12/10/2021

Fisher & Paykel Healthcare Limited
Reena Daken
Regulatory Affairs Market Manager
15 Maurice Paykel Place, East Tamaki
Auckland, 2013
New Zealand

Re: K211560
Trade/Device Name: Airvo Nebulizer Adapter
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: November 12, 2021
Received: November 12, 2021

Dear Reena Daken:

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 Blakely
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211560

Device Name
Airvo Nebulizer Adapter

Indications for Use *(Describe)*
Indications for use - AIRVO nebulizer adapter:
When used with a nebulizer:
The nebulizer adapter is a medical device accessory for single-patient use to facilitate aerosolization of Albuterol sulfate for inhalation to adult patients receiving high-flow humidified breathing gases via tracheostomy patient interface.
Intended for use by healthcare professionals in hospitals or long-term care facilities.
When used without a nebulizer:
For use in hospitals and long-term care facilities, for the delivery of humidified respiratory gases to patients via nasal, tracheostomy and mask interfaces.

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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510(k) Summary

As Required by 21 CFR 807.92(c)

I. SUBMITTER

Company Name and Address	Fisher & Paykel Healthcare Limited 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	10 December 2021

II. SUBJECT DEVICE

Name of Device	Airvo Nebulizer Adapter
Common/Usual Name	Airvo Nebulizer Adapter
Classification Name	Nebulizer (Direct Patient Interface) Class II (21 CFR §868.5630)
Product Code	CAF

III. PREDICATE DEVICE

Aeroneb Solo Nebulizer System / Aeroneb Solo Adapter (K133360)

IV. DEVICE DESCRIPTION

The Airvo Nebulizer Adapter (hereafter named "nebulizer adapter") is a single use accessory device designed to facilitate aerosolization of a physician-prescribed solution for inhalation to patients receiving high flow humidified breathing gases. The nebulizer adapter is a prescription-only accessory device, provided in a non-sterile state.

The nebulizer adapter is kitted with the AirSpiral tube and MR290 humidification chamber cleared in K162553, to be used in conjunction with Airvo series humidifiers (K131895) along with patient interfaces cleared in K162553.

The device is labelled for use with Salbutamol/ Albuterol only.

V. INDICATIONS FOR USE

Indications for use - AIRVO nebulizer adapter:

When used with a nebulizer:
The nebulizer adapter is a medical device accessory for single-patient use to facilitate aerosolization of Albuterol sulfate for inhalation to adult patients receiving high-flow humidified breathing gases via tracheostomy patient interface. Intended for use by healthcare professionals in hospitals or long-term care facilities.
When used without a nebulizer:
For use in hospitals and long-term care facilities, for the delivery of humidified respiratory gases to patients via nasal, tracheostomy and mask interfaces.

VI. NON-CLINICAL PERFORMANCE DATA

The following tests were completed:

- Shelf life simulation was based on ASTM F1980-07, and ISO 291:2008(E).
- Transportation simulation was based on ISTA 2A Packaged-Products weighing 150lb (68kg) or less.
- Additional performance testing has also been completed to confirm the safety and effectiveness of the nebulizer adapter.
    - Nebulizer performance testing to demonstrate that nebulizing performance is equivalent when using an Airvo nebulizer adapter to when using an Aerogen T-piece.
    - Testing to verify that the Airvo system meets the requirements of ISO 80601-2-74 when used with the nebulizer adapter
    - Testing to establish that the usability of the Airvo nebulizer adapter is safe and effective for its intended users, uses, and use environments.
    - Testing to verify that the wear and stresses associated with the distribution of the packaged product does not cause damage to either the product or packaging.
    - Testing to verify that nebulization via the Airvo nebulizer port does not adversely affect the Airvo 2 or AirSpiral tube.
    - Testing to verify that the port cap will stay in place and not fall out of the nebulizer port during use with the Airvo 2 system
    - Testing to measure the total volume of condensate, with the potential to reach the patient, that forms over 24 hours in an Airvo system when used with the Airvo nebulizer adapter.

The Airvo Nebulizer Adapter has been tested to applicable requirements of the following standards:

- ISO 80601-2-74 Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications, Part 1: Evaluation and testing within a risk management process.

VII. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

Feature/Function	**Subject Device** **Nebulizer Adapter**	**Predicate Device** **Aerogen T-piece (cleared as part of Aerogen Solo system K133360)**	**Comments**
Product Code Device Classification Classification Panel	CAF Class II (21 CFR §868.5630) Anesthesiology	CAF Class II (21 CFR §868.5630) Anesthesiology	Identical
Intended Use	Used for attaching a nebulizer system to a breathing circuit to allow the delivery of nebulized medication	Used for attaching a nebulizer system to a breathing circuit to allow the delivery of nebulized medication	Identical
Indications for Use	**Indications for use - AIRVO nebulizer adapter:** When used with a nebulizer: The nebulizer adapter is a medical device accessory for single-patient use to facilitate aerosolization of Albuterol sulfate for inhalation to adult patients receiving high-flow humidified breathing gases via tracheostomy patient interface. Intended for use by healthcare professionals in hospitals or long-term care facilities. When used without a nebulizer: For use in hospitals and long-term care facilities, for the delivery of humidified respiratory gases to patients via nasal, tracheostomy and mask interfaces.	*As the Aerogen T-piece was cleared as part of the Aerogen Solo system K133360, it does not have its own Indications for Use statement.* *The Indications for Use statement of the Aerogen Solo system is:* The Aerogen 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.	Equivalent to predicate Both, the subject device and predicate have the same general intended use: to be used with an Aerogen Solo nebulizer to introduce nebulized drug into a respiratory breathing circuit, however, only Salbutamol/Albuterol can be delivered through this adapter.
Availability	Prescription use. (Part 21 CFR 801 Subpart D)	Prescription use. (Part 21 CFR 801 Subpart D)	Identical

Feature/Function	**Subject Device** **Nebulizer Adapter**	**Predicate Device** **Aerogen T-piece (cleared as part of Aerogen Solo system K133360)**	**Comments**
Application	Nebulization within a humidified high flow therapy system	Nebulization within a non-specific breathing support system	Equivalent to predicate. The subject device functions within a subset of the predicate device.
Environment of Use	Hospital	Hospital	Identical
Connection to breathing circuit	Airvo nebulizer adapter has proprietary connectors	T-piece with 22mm ISO medical tapers (Male inlet and Female outlet)	The subject device is proprietary to the Airvo system while the predicate is a T-piece able to be connected to any breathing circuit.
Nebulizer port orientation when attached to a humidification chamber	Nebulizer port at 15° above horizontal	Nebulizer port at 15° above horizontal	Identical
Position in circuit	Wet side of humidification chamber in single-limb circuit	End of inspiratory limb in a dual-limb circuit or dry side of humidification chamber in a single-limb circuit	The subject device functions within a subset of the predicate device (subject device has no dual-limb configuration). Comparative testing done on the two systems shows equivalence between the drug delivery to the patient on both systems, when predicate is tested with “dry side of humidification chamber” nebulizer positioning as per predicate Instructions For Use.
Sterility	Device not provided sterile	Device not provided sterile	Identical
Reusability	Single use	Single use	Identical
Maximum duration of use with nebulized drugs	7 days continuous use	7 days continuous use	Identical
Shelf life	3 years	Not specified	Shelf life is not specified for the predicate

Feature/Function	**Subject Device** **Nebulizer Adapter**	**Predicate Device** **Aerogen T-piece (cleared as part of Aerogen Solo system K133360)**	**Comments**
Flow path gas flow range when nebulizing albuterol via a tracheostomy	10 – 30 L/min	Not defined	Flow range is not defined for predicate device
Flow path gas pressure range	Less than 25 cm H_2O	Less than 90 cm H_2O	The subject device's pressure range is within the pressure range of the predicate
On-label Drugs for Delivery	Salbutamol/Albuterol only	General purpose nebulizer	The on-label drugs for use with the subject device is a subset of the drugs for use on the predicate device.
Respirable dose (1 - 5 µm) when nebulizing albuterol via a tracheostomy	From 2500 µg nebule: 10 L/min – 1293.1 µg 20 L/min – 949.5 µg 30 L/min – 612.6 µg	From 2500 µg nebule: 10 L/min – 1339.3 µg 20 L/min – 991.8 µg 30 L/min – 624.4 µg When nebulizer placed on dry side of humidification chamber	Equivalent to predicate
Median Mass Aerodynamic Diameter (MMAD) when nebulizing albuterol via a tracheostomy	10 L/min – 2.80 µm 20 L/min – 2.73 µm 30 L/min – 2.54 µm	10 L/min – 2.55 µm 20 L/min – 2.63 µm 30 L/min – 2.59 µm When nebulizer placed on dry side of humidification chamber	Equivalent to predicate
Compatibility with Tracheal Patient Interface	Yes, Trache patient interface (OPT970)	Yes, when patient intubated through a trachea interface	Equivalent to predicate

VIII. ACCESSORIES

Port Cap Open and Nebulizer Fitted	Port Cap Closed
When the Port Cap is OPEN, and an Aerogen Solo nebulizer is fitted and used to deliver nebulized albuterol, the Airvo Nebulizer Adapter will be compatible with the following patient interface: • OPT970 tracheostomy interface	When the Port Cap is CLOSED, and only warmed/humidified air/oxygen mixtures are delivered to the patient WITHOUT nebulized medication, the Airvo Nebulizer Adapter will be compatible with the following patient interfaces: • OPT970 tracheostomy interface • OPT942/OPT944/OPT946 Nasal Cannulas • OPT316/OPT318 Nasal Cannulas • OPT980 Mask Interface Adapter

IX. CONCLUSIONS

The comparison of features, performance, and intended use demonstrate that the Airvo nebulizer adapter is substantially equivalent to the predicate Aerogen T-piece (K133360). In addition, performance testing of the nebulizer adapter was completed to determine that the differences between the subject device and the predicate device do not raise new questions of safety or effectiveness. These tests demonstrate substantial equivalence of the nebulizer adapter to the predicate device.