October 31, 2023

Medline Industries LP
Lakshmi Kanuri
Sr. Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K230602
Trade/Device Name: Hudson RCI® TurboMist™ Nebulizer System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: October 5, 2023
Received: October 5, 2023

Dear Lakshmi Kanuri:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Ethan L. Nyberg -S

Ethan Nyberg. Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230602

Device Name
Hudson RCI® TurboMist™ Nebulizer System

Indications for Use *(Describe)*
The Hudson RCI® TurboMist™ Nebulizer is intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing.Its use is indicated when a licensed healthcare professional prescribes or administers medical aerosol to a patient using a small volume nebulizer.

The patient population includes adult and pediatric (greater than 22 lbs or 10 kg) patients that are spontaneously breathing.

The product is a single patient, multi-use, non-sterile, disposable, prescriptive device intended to be used in a hospital or homecare environment.

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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004 - 510(k) Summary

1. **Date Summary Prepared**
   October 5, 2023

2. **Name, Address, Phone and Fax Number of Applicant**
   Medline Industries, LP
   3 Lakes Dr,
   Northfield, IL 60093
   (847) 949-5500
   Registration Number: 1417592

3. **Contact Person**
   Lakshmi Kanuri
   Sr. Regulatory Affairs Specialist
   Email – lkanuri@medline.com

4. **Subject Device**

Trade Name:	Hudson RCI® TurboMist™ Nebulizer System
Common Name:	Nebulizer (Direct Patient Interface)
Product Code:	CAF
Regulation Number:	868.5630
Classification:	Class II
Classification Panel:	Anesthesiology

5. **Primary Predicate Device**

Trade Name:	AirLife Small Volume Nebulizer
Common Name:	Nebulizer (Direct Patient Interface)
Product Code:	CAF
Regulation Number:	868.5630
Classification:	Class II
Classification Panel:	Anesthesiology
510(k) Number:	K123527

6. **Secondary Predicate Device**

Trade Name:	MC 300*
Common Name:	Nebulizer (Direct Patient Interface)
Product Code:	CAF
Regulation Number:	868.5630
Classification:	Class II
Classification Panel:	Anesthesiology
510(k) Number:	K173367

   This submission demonstrates substantial equivalence to the AirLife Small Volume Nebulizer (K123527) and

   MC 300* (K173367) is used as a secondary predicate device to support homecare use.

7. **Device Description**
   The Hudson RCI® TurboMist™ Nebulizer System (herein referred to as “TurboMist system” or “subject device”) consists of the TurboMist small volume nebulizer and a patient interface, which may include a swivel mouthpiece ors an aerosol mask and elbow adaptor. The aerosol mask is available in adult and pediatric versions. The TurboMist small volume

nebulizer is a hand-held, breath-enhanced jet nebulizer designed to aerosolize liquid medications as prescribed by a physician. The nebulizer is powered by an external compressed air or oxygen source, and the aerosol is created by an internal jet located inside the nebulizer jar. The nebulizer is designed to entrain additional room air upon patient inhalation, enhancing aerosol generation and resulting in a faster nebulization rate than traditional jet nebulizers.

8. Indications for Use

The Hudson RCI® TurboMist™ Nebulizer System is intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing. Its use is indicated when a licensed healthcare professional prescribes or administers medical aerosol to a patient using a small volume nebulizer.

The patient population includes adult and pediatric (greater than 22 lbs or 10 kg) patients that are spontaneously breathing.

The product is a single patient, multi-use, non-sterile, disposable, prescriptive device intended to be used in a hospital or homecare environment.

9. Contraindications

None.

10. Technological Characteristics

The TurboMist small volume nebulizer is a breath-enhanced, pneumatic jet nebulizer, and is composed of a jet, jar, and cap. It operates based on the Venturi effect, whereby an external source of compressed air or oxygen is directed through the stem of the jar and upwards towards a narrow restrictive point. This change in flow path creates a low-pressure zone that helps to draw liquid medication upwards from the jar into the space between the jet and the jar through capillary action. When the liquid medication encounters the flow of compressed air or oxygen, it becomes aerosolized into a stream of small droplets. The TurboMist small volume nebulizer cap features an air entrainment port, through which additional room air can be entrained, enhancing aerosol output. The aerosolized medication is delivered to the patient utilizing either a swivel mouthpiece or an aerosol mask and elbow adaptor.

11. Comparison to Primary Predicate and Secondary Predicate

The Subject Device (The TurboMist system), the Primary Predicate (The AirLife Small Volume Nebulizer (K123527)) and the Secondary Predicate, (The MC 300* Nebulizer (K173367)) are identical in intended use, core technology, and mode of operation. Only minor differences exist between the subject, the primary predicate and the secondary predicate, which do not introduce issues of safety and effectiveness.

Table 004-1 illustrates the similarities and differences between the subject and Primary Predicate and Secondary Predicate.

004 - 510(k) Summary

Table 004-1 Comparison of Subject Device to Primary Predicate and Secondary Predicate

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate	Substantial Equivalence Discussion
Device Name	**Hudson RCI® TurboMist™ Nebulizer**	**AirLife Misty Fast Small Volume Nebulizer**	**MC 300***	
510(k) Number	**K230602**	**K123527**	**K173367**	
Classification Name	Nebulizer (Direct Patient Interface)	Nebulizer (Direct Patient Interface)	Nebulizer (Direct Patient Interface)	Identical
Common Name	Small Volume Nebulizer	Small Volume Nebulizer	Small Volume Nebulizer	Identical
Regulation Number	868.5630	868.5630	868.5630	Identical
Classification Product Code	CAF	CAF	CAF	Identical
Regulatory Class	Class II	Class II	Class II	Identical
Intended Use	The Hudson RCI® TurboMist™ Nebulizer is **intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing.**	This AirLife Small Volume Nebulizer is **intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing.** The patient population includes adults, pediatrics, and infants that are spontaneously breathing	This MC300 Nebulizer is **intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing.**	Identical

004 - 510(k) Summary

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate	Substantial Equivalence Discussion
Device Name	**Hudson RCI® TurboMist™ Nebulizer**	**AirLife Misty Fast Small Volume Nebulizer**	**MC 300***	
510(k) Number	**K230602**	**K123527**	**K173367**	
Indications for use	The Hudson RCI® TurboMist™ Nebulizer is intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing. Its use is indicated when a licensed healthcare professional prescribes or administers medical aerosol to a patient using a small volume nebulizer. The patient population includes adult and pediatric (greater than 22 lbs or 10 kg) patients that are spontaneously breathing. The product is a single patient, multi-use, non-sterile, disposable, prescriptive device intended to be used in a hospital or homecare environment..	This device is intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient far breathing. The patient population includes adults, pediatrics, and infants that are spontaneously breathing. The product is a prescriptive device intended to be used in hospital setting.	The nebulizer is intended to be used with pediatric (ages 2 years and above) and adult patients, who are under the care of a licensed healthcare provider or physician. The device is designed to aerosolize prescribed medication for inhalation by a patient in the hospital, clinic or home care environment. The nebulizer is a single patient use device.	Identical Primary Predicate is used for hospital environment only Secondary Predicate is used for both hospital and home care environment
Contraindications	None	None	None	Identical
Patient Population	Adult and pediatric greater than 22 lbs or 10 kg) patients	Adult, pediatric, and infant	Adult and pediatric (ages 2 years and above) patients	Equivalent: Both the primary predicate and the secondary predicate are inclusive of the subject device

004 - 510(k) Summary

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate	Substantial Equivalence Discussion
Device Name	**Hudson RCI® TurboMist™ Nebulizer**	**AirLife Misty Fast Small Volume Nebulizer**	**MC 300***	
510(k) Number	**K230602**	**K123527**	**K173367**	
				populations (Adult and Pediatric greater than 22 lb or 10 kg patients)
Patient interface	Mouthpiece and aerosol mask with elbow adaptor	Mouthpiece and aerosol mask	Mouthpiece and aerosol mask	Identical
Type of device	Disposable, hand-held, non-sterile, single patient, multi-use	Disposable, hand-held, non-sterile, single patient, multi-use	Disposable, handheld, non-sterile, single patient use for multiple treatments	Identical
Core Technology	Pneumatic jet nebulizer	Pneumatic jet nebulizer	Pneumatic jet nebulizer	Identical
Principle of Operation	Venturi	Venturi	Venturi	Identical
Principle of Operation	The nebulizer is connected to an external compressed air or oxygen source using oxygen tubing. The air passes through an internal jet, and the solution inside the jar is aerosolized. Additional room air is entrained through an air entrainment port, enhancing aerosol output.	The nebulizer is connected to an external compressed air or oxygen source using oxygen tubing. The air passes through an internal jet, and the solution inside the jar is aerosolized. Additional room air is entrained through an air entrainment port, enhancing aerosol output.	Compressed air is driven through a converging nozzle, where it accelerates and emerges at a high velocity, creating a vacuum (venturi effect). The vacuum draws a liquid residing in a reservoir up through a cylindrical channel and into the emerging airstream formed by the nozzle, to mix with air and impact upon a rigid surface. This process uses energy from the airstream to convert liquid into small droplets called aerosol. Upon reaching the user aerosol is suitably refined to enter the lungs effectively.	Equivalent The subject device, the primary predicate and the secondary predicate use the same core technology, principle of operation and type of gas source.

004 - 510(k) Summary

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate	Substantial Equivalence Discussion
Device Name	Hudson RCI® TurboMist™ Nebulizer	AirLife Misty Fast Small Volume Nebulizer	MC 300*	
510(k) Number	K230602	K123527	K173367	
Entrains additional room air through an air entrainment port to enhance aerosol output (breath-enhanced)	Yes	Yes	Yes	Identical
Type of Gas source	Compressed air or oxygen	Compressed air or oxygen	Compressed air or oxygen	Identical
Nebulizer driving gas flow rate (LPM)	8 LPM	8 ± 1 LPM	8 LPM	Identical
Maximum Fill Capacity	10 mL	10 mL	6 mL	Equivalent
Patient Contact Type	External communicating (Indirect gas pathway) Tissue/bone/dentin communicating Duration of Use – Permanent (> 30 days due to potential for cumulative use) And Surface Contact Mucosal Membrane Duration of Use – Permanent (> 30 days due to potential for cumulative use)	External communicating (Indirect gas pathway) Tissue/bone/dentin communicating Duration of Use – Permanent (> 30 days due to potential for cumulative use) And Surface Contact Mucosal Membrane Duration of Use – Permanent (> 30 days due to potential for cumulative use)	External communicating (Indirect gas pathway) Tissue/bone/dentin communicating Duration of Use – Permanent (> 30 days due to potential for cumulative use) And Surface Contact Mucosal Membrane Duration of Use – Permanent (> 30 days due to potential for cumulative use)	Identical
Environment of Use	Hospital and Home care setting	Hospital setting	Hospital and Home care setting	Identical to Primary predicate for Hospital use. Equivalent to Secondary predicate for home care Use

004 - 510(k) Summary

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate	Substantial Equivalence Discussion
Device Name	**Hudson RCI® TurboMist™ Nebulizer**	**AirLife Misty Fast Small Volume Nebulizer**	**MC 300***	
510(k) Number	**K230602**	**K123527**	**K173367**	
Shelf Life	5 years	5 years	Not Available Publicly	Identical
Useful life	7 days (assumes a maximum of 6 cleaning cycles per day plus a safety factor) or 50 cleaning cycles	Cumulative duration of use not to exceed 24 hours or 50 cleaning cycles	The nebulizer is a single patient, disposable device for use up to 7 days	Equivalent
Cleaning and Disinfection Instructions	Disassemble the nebulizer by removing the oxygen tubing and all accessory components. Unscrew the cap and remove the jet from the jar. Wash the nebulizer and accessory components by submerging in a warm water and liquid dish soap solution and wipe with a cloth for 1 minute. Rinse with warm water. Inspect device for visible soil and repeat cleaning procedure if necessary. Disinfect the nebulizer and accessory components by submerging in 70% isopropyl alcohol for 10 minutes. Air dry completely before reassembling.	Unscrew the nebulizer cap and bottle. Remove the one-piece jet by pulling and twisting the jet off the jet stem. Wash all components in warm soapy water and rinse well. Sterile water may also be used in place of soapy water. Shake out/off excess water or sterile water and air dry for 30 minutes. Alternatively, shake out/off excess water or sterile water and wipe the device with a clean lint free cloth until dry. To aid in the drying process, you may also use the compressed air supply to clear the orifice. Reseat the jet by placing the jet over the jet stem and snap into place. Reattach the nebulizer cap and bottle.	For home, hospital or clinic • The exterior surfaces of the nebulizer may be wiped with a gauze lightly moistened with either distilled water or 70% isopropyl alcohol (solvent) • Remove the tubing from the bottom of the device, and disassemble the nebulizer into its parts (mouthpiece, corrugated tube (if supplied), green nozzle cover, top and cup). Corrugated tubing should be fully extended for cleaning and until dry. • Cleaning of the nebulizer is recommended after each aerosol treatment Any of the following four methods may be used: A Sterile Water: Rinse the disassembled nebulizer parts thoroughly in sterile water. Shake to remove excess water.	Equivalent The primary predicate and the secondary predicate have cleaning and disinfection steps

004 - 510(k) Summary

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate	Substantial Equivalence Discussion
Device Name	Hudson RCI® TurboMist™ Nebulizer	AirLife Misty Fast Small Volume Nebulizer	MC 300*	
510(k) Number	K230602	K123527	K173367	
			B 70% Isopropyl Alcohol: Wipe the outside of the nebulizer with a tissue dipped in 70% isopropyl alcohol. Submerge the four parts in 70% isopropyl alcohol for 1 minute. Shake to remove any excess isopropyl alcohol. C Air Dry: Disassemble the nebulizer and shake out any excess drug. D Hand Washing: Wash the disassembled parts in a warm water and liquid dish soap solution. Rinse in clean warm water. • After cleaning, inspect the device to ensure it is clean. If any residual soil is detected, repeat the selected cleaning step. • For all methods, always allow to air dry completely (or dry with a lint free cloth) before reassembling. It is recommended the nebulizer bottom be briefly reconnected to the air supply to clear the air pathway.	

Further on, Medline also considered the FDA Draft Guidance "*Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission"* to identify valid Primary predicate and secondary predicate device. Publicly available 510(k) Summary and Indications for Use documents for each device being considered as a valid predicate device has been reviewed in addition to application of the best practices identified in Table 004-2 below to support the submission.

Table 004-2 Best Practices for Selecting Primary and Secondary Predicate Devices

Valid Predicate Device	A	B	C	D
	Well established methods	**Meets or exceeds expected predicate performance**	**Unmitigated use-related or design-related safety issues**	**Associated design-related recall**
Primary Predicate Device **AirLife Misty Fast Small Volume Nebulizer (K123527)**	Used relevant methods that were published in the public domain	Expected frequency of reported adverse events	No known unmitigated use related or design-related safety issues	No design related recall identified
Secondary Predicate Device **MC 300* Nebulizer (K173367)**	Used relevant methods that were published in the public domain	Expected frequency of reported adverse events	No known unmitigated use related or design-related safety issues	No design related recall identified

12. Summary of Non-Clinical Testing

The following non-clinical tests were completed to demonstrate substantial equivalence of the subject device to primary predicate device and a review of key published performance test data in the 510k summary table of the secondary predicate.

12.1 Particle Size characterization

Particle characterization testing was performed on the subject device with both proposed patient interfaces (mouthpiece and aerosol mask), as well as on the primary predicate with a mouthpiece and aerosol mask and a review of published test data in the 510(k) summary table of the secondary predicate (K173367) was completed.

Cascade Impactor vacuum flow rate of 15 LPM was utilized for the testing subject and primary predicate devices and review of published data for secondary predicate device per FDA's *"Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators"* (FDA/CDRH – 1993).

Particle size characterization results for the TurboMist nebulizers and both patient interfaces (mouthpiece & mask) using 15 LPM impactor vacuum flow rate met all pre-determined acceptance criteria and demonstrated that the device meets its product specifications.

When comparing particle size characterization and overall performance of the TurboMist system, the primary predicate and secondary predicate device at 15 LPM Cascade Impactor vacuum flow rate, results for all devices are considered to be comparable and within the clinically acceptable range.

12.2 Shelf life

Shelf life testing was performed on the subject device with both proposed patient interfaces (mouthpiece and aerosol mask) after the equivalent of five years aging. Real time aging studies have been initiated.

12.3 Useful life

Useful life testing was performed on the subject device with both proposed patient interfaces (mouthpiece and aerosol mask) and determined to be 7 days or 50 cleaning cycles

12.4 Cleaning & Disinfection

Cleaning and Disinfection testing was performed on the subject device with both proposed patient interfaces (mouthpiece and aerosol mask).

The cleaning and disinfection validation tests were based on the guidelines set forth in the following references

- FDA Guidance: *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*
- AAMI TIR12:2010 *"Designing, Testing And Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities: A Guide For Medical Device Manufacturers"*
- AAMI TIR30:2011 *"A Compendium Of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable Medical Devices"*

All testing concluded that the nebulizer could be cleaned and disinfected effectively by use of the methods stated in the IFU.

12.5 Biocompatibility

Biocompatibility evaluation and testing was performed on the subject device as well as both proposed patient interfaces (mouthpiece and aerosol mask). The materials contacting the patient have been characterized as external communicating (indirect gas pathway), tissue/bone/dentin communicating with a potential for permanent contact due to cumulative use and surface contacting, mucosal membrane, with a potential for permanent contact due to cumulative use. Contact of device materials with commonly aerosolized medications was taken into consideration when designing the test studies.

Table 4 details the biological endpoints that were evaluated and/or /tested based on the nature and duration of contact.

Table 4 Summary of Biological Endpoints Evaluated/tested

Standard	Biological Endpoints
ISO 10993-3:2014	Carcinogenicity
ISO 10993-3:2014	Genotoxicity
ISO 10993-5:2009	Cytotoxicity
ISO 10993-10:2010	Sensitization

Standard	Biological Endpoints
ISO 10993-11:2017	Irritation or Intracutaneous Reactivity
ISO 10993-11:2017	Material Mediated Pyrogenicity
ISO 10993-11:2017	Acute Systemic Toxicity
ISO 10993-11:2017	Subacute Toxicity
ISO 10993-11:2017	Subchronic Toxicity
ISO 10993-11:2017	Chronic Toxicity
ISO 10993-6:2017	Implantation
ISO 10993-17: 2002	Extractables/Leachables
ISO 10993-18:2020	Chemical characterization of materials

12.6 Gas Pathway

Gas pathway evaluation and testing was performed on the subject device as well as both proposed patient interfaces (mouthpiece and aerosol mask) per ISO 18562-1.

Table 5 details the Gas Pathway endpoints evaluated and/or /tested

Table 5 Summary of Gas Pathway evaluated/tested

Standard	Endpoint Assessed
ISO 18562-2:2017	Tests for Emissions of Particulate Matter (including PM2.5)
ISO 18562-3:2017	Tests for Emissions of Volatile Organic Compounds (VOCs)
ISO 18562-4:2017	Evaluated Leachables In Condensate

13 Conclusions

Based on testing data, including biocompatibility tests and aerosol particle performance tests, the TurboMist™ Nebulizer System meets the requirements of its pre-defined acceptance criteria and intended use. Therefore, the subject device TurboMist™ Nebulizer System is substantially equivalent to the primary predicate device for hospital setting and secondary predicate device for homecare setting.