DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 17, 2017

Carefusion/Vyaire Medical, Inc.
Colleen O'Keeffe
Acting Director, Regulatory Affairs
26125 Riverwoods Blvd
Mettawa, IL 60045

Re: K153748
Trade/Device Name: AirLife™ Misty Finity™ Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: April 12, 2017
Received: April 17, 2017

Dear Colleen Okeeffe:

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" (21 CFR 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153748

Device Name
AirLife™ Misty Finity™ Nebulizer

Indications for Use *(Describe)*
The Misty Finity is a nebulizer designed for administration of aerosolized drug to the respiratory system. Misty Finity may be used with pediatric (ages 2 years and above) and adult patients. The product is single patient use device, non-sterile and used in professional healthcare environments under a doctor's supervision and by skilled clinician.

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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510K Summary

1. Submitter

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Phone: (224) 706-6818

Contact Person: Colleen O'Keeffe
Acting Director, Regulatory Affairs

Date Prepared: May 16, 2017

2. Device

Trade name	AirLife™ Misty Finity™ Nebulizer
Common Name:	Small Volume Nebulizer
Classification Name:	Nebulizer 21 CFR 868.5630
Regulatory Class:	II
Product Code:	CAF

3. Predicate Device

Uni-HEART K943600 cleared on 10/13/1994.

4. Device Description

The Misty Finity nebulizer is a small volume nebulizer designed to deliver continuous aerosolized drugs to the respiratory system over extended periods of time. The Misty Finity is a single patient use device, and may be used for multiple treatments. The nebulizer is filled with a liquid, typically respiratory medication and connected to the air source via flexible tubing operating between 2 LPM and 4 LPM. The nebulizer is disassembled and reassembled after adding the medication in the bottom (reservoir), and then the device is reassemble in a snap fit. The Misty Finity consists of three components: nebulizer top, one-piece jet, and nebulizer bottom. The Nebulizer is marketed with oxygen tubing and an adult aerosol mask. Both tubing and mask are single-use accessories. The pediatric aerosol mask can be ordered online/from the company website.

5. Principal of Operation

The nebulizer works by having the fluid come into contact with the stream of gas. The gas shatters the liquid into small particles (approximately 15-500 microns in size). These particles then impact a baffle that further reduces the size of the particles (< 15 microns). The majority of larger particles settle inside the nebulizer as a result of gravity and inertia, returning the mist to liquid to repeat the nebulization process. The smaller

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particles (<5 microns) are then administered as the patient inhales. The treatment is completed when the majority of fluid is nebulized.

6. Indication for use

The Misty Finity is a nebulizer designed for administration of aerosolized drug to the respiratory system. Misty Finity may be used with pediatric (ages 2 years and above) and adult patients. The product is single patient use device, non-sterile and used in professional healthcare environments under a doctor's supervision and by skilled clinician.

7. Comparison of technological characteristics with the predicate device

Element of comparison	Proposed Device K153748	Predicate Device K943600	Comparison Assessment
Indications for Use	The Misty Finity is a nebulizer designed for administration of aerosolized drug to the respiratory system. Misty Finity may be used with pediatric (ages 2 years and above) and adult patients. The product is single patient use device, non-sterile and used in professional healthcare environments under a doctor's supervision and by skilled clinician.	The proposed device is intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing for all patients' populations requiring nebulized medications.	Although worded differently, the indications for use (IFU) statements identify the same: 1) principle of operation (i.e., both devices aerosolize drugs so they can be delivered to the respiratory system) and 2) both devices are intended for all populations requiring nebulized medications (i.e., ages 2 years and above) and adults). Although not stated in the predicate device IFU, both devices are: 1) single use (see discussion below), 2) are provided non-sterile and 3) are prescription products which require that they are used in professional healthcare environments under a doctor's supervision and by skilled clinician. The difference in verbiage in the IFU for the Misty Finity Nebulizer and the predicate device does not present any new questions of safety and effectiveness.
Principle of Operation	Pneumatic Jet	Pneumatic Jet	Same
Characteristics			
Flow rates	2-4 LPM	2-4 LPM	Same
Maximum Fill Capacity (capacity of medication cup)	10 ml	10 ml	Same
Shelf life	11 months	unknown	The Shelf-life and the Useful Life

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Element of comparison	Proposed Device K153748	Predicate Device K943600	Comparison Assessment
Useful life	48 hours	unknown	of the predicate device has not been published. The real-time aging and Biocompatibility testing of the subject device support the indicated Shelf-life and Useful life and do not present any new questions of safety and effectiveness.
Type of the device	Disposable Single patient use Non sterile	Disposable Single use Non sterile	The predicate device labeling indicates that it is single use (i.e., used once). Misty Finity is a single patient use device (i.e., the same patient may use it more than once). The cleaning validations of the subject device support substantial equivalence without posing any new questions of safety and effectiveness.
Type of gas source	Compressed air or oxygen	Compressed air or oxygen	Same

8. Performance Data

The proposed device was tested to ensure compliance to the following standards:

8.1 Performance Testing

Performance Characteristic	Standard
Products for Nebulization – Characterization Test	USP 38 <601>

Aerosol Characterization using 7- stage Cascade Impaction (NGI) for three common aerosolized medications [1]

Drug Description	Aerosol Characteristics	2 lpm		4 lpm	
		(mean ± 95% CI)		(mean ± 95% CI)	
Albuterol Sulfate: 2.5 mg/ 3 ml	MMAD (µm) [2]	3.4 ± 0.3		2.7 ± 0.3	
	GSD [3]	2.8 ± 0.2		2.6 ± 0.1	
	Units	% (mass) [4]	µg [5]	% (mass) [4]	µg [5]
	Particles (≤ 1 µm)	15.7 ± 2.9	523 ± 96	18.4 ± 2.7	1531 ± 184
	Particles (1-5 µm)	46.6 ± 2.9	1553 ± 96	52.8 ± 2.0	4400 ± 168
	Particles (≤ 5 µm)	62.3 ± 3.3	2076 ± 109	71.2 ± 3.2	5931 ± 263
	Particles (≥ 5 µm)	37.7 ± 3.3	1258 ± 109	28.8 ± 3.2	2402 ± 263
	Total Mass of Drug in Nebulizer (µg) [6]	3333		8333	

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	Calculated Time to Deliver 100% of Dose (minutes) [7,8]	94 ± 12		104 ± 10	
Budesonide Suspension: 0.5 mg/ 2 ml	MMAD (µm)	3.8 ± 0.3		4.2 ± 0.2	
	GSD	3.1 ± 0.2		2.4 ± 0.2	
	Units	% (mass) [4]	µg [5]	% (mass) [4]	µg [5]
	% Particles (≤ 1 µm)	16.2 ± 1.4	162 ± 14	14.5 ± 1	361 ± 24
	% Particles (1-5 µm)	38.7 ± 1.3	387 ± 13	40.6 ± 2.1	1015 ± 53
	% Particles (≤ 5 µm)	54.9 ± 1.6	549 ± 16	55.1 ± 2	1377 ± 50
	% Particles (≥ 5 µm)	45.1 ± 1.6	451 ± 16	44.9 ± 2	1123 ± 50
	Total Mass of Drug in Nebulizer (µg) [6]	1000		2500	
	Calculated Time to Deliver 100% of Dose (minutes) [7]	73 ± 8		91 ± 13	
Cromolyn Sodium: 20 mg/ 2 ml	MMAD (µm)	2.3 ± 0.3		3.6 ± 0.4	
	GSD	3.5 ± 0.3		2.5 ± 0.1	
	Units	% (mass) [4]	µg [5]	% (mass) [4]	µg [5]
	% Particles (≤ 1 µm)	16.7 ± 2.3	6693 ± 924	23 ± 2.4	22953 ± 2386
	% Particles (1-5 µm)	51.9 ± 2.9	20751 ± 1152	38.5 ± 2	38545 ± 1618
	% Particles (≤ 5 µm)	68.6 ± 4.9	27444 ± 1956	61.5 ± 3.5	61498 ± 3522
	% Particles (≥ 5 µm)	31.4 ± 4.9	12556 ± 1956	38.5 ± 3.5	38502 ± 3522
	Total Mass of Drug in Nebulizer (µg) [6]	40000		100000	
	Calculated Time to Deliver 100% of Dose (minutes) [7]	117 ± 16		108 ± 10	

[1] Performance data using Cascade Impactor (NGI) per USP 35 <1601> chilled to 5 °C with an extraction flow of 15 L/min for three commonly aerosolized medications. Values represent the Mean and 95% confidence interval of the mean.
[2] MMAD is Mass Median Aerodynamic Diameter.
[3] GSD is Geometric Standard Deviation.
[4] Values are the percent (by mass) of drug substance delivered in the specified range of aerosol particles.
[5] Values are the total drug mass in nebulizer, multiplied by the % (mass) for each micron range. This assumes 100% dose delivery and represents the theoretical maximum drug mass for a given micron range.
[6] Total Mass of Drug in Nebulizer is the mass of drug substance placed in the nebulizer cap for dose listed. At the drug concentrations specified, these drug masses equate to a 4 ml fill volume for 2 lpm, and a 10 ml fill volume for 4 lpm.
[7] Calculated by dividing the Total Mass of Drug in Nebulizer, by the Drug Delivery Rate. This is a theoretical calculation which assumes 100% dose delivery.
[8] Calculated time to deliver 100% of 3 ml dose of Albuterol sulfate at 2.5 mg/3 ml concentration:

- 68 minutes @ 2 lpm
- 30 minutes @ 4 lpm

The aerosol characterization testing with the adult and pediatric face mask demonstrated that the proposed device performance is equivalent to the predicate device.

8.2 Biocompatibility

Tests for an externally communicating, tissue by way of gas path and direct mucosal contact with prolonged contact (greater than 24 hours but less than 30 days): Cytotoxicity, Sensitization, Irritation, Muscle Implantation, Genotoxicity and Extractables/Leachables.

Performance Characteristic	Standard
Biological Evaluation of Medical Devices–Part 1: Evaluation and Testing	AAMI/ANSI/ISO 10993-1:2009

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Performance Characteristic	Standard
Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	AAMI/ANSI/ISO 10993-3:2009 (R2014)
Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity	AAMI/ANSI/ISO 10993-5:2009 (R2014)
Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	AAMI/ANSI/ISO 10993-6:2009 (R2014)
Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization.	AAMI/ANSI/ISO 10993-10:2010 (R2014)
Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	AAMI/ANSI/ISO 10993-11:2006 (R2010)
Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	AAMI/ANSI/ISO 10993-12: 2012
Biological Evaluation of Medical Devices Part 17: Establishment of allowable limits for leachable substances	AAMI/ANSI/ISO 10993-17:2002
Biological Evaluation of Medical Devices Part 18: Chemical characterization of materials	AAMI/ANSI/ISO 10993-18:2005

9. Conclusion

The non-clinical data demonstrate that the Misty Finity nebulizer is as safe and as effective as the predicate and therefore substantially equivalent to the predicate device.