuterol: 526.94 – 545.23<br>Ipratropium: 144.51 – 152.04<br>Budesonide: 229.62 – 245.20 | Additional data provided |
| **Particle size (MMAD) (Microns)** | Albuterol: 2.90 – 3.23<br>Ipratropium: 3.07 – 3.42<br>Budesonide: 3.45 – 3.79 | Albuterol: 2.80 – 3.05 | Albuterol: 4.39 – 4.53<br>Ipratropium: 3.76 – 4.02<br>Budesonide: 4.90 – 5.01 | Similar Cascade Impactor performance and NGI performance |
| **Geometric Std. Dev. (GSD)** | Albuterol: 2.09 – 2.35<br>Ipratropium: 1.80 – 1.93<br>Budesonide: 1.92 – 2.14 | Albuterol: 2.26 – 2.36 | Albuterol: 2.09 – 2.16<br>Ipratropium: 2.28 – 2.41<br>Budesonide: 2.06 – 2.14 | Similar Cascade Impactor performance and NGI performance |
| **Total Respirable Dose (0.0-5 microns)** | Albuterol: 67.66 – 73.50<br>Ipratropium: 71.78 – 76.69<br>Budesonide: 62.32 – 66.90 | Albuterol: 70.88 – 73.94 | Albuterol: 54.42 – 56.10<br>Ipratropium: 59.57 – 63.06<br>Budesonide: 49.32 – 50.91 | Similar Cascade Impactor performance and NGI performance |
| **Coarse Particle Dose (>4.7 micron)** | Albuterol: 27.00 – 31.11<br>Ipratropium: 23.62 – 28.21<br>Budesonide: 32.31 – 36.12 | Albuterol: 28.73 – 32.03 | Albuterol: 46.69 – 48.78<br>Ipratropium: 39.87 – 43.38<br>Budesonide: 53.51 – 54.99 | Similar Cascade Impactor performance and NGI performance |
| **Fine Particle Dose (<4.7 micron)** | Albuterol: 66.33 – 72.07<br>Ipratropium: 68.58 – 73.84<br>Budesonide: 59.36 – 64.17 | Albuterol: 67.97 – 71.27 | Albuterol: 51.23 – 53.31<br>Ipratropium: 56.62 – 60.13<br>Budesonide: 45.01 – 46.49 | Similar Cascade Impactor performance and NGI performance |
| **Ultra-fine Particle Dose (< 1.0 micron)** | Albuterol: 5.91 – 9.93<br>Ipratropium: 1.85 – 4.19<br>Budesonide: 2.36 – 4.51 | Albuterol: 10.13 – 12.02 | Albuterol: 2.86 – 3.70<br>Ipratropium: 8.24 – 12.89<br>Budesonide: 2.78 – 3.41 | Similar Cascade Impactor performance and NGI performance |
| **Confidence level of testing** | 95% confidence level | 95% confidence level | 95% confidence level | |

**Discussion of Substantial Equivalence**

The proposed modification of the existing Aerogen® Solo Nebulizer System and Aerogen® USB Controller System to introduce a Fully Adhesive Bonded (F.A.B) Core to the Aerogen® Solo Nebulizer is viewed as substantially equivalent to the predicate device for the following reasons:

**Indications for Use –**
The Aerogen® Solo Nebulizer System includes the Aerogen® Solo Nebulizer, which is intended to aerosolize physician-prescribed medications for inhalation to patients on and off ventilation or other positive pressure breathing assistance in the hospital environment.

Aerogen® Solo Nebulizer is for single-patient use. The Aerogen® Solo nebulizer is for pediatric (29 days or older) and adult patients.

The Aerogen® USB Controller System includes the Aerogen® Solo Nebulizer, which is 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.

Aerogen® Solo Nebulizer is for single patient use. The Aerogen® Solo nebulizer is for pediatric (29 days or older) and adult patients.

**Discussion -**
The indications for use are the same for the proposed modified device and the predicate device. We have consolidated past intended use and information in previous labeling into a more complete indications for use description.

**Patient Population –**
Pediatric (29 days or older) through adult patients.
**Discussion -**
The patient population is the same for the proposed modified device and the predicates. The pediatric population is defined as 29 days or older for both the modified device and predicates.

**Environment of Use –**
The Aerogen® Solo Nebulizer System is intended for use in critical, acute, and sub-acute care settings, and during patient transport [Hospital].

The Aerogen® USB Controller System incorporating the Aerogen® Solo Nebulizer is intended for use in the hospital and homecare environments (on-vent only in the homecare environment).
**Discussion –**
The environment of use is the same for the proposed modified device and the predicate 510 (k)'s.

**Technology –**
The Aerogen® Solo Nebulizer technology consists of a domed vibrating mesh aperture plate, which receives liquid medication on its top surface. The plate vibrates and extrudes the liquid through the plate. It forms a fine droplet mist to create the characteristic aerosol. The fine particle mist enables drugs to be absorbed through the lungs while maintaining their integrity, providing a unique level of efficiency for the acute respiratory care market.

**Discussion –**
The technology is the same for the proposed modified device and the predicate and reference.

**Biocompatibility of Patient Contacting Materials –**
The materials in patient / drug contact are characterized as:

- External Communicating (Indirect gas pathway)
- Tissue / Bone / Dentin communicating
- Duration of Use – permanent (> 30 days)

**Discussion -**
Aerogen performed biocompatibility testing as listed in **Table 1** and the results were acceptable for the intended use.

**Comparative Performance and Specifications**

Comparative bench testing supported that the modification to the Nebulizer is equivalent to the predicate. See **Table 2** above.

**Discussion of Differences and Substantial Equivalence Conclusion**

The performance testing and comparison of the indications for use, performance specifications to the predicate and reference demonstrate that the proposed modification to the Aerogen® Solo Nebulizer are substantially equivalent.