December 3, 2020

AireHealth Inc.
% Jessica Czamanski
Project Engineer
Regulatory and Quality Solutions, LLC
2790 Mosside Blvd #800
Monroeville, Pennsylvania 15146

Re: K201167
Trade/Device Name: AireHealth™ Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: November 2, 2020
Received: November 3, 2020

Dear Jessica Czamanski:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Brandon L. Blakely, Ph.D.
Acting Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K201167

Device Name
AireHealth™ Nebulizer

Indications for Use *(Describe)*
The AireHealth™ Nebulizer electronic vibrating mesh nebulizer is designed to nebulize liquid medications for inhalation by a patient. The AireHealth™ Nebulizer may be used in adults or children 5 years of age and older. The AireHealth™ Nebulizer is a portable Nebulizer for use in and out of the home environment.

The AireHealth™ Nebulizer is not intended as a life sustaining or life-supporting device.

The AireHealth™ Nebulizer is not intended for use with Pentamidine.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## 510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92 on December 3rd, 2020.

### I. Submitter

| | |
|---|---|
| Submitter's Name: | AireHealth Inc. |
| Contact Person: | Rusty Kelly<br>Head of Quality and Regulatory |
| Address: | 3251 Progress Dr., Suite F<br>Orlando, FL 32826 |
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| Email: | rusty.kelly@aire.health |

### II. Application Correspondent

| | |
|---|---|
| Contact's Name: | Regulatory and Quality Solutions, LLC. |
| Contact Person: | Jessica Czamanski<br>Regulatory Consultant |
| Address: | 2790 Mosside Blvd #800<br>Monroeville, PA 15146 |
| Telephone: | (877) 652-0830 ext. 208 |
| Email: | jczamanski@rqteam.com |

### III. Device

| | |
|---|---|
| Trade Name: | AireHealth™ Nebulizer |
| Common Name: | Nebulizer |
| Classification Name: | Nebulizer (Direct Patient Interface) |
| Product Classification: | Class II |
| Regulation Number: | 868.5630 |
| Product Code: | CAF |

## IV. Predicate Device

MicroVapor Devices POCKET NEB, K142541 (MicroVapor Devices) FDA cleared on 01/22/2016.

## V. Device Description

The AireHealth™ Nebulizer, model AH-04, is a portable electronic vibrating mesh nebulizer is designed to nebulize liquid medications for inhalation by a patient in and out of the home environment. The Nebulizer may be used in adults or children 5 years of age and older.

The AireHealth™ Nebulizer vibrating mesh nebulizer incorporates a piezoelectric transducer that vibrates at a nominal frequency (115kHz) when electrical current is applied. The vibration of the transducer is transmitted to a metal alloy mesh vapor disk that contains approximately 5,000 holes that are in contact with the liquid to be nebulized. An electrical charge applied to the piezoelectric transducer, in turn, leads to vibration (inward and outward movement of the mesh vapor disk), passing the liquid through the holes to form an aerosol. The AireHealth™ Nebulizer is battery operated. The handset in the AireHealth™ Nebulizer has a use life of 3 years.

Liquid medication is placed in the medicine cup which should be cleaned after every use. The medicine cup should be replaced every 90 days.

The Nebulizer is capable of providing use and status information to a companion application wirelessly via Bluetooth connection. The companion application is an optional accessory for displaying purposes only and will not allow operation or control of the nebulizer. The companion application is not a medical device.

## VI. Intended Use and Indications for Use

The AireHealth™ Nebulizer electronic vibrating mesh nebulizer is designed to nebulize liquid medications for inhalation by a patient. The AireHealth™ Nebulizer may be used in adults or children 5 years of age and older. The AireHealth™ Nebulizer is a portable Nebulizer for use in and out of the home environment.

The AireHealth™ Nebulizer is not intended as a life sustaining or life-supporting device.

The AireHealth™ Nebulizer is not intended for use with Pentamidine.

## VII. Comparison of Technological Characteristics with the Predicate Devices

The proposed and predicate devices are nebulizers used to nebulize liquid medications for inhalation by a patient.

The following table (**Table 7-1**) provides an overview of general technological characteristics in comparison to the predicate device.

**Table 7-1: General Technological Characteristics Comparison**

| Product Features | Proposed<br>AireHealth™ Nebulizer | Predicate<br>MicroVapor Devices POCKET NEB<br>(K142541) |
|---|---|---|
| **Classification** | Class II | -same- |
| **Product Code** | CAF | -same- |
| **Regulation Number** | §868.5630 | -same- |
| **Regulation Name** | Nebulizer | -same- |
| **Intended Use** | The AireHealth™ Nebulizer electronic vibrating mesh nebulizer is designed to nebulize liquid medications for inhalation by a patient. The AireHealth™Nebulizer may be used in adults or children 5 years of age and older. The AireHealth™ Nebulizer is a portable Nebulizer for use in and out of the home environment.<br>The AireHealth™ Nebulizer is not intended as a life sustaining or life-supporting device.<br>The AireHealth™ Nebulizer is not intended for use with Pentamidine. | The Model, MVD-70, POCKET NEB electronic vibrating mesh nebulizer is designed to nebulize liquid medications fir inhalation by a patient. The POCKET NEB may be used by children or adults. The POCKET NEB is a portable unit for use in and out of the home environment.<br>The POCKET NEB is not intended as a life sustaining or life-supporting device.<br>The POCKET NEB is not intended for use with Pentamidine. |
| **Indications for Use** | The AireHealth™ Nebulizer electronic vibrating mesh nebulizer is designed to nebulize liquid medications for inhalation by a patient. The AireHealth™Nebulizer may be used in adults or children 5 years of age and older. The AireHealth™ Nebulizer is a portable Nebulizer for use in and out of the home environment.<br>The AireHealth™ Nebulizer is not intended as a life sustaining or life-supporting device.<br>The AireHealth™ Nebulizer is not intended for use with Pentamidine. | The Model, MVD-70 POCKET NEB electronic vibrating mesh nebulizer is designed to nebulize liquid medications for inhalation by a patient. The POCKET NEB may be used in adults or children 2 years of age and older. The POCKET NEB is a portable unit for use in and out of the home environment.<br>The POCKET NEB is not intended as a life sustaining or life-supporting device.<br>The POCKET NEB is not intended for use with Pentamidine.<br>Labeling for this device in accordance with FDA regulations and will read:<br>“Federal Law Restricts This devices to sale By Or On the Order of A Physician” |
| **Environment of Use** | In Home or Out of Home Use | -same- |

**Table 7-1: General Technological Characteristics Comparison**

| Product Features | Proposed<br>AireHealth™ Nebulizer | Predicate<br>MicroVapor Devices POCKET NEB<br>(K142541) |
|---|---|---|
| **Principle of Operation** | The AireHealth™ Nebulizer vibrating mesh nebulizer incorporated a piezoelectric transducer that vibrates at a frequency (115kHz) when electrical current is applied. The vibration of the transducer is transmitted to a metal allow mesh vapor disk that contains approximately 5,000 holes that are in contact with the liquid to be nebulized. An electrical charge applied to the piezoelectric transducer, in turn, leads to vibration (inward and outward movement of the mesh vapor disk), passing the liquid through the holes to form an aerosol. AireHealth™ Nebulizer is battery operated. | The MVD-70, POCKET NEB vibrating mesh nebulizer incorporated a piezoelectric transducer that vibrates at a frequency (115kHz) when electrical current is applied. The vibration of the transducer is transmitted to a metal allow mesh vapor disk that contains approximately 5,000 holes that are in contact with the liquid to be nebulized. An electrical charge applied to the piezoelectric transducer, in turn, leads to vibration (inward and outward movement of the mesh vapor disk), passing the liquid through the holes to form an aerosol. The POCKET NEB is battery operated. |
| **User Profile** | Children 5 years of age or older and adults | Children 2 years of age or older and adults |
| **Use Life Nebulizer** | 3 years | 1 year |
| **Use Life Medcup** | 90 days | 45 days |
| **Materials (patient-contacting)** | Mouthpiece: polyethylene<br>Handset: polycarbonate | -same- |
| **Nebulization Rate** | 0.25mL/min minimum | -same- |
| **Single Use** | Single Patient Use | -same- |
| **Power Supply** | Rechargeable Li Ion battery | -same- |
| **Operating Temperature** | 5°C to 38°C | 5°C to 40°C |
| **Operating Humidity** | 15% to 90% Relative Humidity | 15% to 93% Relative Humidity |
| **Companion Application Connectivity** | Optional connectivity via Bluetooth | N/A |

## VIII. Non-Clinical Data

The following performance data was considered in support of the substantial equivalence determination.

**Biocompatibility**

The proposed AireHealth™ Nebulizer is manufactured by MicroVapor Devices using the same components and materials cleared under K142541. An authorization letter from MicroVapor Devices, granting authorization to AireHealth Inc. to use the biocompatibility information within submission K142541 is included within the biocompatibility section of this submission. The latter includes cytotoxicity, sensitization, and irritation testing per ISO 10993-1, as well as an assessment to demonstrate compliance to the ISO 18562 standard series, including volatile organic compounds, particulate testing, and extractables and leachables testing ..

**Software Verification and Validation Testing**

The proposed AireHealth™ Nebulizer contains firmware which was subjected to software verification testing and cybersecurity assessment.

**Electrical Safety and Electromagnetic Compatibility (EMC)**

Electrical Safety in compliance with IEC60601-1 and IEC 60601-1-11 and EMC testing in compliance with IEC 60601-1-2 have been completed for the AireHealth™ Nebulizer.

**Performance Testing – Bench**

The following tests were performed to demonstrate that the proposed AireHealth™ Nebulizer met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards.

- Use Life Testing for Medication Cup and Handset was performed to demonstrate the handset has a use life of 3 years and the medication cup has a use life of 90 days. Respectively, these components were subjected to continuous use, equivalent to maximum possible use during a 3-year and 90-day period.
- Usability Testing was completed to demonstrate compliance with IEC 60601-1-6.
- Bluetooth Testing was performed to demonstrate successful pairing.
- Cascade Impactor Testing from the predicate device was leveraged through a comparative analysis, demonstrating identicality of critical components among subject and predicate devices.
- Delivery and Residual Volume Testing were performed to demonstrate delivery rate among subject and predicate devices.
- Cleaning Validation was performed to demonstrate functionality is not affected after maximum number of cleaning cycles.
- Battery Capacity and Delivery Rate Testing was performed to ensure battery power allows for appropriate delivery rate and time of use as stated in the device IFU.

**Performance Testing – Animal**

This submission does not include any animal performance testing. It was determined that no such testing was required to demonstrate substantial equivalence.

**Performance Testing – Clinical**

This submission does not include any clinical performance testing. It was determined that no such testing was required to demonstrate substantial equivalence.

## IX. Conclusion

The proposed AireHealth™ Nebulizer has the same intended use, environment, materials, operating principle, and fundamental technology as the predicate device. The differences in technology allow the subject device to connect to an optional, diary companion application via Bluetooth connectivity. Therefore, the information provided in this submission supports substantial equivalence of the subject device to its predicate for its intended use.