November 2, 2017

Respironics
Respiratory Drug Delivery (UK) Ltd.
% Paul Dryden
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K170853
Trade/Device Name: InnoSpire Go
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: Class II
Product Code: CAF
Dated: September 29, 2017
Received: October 2, 2017

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 (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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S

for
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)*

K170853

Device Name

InnoSpire Go

Indications for Use *(Describe)*

The InnoSpire Go is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (2 years and older), defined by the prescribed medication, and adults patients in the home environment or in a hospital/clinic setting.

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

XX 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
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2-Nov-17

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Official Contact: Filippo Quadrelli – Project Manager

Proprietary or Trade Name: InnoSpire Go

Common/Usual Name: Nebulizer (Direct Patient Interface)

Classification Name: CAF

Regulation number: 21 CFR 868.5630

Class II

Predicate Device: K081650 – Aerogen AeroNeb nebulizer

Device Description:
The InnoSpire Go nebulizer is a small, handheld, internally powered nebulizer which utilizes vibrating mesh technology to generate aerosol.

Indications for Use:
The InnoSpire Go is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (2 years and older), defined by the prescribed medication and adult patients in the home environment or in a hospital/clinic setting.

Patient Population:
Pediatric (2 years or older), defined by the prescribed medication, and adult patients

Environment of Use:
The InnoSpire Go is intended to be used in home environment or in a hospital/clinic setting.

Contraindications:
None.

Predicate Device Comparison
As indicated the subject device utilizes the vibrating mesh technology of the predicate, K081650 – Aerogen Aeroneb® Go.

The primary differences between the devices is the design related to form factor, otherwise they are very similar. We will present a comparison of the proposed device and a predicate in **Tables 1** to **4** and then discuss the table and any differences.

Table 1 – Substantial Equivalence Comparative Table - Nebulizer

Features	Predicate Aerogen AeroNeb® Go K081650	Proposed InnoSpire Go Nebulizer
Indications for use	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.	The InnoSpire Go is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (2 years and older), defined by the prescribed medication and adult patients in the home environment or in a hospital/clinic setting.
Patient Population	Pediatric and adult patients	
Environment of Use	None specified, but known to be used in the home, hospital, and sub-acute care settings	
Contraindications	None	None
Principle of Operation and rate	Vibrating mesh - Palladium nickel 128 kHz	Vibrating mesh - Palladium nickel 137 KHz
Aerosolization	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation
Compressed gas source	None needed	None needed
Reservoir volume	6 ml	8 ml
Nebulization rate	>0.3 ml/min	>0.45 ml/min
Duration of Use	Home setting Single patient, multi-use	Home and clinical setting Single patient, multi-use
Nebulizer components cleanable	Yes	Yes
Software driven	Yes	Yes
Patient interface	Mouthpiece and multiple size mask	Mouthpiece and 2 mask sizes Internal volume Large – 99 ml Medium (2 yo – 5 yo) – 34 ml
Power source	"AA" battery AC Adapter 100-240 V	Rechargeable battery AC Adapter 100-240 V
Power consumption	< 2 W	< 5 W when charging
Weight	Nebulizer – 65g Control module – 260g (excluding battery)	<130g (including battery)
Dimensions (mm)	Nebulizer - 40 x 105 x 95mm Control module – 70 x 110 x 32mm	46 x 130 x 70mm (approx.)

Features	Predicate Aerogen AeroNeb® Go K081650	Proposed InnoSpire Go Nebulizer
Operating Conditions	5 to 45°C / up to 95%% RH	+5°C to +40°C 15% to 93% RH, non-condensing Atmospheric pressure 70 kPa to 106 kPa
Storage Conditions	-20 to + 60°C / up to 95% RH	-25°C to +70°C, 10% to 93% RH, non-condensing Atmospheric pressure 50 kPa to 106 kPa
User interface	On/Off switch LED indicators	On/Off switch LED indicators
Standards met	ES 60601-1 IEC 60601-1-2	AAMI ANSI ES 60601-1: 2005 +A1: 2012 IEC 60601-1-2:2014 IEC 60601-1-6:2013 IEC 60601-1-1:2015
Performance		
Materials per ISO 10993-1	External Communicating (Indirect gas pathway) Tissue / Bone / Dentin communicating Duration of Use – permanent (> 30 days) And Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days)	External Communicating (Indirect gas pathway) Tissue / Bone / Dentin communicating Duration of Use – permanent (> 30 days) And Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days)

Table 2 – Substantial Equivalence Comparative Table - Face Mask

Face mask	**Reference Device** **K110293** **Optichamber Diamond Valved Holding Chamber** **Respironics New Jersey (Philips)**	**Proposed InnoSpire Go Nebulizer**
Sizes	2	2 It is intended that patient 2 to 5 years old use a face mask
Internal volume	Large – 99 ml Medium (2 yo – 5 yo) – 34 ml	Large – 99 ml Medium (2 yo – 5 yo) – 34 ml

Note the intended face masks are the identical mask cleared under a sister company.

Table 3 – Comparative Aerosol Performance – Adult Flow Rate – 30 lpm
(Values shown are mean and 95% confidence interval)

Parameter	Drug	InnoSpire Go	Aeroneb Go
Delivered dose (µg) *	Salbutamol (5 mg / 2.5 mL)	2370 ± 113	2206 ± 216
	Ipratropium bromide (500 µg / 2 mL)	234 ± 6	229 ± 12
	Sodium cromoglicate (20 mg / 2 mL)	10146 ± 507	9210 ± 500
Mass median aerodynamic diameter / MMAD (µm)	Salbutamol (5 mg / 2.5 mL)	3.90 ± 1.04	4.06 ± 0.47
	Ipratropium bromide (500 µg / 2 mL)	3.87 ± 0.9	3.79 ± 0.20
	Sodium cromoglicate (20 mg / 2 mL)	4.02 ± 0.91	4.15 ± 0.32
Geometric standard deviation / GSD	Salbutamol (5 mg / 2.5 mL)	2.02 ± 0.11	2.00 ± 0.05
	Ipratropium bromide (500 µg / 2 mL)	2.02 ± 0.18	2.06 ± 0.07
	Sodium cromoglicate (20 mg / 2 mL)	2.00 ± 0.18	2.02 ± 0.04
Fine particle fraction <5 µm (%)	Salbutamol (5 mg / 2.5 mL)	61.1 ± 14.4	58.9 ± 7.4
	Ipratropium bromide (500 µg / 2 mL)	61.9 ± 11.4	62.4 ± 2.6
	Sodium cromoglicate (20 mg / 2 mL)	59.6 ± 11.6	56.9 ± 4.5
Fine particle dose <5 µm (µg)	Salbutamol (5 mg / 2.5 mL)	1450 ± 389	1300 ± 198
	Ipratropium bromide (500 µg / 2 mL)	145 ± 30	143 ± 13
	Sodium cromoglicate (20 mg / 2 mL)	6047 ± 1407	5240 ± 358
Coarse particle fraction >5 µm (%)	Salbutamol (5 mg / 2.5 mL)	38.9 ± 14.4	41.1 ± 7.4
	Ipratropium bromide (500 µg / 2 mL)	38.1 ± 11.4	37.6 ± 2.6
	Sodium cromoglicate (20 mg / 2 mL)	40.4 ± 11.6	43.1 ± 4.5
Coarse particle dose >5 µm (µg)	Salbutamol (5 mg / 2.5 mL)	920 ± 315	906 ± 188
	Ipratropium bromide (500 µg / 2 mL)	89 ± 25	86 ± 4
	Sodium cromoglicate (20 mg / 2 mL)	4098 ± 1054	3970 ± 556
Respirable fraction 1 - 5 µm (%)	Salbutamol (5 mg / 2.5 mL)	56.0 ± 11.9	53.8 ± 6.6
	Ipratropium bromide (500 µg / 2 mL)	56.6 ± 9	56.4 ± 1.6
	Sodium cromoglicate (20 mg / 2 mL)	47.9 ± 6.4	43.7 ± 1.7
Respirable dose 1 - 5 µm (µg)	Salbutamol (5 mg / 2.5 mL)	1328 ± 328	1187 ± 185
	Ipratropium bromide (500 µg / 2 mL)	132 ± 24	129 ± 10
	Sodium cromoglicate (20 mg / 2 mL)	4859 ± 790	4023 ± 83
Ultra-fine particle fraction <1 µm (%)	Salbutamol (5 mg / 2.5 mL)	5.2 ± 2.6	5.1 ± 0.9
	Ipratropium bromide (500 µg / 2 mL)	5.4 ± 3.2	6.0 ± 1.0
	Sodium cromoglicate (20 mg / 2 mL)	11.7 ± 5.8	13.2 ± 3.4
Ultra-fine particle dose <1 µm (µg)	Salbutamol (5 mg / 2.5 mL)	123 ± 65	112 ± 16
	Ipratropium bromide (500 µg / 2 mL)	12.6 ± 8	13.7 ± 3
	Sodium cromoglicate (20 mg / 2 mL)	1189 ± 643	1217 ± 304

* determined using a simulated breathing pattern (tidal volume = 500 mL, I:E ratio = 1:1, breaths per minute = 15)

Discussion:

The statistical analysis of comparison showed that there are some statistically significant differences in performance at 95% confidence, but in those cases the InnoSpire Go provided either higher Total Dose; smaller particle size (MMAD and GSD); larger Total Respirable Dose.

For the differences in particle size distributions, their differences reflect the results of the Total Respirable Dose, which was an overall higher dose, thus the Coarse, Fine and Ultra- fine particle data would mirror these results as well.

Overall the results are comparable to the predicate and would support a determination of substantial equivalence.

Table 4 – Comparative Aerosol Performance – Pediatric Flow Rate – 15 lpm
(Values shown are mean and 95% confidence interval)

Parameter	Drug	InnoSpire Go	Aeroneb Go
Delivered dose (µg) *	Salbutamol (5 mg / 2.5 mL)	2370 ± 113	2206 ± 216
	Ipratropium bromide (500 µg / 2 mL)	234 ± 6	229 ± 12
	Sodium cromoglicate (20 mg / 2 mL)	10146 ± 507	9210 ± 500
Mass median aerodynamic diameter / MMAD (µm)	Salbutamol (5 mg / 2.5 mL)	3.99 ± 0.73	4.85 ± 0.77
	Ipratropium bromide (500 µg / 2 mL)	3.93 ± 0.74	5.08 ± 0.48
	Sodium cromoglicate (20 mg / 2 mL)	4.27 ± 0.76	4.87 ± 0.54
Geometric standard deviation / GSD	Salbutamol (5 mg / 2.5 mL)	1.82 ± 0.02	2.10 ± 0.09
	Ipratropium bromide (500 µg / 2 mL)	1.82 ± 0.03	2.09 ± 0.11
	Sodium cromoglicate (20 mg / 2 mL)	1.83 ± 0.05	2.00 ± 0.08
Fine particle fraction <5 µm (%)	Salbutamol (5 mg / 2.5 mL)	64.4 ± 12.2	51.1 ± 9.5
	Ipratropium bromide (500 µg / 2 mL)	65.3 ± 12.3	48.4 ± 5.1
	Sodium cromoglicate (20 mg / 2 mL)	59.8 ± 11.6	51.0 ± 6.7
Fine particle dose <5 µm (µg)	Salbutamol (5 mg / 2.5 mL)	1526 ± 285	1129 ± 324
	Ipratropium bromide (500 µg / 2 mL)	153 ± 29	111 ± 6
	Sodium cromoglicate (20 mg / 2 mL)	6070 ± 1460	4689 ± 375
Coarse particle fraction >5 µm (%)	Salbutamol (5 mg / 2.5 mL)	35.6 ± 12.2	48.9 ± 9.5
	Ipratropium bromide (500 µg / 2 mL)	34.7 ± 12.3	51.6 ± 5.1
	Sodium cromoglicate (20 mg / 2 mL)	40.2 ± 11.6	49.1 ± 6.7
Coarse particle dose >5 µm (µg)	Salbutamol (5 mg / 2.5 mL)	844 ± 305	1076 ± 109
	Ipratropium bromide (500 µg / 2 mL)	81 ± 29	118 ± 18.1
	Sodium cromoglicate (20 mg / 2 mL)	4076 ± 1000	4521 ± 852
Respirable fraction 1 - 5 µm (%)	Salbutamol (5 mg / 2.5 mL)	62.7 ± 11.6	47.2 ± 0.2
	Ipratropium bromide (500 µg / 2 mL)	63.6 ± 11.8	64.3 ± 0.2
	Sodium cromoglicate (20 mg / 2 mL)	58.3 ± 11.2	59.3 ± 11.2
Respirable dose 1 - 5 µm (µg)	Salbutamol (5 mg / 2.5 mL)	1485 ± 270	1042 ± 100
	Ipratropium bromide (500 µg / 2 mL)	149 ± 28	147 ± 8.3
	Sodium cromoglicate (20 mg / 2 mL)	5922 ± 1403	5458 ± 750
Ultra-fine particle fraction <1 µm (%)	Salbutamol (5 mg / 2.5 mL)	1.7 ± 0.6	1.0 ± 0.2
	Ipratropium bromide (500 µg / 2 mL)	1.8 ± 0.6	1.0 ± 0.2
	Sodium cromoglicate (20 mg / 2 mL)	1.5 ± 0.5	0.4 ± 0.4
Ultra-fine particle dose <1 µm (µg)	Salbutamol (5 mg / 2.5 mL)	41 ± 15	23 ± 5
	Ipratropium bromide (500 µg / 2 mL)	4.1 ± 1.4	2.2 ± 0.4
	Sodium cromoglicate (20 mg / 2 mL)	148 ± 58.2	40 ± 36.1

* determined using a simulated breathing pattern (tidal volume = 500 mL, I:E ratio = 1:1, breaths per minute = 15)

Discussion:

The statistical analysis of comparison showed that there are some statistically significant differences in performance at 95% confidence, but in those cases the InnoSpire Go provided either higher Total Dose; smaller particle size (MMAD and GSD); larger Total Respirable Dose.

For the differences in particle size distributions, their differences reflect the results of the Total Respirable Dose, which was an overall higher dose, thus the Coarse, Fine and Ultra- fine particle data would mirror these results as well.

Overall the results are comparable to the predicate and would support a determination of substantial equivalence.

Performance differences With and Without a Mask
Comparative performance testing was performed as to the reduction in delivered dose, Fine Particle ad Respirable Dose with and without a mask as compared to the predicate.
Discussion:
The results show a decrease in delivered dose and respirable dose as compared to performance with a mouthpiece, however the reduced performance is substantially equivalent to the predicate with a face mask.

Substantial Equivalence Discussion and Differences Between Predicate Devices
The InnoSpire Go nebulizer is viewed as substantially equivalent to the predicate device because:

Indications for Use – The proposed indications for use are to aerosolize commonly prescribed medications.
Discussion - The indications for use are similar for the proposed device and the predicate – K081650 – Aerogen Aeroneb® Go nebulizer.

Patient Population – The patient population of adult and pediatric (defined by the prescribed medication) patients that is consistent with the indications for the aerosol medication. This is similar to the predicate – K081650 – Aerogen Aeroneb® Go nebulizer.
Discussion - The patient population is similar for the proposed device and the predicate – K081650 – Aerogen Aeroneb® Go nebulizer.

Environment of Use – The proposed environments of use are common and usual for handheld nebulizers, namely home and hospital/clinic settings.
Discussion – The environment of use is identical for the proposed device and the predicate – K081650 – Aerogen Aeroneb® Go nebulizer.

Technology – The design is a vibrating mesh nebulizer which is the same principle of operation.
Discussion – The technology is similar for the proposed device as compared to the predicate – K081650 – Aerogen Aeroneb® Go nebulizer.

Non-clinical performance testing

Biocompatibility / Materials –
The materials in patient / drug contact have been tested they are characterized as:

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

And

- Surface Contact, Mucosal membrane, Duration of Use – permanent (> 30 days)

Discussion -
We performed the following tests with guidance from ISO 10993-1 and the results were acceptable.

- Cytotoxicity – ISO 10993-5:2009
- Sensitization – ISO 10993-10:2010
- Irritation (for surface contact materials) – ISO 10993-10:2010

- Leachable and Extractables – polar and non-polar – ISO 10993-12:2012 and ISO 10993-18:2005
- Gas emission VOC - ASTM D 5466-01:2015
- $PM_{2.5}$
- Risk based assessment – ISO 10993-17:2002(R)2012

Bench Testing

We have performed a number of tests which are discussed in detail in the respective sections of this submission. These include:

- Durability Testing
- Simulated Life Cycle testing
- Cleaning validation
- Storage and Transportation – ISTA 2A
- Electrical Safety, EMC, Battery safety - IEC 60601-1:2005 (Third Edition)+ CORR. 1:2006 + CORR. 2:2007+ A1:2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015; IEC 62133:2012
- Particle Characterization – Comparative at 15 lpm and 30 lpm
- Intra- and Inter- Sample Variability

Substantial Equivalence Conclusion
As discussed: the indications for use, patient population, environment of use, technology or principle of operation, and performance are substantially equivalent to the predicate.

Based upon the comparative performance testing we can conclude that the proposed device can be determined as substantially equivalent to the stated predicate.