DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 2, 2017

Convexity Scientific LLC
% Susan Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K162041
Trade/Device Name: Airworks™ Nebulizer pe1200m
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: March 29, 2017
Received: March 30, 2017

Dear Ms. Goldstein-Falk:

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,

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)*
K162041

Device Name

Airworks™ Nebulizer pe1200m

Indications for Use *(Describe)*

The Airworks™ Nebulizer pe1200m, for use by adolescent and adult patients, is intended to aerosolize healthcare provider-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer. Airworks™ Nebulizer pe1200m is intended for use at home or a medical facility, such as a hospital or doctor's office.

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
K162041

Convexity Scientific LLC
36 Church Lane
Westport, CT 06880
Tel: (203) 557-6254

Date: May 1, 2017

Official Contact: Paul Reiferson—President

Proprietary or Trade Name: Airworks™ Nebulizer pe1200m

Common/Usual Name: Nebulizer

Classification Name/Code: CAF, Class 2, Nebulizer
CFR 868.5630

Predicate Device: Aerogen, Inc.—Aeroneb® Go Nebulizer—K032849

Device Description

The Airworks™ Nebulizer pe1200m, for use by adolescent and adult patients, is intended to aerosolize healthcare provider-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer.

The Airworks™ Nebulizer pe1200m uses a vibrating mesh technology, which is comprised of a medical-grade stainless steel disk containing 1,000 precision-formed holes. When energy is applied, the disk vibrates approximately 110,000 times per second. This rapid vibration causes a difference in pressure on either side of each aperture, drawing liquid through the holes to form consistently sized droplets.

The Airworks™ Nebulizer pe1200m is lightweight, compact and virtually silent. A rechargeable lithium-ion battery powers the device.

Indications for Use

The Airworks™ Nebulizer pe1200m, for use by adolescent and adult patients, is intended to aerosolize healthcare provider-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer. Airworks™ Nebulizer pe1200m is intended for use at home or a medical facility, such as a hospital or doctor's office.

Comparison and Equivalence of Proposed Device and Predicate Device

Features	Proposed Device	Predicate Device (K032849)	Substantially Equivalent (SE) or Different
Device Name	Airworks™ Nebulizer pe1200m	Aeroneb® Go nebulizer	
510(k) Number	K162041	K032849	
Indications for use	The Airworks™ Nebulizer pe1200m, for use by adolescent and adult patients, is intended to aerosolize clinician-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer. Airworks™ Nebulizer pe1200m is intended for use at home or a medical facility, such as a hospital or doctor's office.	The Aeroneb® Go nebulizer, for use by pediatric and adult patients, is intended to aerosolize physician-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer.	SE
Target Population	Adolescent to adult	Pediatric to adult	Different
Mode of Operation			
Energy Source	Lithium-ion battery (rechargeable) 3.7 VDC, 500mA	Battery—3 "AA" disposable or rechargeable batteries, 4.5 VDC, 350 mA	Different
Anatomical Site	Mouth	Mouth	SE
Mode of Operation	Piezoelectric/Ultrasonic	Piezoelectric/Ultrasonic	SE
Energy Type	Electricity	Electricity	SE
Nebulizing method	Vibrating mesh	Vibrating mesh	SE
Aerosolization Element	Aperture disk	Aperture disk	SE
Software-driven	No	No	SE
User Interface			
Patient Connector	Mouthpiece	Mouthpiece or optional mask	SE
Patient Interface	Hand-Held	Hand-Held	SE
Use	Single Patient	Single Patient	SE
Physical Description			
Components Cleanable	Yes	Yes	SE
Operating Conditions	5°C to 40°C to 95% RH	5°C to 45°C to 95% RH	SE
Storage Conditions	-10°C to 45°C to 93% RH	-20°C to 60°C to 95% RH	Different
Dimensions (Main Unit)	27 x 119 x 54 mm	40 x 105 x 95 mm	Different
Weight	103 g	325 g	Different
Portable	Yes	Yes	SE
Reservoir (mL)	5 mL	6 mL	Different

Differences Between Proposed Device and Predicate Device

The differences between the proposed device and the predicate device are:

- Energy source: the proposed device uses a rechargeable lithium-ion battery; the predicate device uses 3 "AA" disposable or rechargeable batteries.

- Dimensions and weight: the proposed device is smaller than the predicate device. The smaller size of the proposed device's Main Unit is largely attributable to its internalized mouthpiece, which can be engaged into position when needed. The predicate device also includes a separate control module that uses 3 "AA" batteries, which adds 260 g to its weight.

- Storage conditions: the proposed device uses an IEC 62133-certified, rechargeable lithium-ion battery whose specifications indicate storage conditions of -10ºC to +45ºC. The only component affected by storage temperature is the battery. Conditions for storage and transport were taken into consideration for the selection of materials used in the subject device's construction: namely, a battery that complies with applicable consensus standards.

- Reservoir: the proposed device has a 5mL capacity reservoir; the predicate device has a 6mL capacity reservoir. The proposed device's smaller reservoir mitigates the hazard a patient could inhale two medication ampules in one sitting.

These are not significant differences that affect the safety or effectiveness of the intended device compared to the predicate device.

Substantial Equivalence

The Airworks™ Nebulizer pe1200m is viewed as substantially equivalent to the predicate device because:

Indications for Use—
The indications for use are as a general-purpose nebulizer intended to aerosolize clinician-prescribed solutions for inhalation by adolescent and adult patients.
Discussion—The indications for use statements are nearly identical except for patient population. The subject device's patient population is more restrictive than the predicate device's. Since non-physician clinicians may prescribe nebulizers, we have substituted the word "clinician" for "physician" above. Both devices are indicated for use as a general-purpose nebulizer.

Technology—
Both the proposed and the predicate device use piezoelectric energy to vibrate an element with precisely drilled holes ("vibrating mesh") to create an aerosol. The proposed device uses a different battery technology than the predicate.
Discussion—The particle characterization performance demonstrates that the two devices perform substantially equivalently. The proposed device's battery decreases its weight and, relative to disposable batteries, its long-term cost of use. The battery is IEC 62133-compliant and does not raise new safety issues.

Non-Clinical Testing Summary

Particle characterization —
Comparative particle test results via Cascade Impactor are shown below:

(All data shown at a 95% confidence level)

Characteristic	Airworks™ Nebulizer pe1200m (K162041)			Predicate Device – Aeroneb Go (K032849)		
	Albuterol Sulfate	Ipratropium Bromide	Cromolyn	Albuterol Sulfate	Ipratropium Bromide	Cromolyn
	2.5mg/3ml	0.5mg/2ml	4.0mg/2ml	2.5mg/3ml	0.5mg/2ml	4.0mg/2ml
MMAD (µm)	2.21 - 2.41	2.12 - 2.22	2.15 - 2.37	1.96 - 2.26	1.92 - 2.12	1.65 - 2.17
GSD (µm)	1.53 - 1.67	1.45 - 1.51	1.48 - 1.60	2.04 - 2.50	1.83 - 2.29	1.96 - 2.20
Respirable Particle Fraction (%)	84.2 - 91.4	87.4 - 93.2	83.5 - 92.7	78.8 - 83.2	84.0 - 91.2	76.7 - 86.3
Total Respirable Dose (0.4 - 4.7 µm) (µg)	851.3 - 991.9	194.5 - 224.3	773.3 - 942.1	818.2 - 1031.4	197.3 - 235.3	608.5 - 981.9
Total Delivered Dose (µg)	984.3 - 1093.5	211.6 - 250.1	897.0 - 1019.9	1012.7- 1257.0	221.8 - 270.5	758.7 - 1186.60
Total Coarse Particle Dose (>4.7 µm) (µg)	33.1 - 105.3	3.6 - 11.2	48.5 - 122.9	110.6 - 177.4	17.0- 35.6	66.4 - 171.8
Total Fine Particle Dose (<4.7 µm) (µg)	895.5 - 1043.9	207.1 - 239.7	791.8 - 953.6	891.0 - 1090.8	200.0 - 239.7	665.5 - 1041.5
Total Extra-Fine Particle Dose (<1.0 µm) (µg)	332.9 - 416.9	83.1 - 96.5	309.3 - 404.1	463.5 - 585.4	99.7 - 140.2	411.3 - 573.8
Respirable Drug Delivery Rate (µg/min)	133.5 - 169.1	24.6 - 39.0	147.6 - 169.2	143.5 - 238.5	34.2 - 46.4	133.5 - 213.7

Summary of results –
The Airworks™ Nebulizer pe1200m was found to be substantially equivalent in all performance areas having therapeutic effects except as noted below: differences in GSD and Respirable Particle Fraction (albuterol and cromolyn only) are explained by the subject device's relative outperformance of the predicate. Differences in MMAD within the desired range does not raise new questions of safety and effectiveness. Respirable Drug Delivery Rate (ipratropium only) was slower than the predicate device; however, because this slower rate did not result in a statistically significant difference in either Respirable Particle Fraction, Total Respirable Dose, or Total Delivered Dose, the difference does not raise new questions of safety and effectiveness.

Differences in Total Coarse Particle Dose (for albuterol and ipratropium only) are explained by the subject device's relative outperformance in Total Respirable Dose. Differences in Total Extra-Fine Particle Dose do not raise new questions of safety and effectiveness.

Based on these comparative results, the subject device is substantially equivalent to the predicate device.

Materials—
Materials in patient contact or in the gas pathway were tested in accordance with ISO 10993-1 (2009, Revised 2013) and the results satisfied the requirements. Testing included Ozone, Carbon Monoxide and Carbon Dioxide, VOC, $PM_{2.5}$, Cytotoxicity, Sensitization, Irritation, Ames Assay, Chromosomal Aberration, Mouse Lymphoma, Implantation, and Leachability and Extractability at 50˚C for 72 hours with a complete Risk Assessment.

Non-Clinical Testing (Aerosol Performance)—

- Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators, Cleaning and Disinfection Validation, Office of Device Evaluation, Division of Cardiovascular and Respiratory Devices, October 1, 1993.

Cleaning and Disinfection Validation—

- AAMI / ANSI / ISO 11737-1:2006(R)2011
- ISO / TS 15883-5:2005
- AAMI TIR 12:2010
- AAMI TIR 30:2011
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff, March 17, 2015.

Electromagnetic Compatibility, Electrical Safety and Battery Testing—
The proposed device was tested to comply with the following standards, met all of the acceptance criteria of the tests and no safety or efficacy issues were discovered:

- IEC 62133 (2012)
- IEC 60601-1 (2012)
- IEC 60601-1-11 (2010)
- IEC 60601-1-2 tests evaluated to the requirements in ed4.0 (2014-02)

Substantial Equivalence Conclusion

Convexity Scientific LLC has demonstrated through the performance testing and non-clinical testing discussed above that the proposed device has been found to be substantially equivalent to the predicate. Differences between the proposed device and the predicate do not raise new questions of safety or efficacy.