June 23, 2023

Medline Industires, Inc.
% Joy Gutermuth
Senior Specialist (Consultant)
Rqm+
2790 Mosside Blvd.
Suite 800
Monroeville, Pennsylvania 15146

Re: K220955
Trade/Device Name: Hudson RCI Variable concentration Large Volume Nebulizer (1770)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 26, 2023
Received: May 26, 2023

Dear Joy Gutermuth:

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,

Ting Song -S

For
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220955

Device Name
Hudson RCI Large Volume Nebulizer

Indications for Use *(Describe)*
The non-prefilled nebulizer is indicated for use when humidity needs to be added to the air flow going to a patient in the form of an aerosol. The large volume nebulizer also allows for the provision of humidified oxygen at select oxygen concentrations from 28% to 98%. This product is for single patient use and is designed to be used in hospital, nursing homes, extended care facilities, outpatient clinics as prescribed by a healthcare professional.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

DATE PREPARED
June 23, 2023

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Hudson RCI Variable Concentration Large Volume Nebulizer
Common Name:	Large Volume Nebulizer
Regulation Number:	§868.5630
Class:	II
Product Code:	CAF

PREDICATE DEVICE IDENTIFICATION
The Hudson RCI Variable Concentration Large Volume Nebulizer is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K041418	AirLife Misty Finity Large Volume Continuous Neublizer	✓
K141214	Hudson RCI® AquaPak® Prefilled Nebulizer	Reference Device

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

The large volume nebulizer is a non-prefilled reservoir nebulizer for supplying humidity for inhalation therapy. The device features a wing nut style connector that fits standard flow metered medical gas sources and includes a 500mL capacity jar with minimum and maximum fill lines. Large volume nebulizers utilize an internal venturi nozzle to draw the solution up from the jar through a small plastic pickup tube and into the gas stream to be aerosolized. A rotating collar sets the delivered oxygen concentration by controlling the size of the room air opening around the venturi. A bull-nose style output connector is used to connect 22mm aerosol tubing for delivery to the patient.

INDICATIONS FOR USE

The non-prefilled nebulizer is indicated for use when humidity needs to be added to the air flow going to a patient in the form of an aerosol. The large volume nebulizer also allows for the provision of humidified oxygen at select oxygen concentrations from 28% to 98%. This product is for single patient use and is designed to be used in hospital, nursing homes, extended care facilities, outpatient clinics as prescribed by a healthcare professional.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Medline Industries believes that the large volume nebulizer is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions, and uses similar or identical materials as the devices cleared in K041418 and K141214. The subject device has the same intended use and similar technological characteristics to the devices cleared in both K041418 and K141214. The device has similar instrumentation to the device cleared in K041418 and K141214. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicates.

Product Features	**Proposed** **Hudson RCI Variable Concentration Large Volume Nebulizer**	**Predicate** **AirLife Misty Finity Large Volume Continuous Nebulizer (K041418)**	**Reference Device** **Hudson RCI® AquaPak® Prefilled Nebulizer (K141214)**
Classification	Class II	Class II	Class II
Product Code	CAF	CAF	CAF
Regulation Number	§868.5630	§868.5630	§868.5630
Regulation Name	Nebulizer	Nebulizer	Nebulizer

Product Features	**Proposed** **Hudson RCI Variable Concentration Large Volume Nebulizer**	**Predicate** **AirLife Misty Finity Large Volume Continuous Nebulizer (K041418)**	**Reference Device** **Hudson RCI® AquaPak® Prefilled Nebulizer (K141214)**
Intended Use	To add humidity in aerosol form to a patient's breathing gases.	This device is intended to be used to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing.	To add humidity in aerosol form to a patient's breathing gases.
Indications for Use	The non-prefilled nebulizer is indicated for use when humidity needs to be added to the air flow going to a patient in the form of an aerosol. The large volume nebulizer also allows for the provision of humidified oxygen at select oxygen concentrations from 28% to 98%. This product is for single patient use and is designed to be used in hospital, nursing homes, extended care facilities, outpatient clinics as prescribed by a healthcare professional.	This device is intended to be used to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Continuous Large Volume Nebulizer. This product is a single patient use, non-sterile prescriptive device and is designed to be used under medical supervision in hospitals, nursing homes, extended care facilities or outpatient clinics.	The Hudson RCI® AquaPak® Prefilled Nebulizer adds sterile water or saline solution in aerosol form to a patient's breathing gases.

Product Features	**Proposed** **Hudson RCI Variable Concentration Large Volume Nebulizer**	**Predicate** **AirLife Misty Finity Large Volume Continuous Nebulizer (K041418)**	**Reference Device** **Hudson RCI® AquaPak® Prefilled Nebulizer (K141214)**
Representative Image			

Product Features	**Proposed** **Hudson RCI Variable Concentration Large Volume Nebulizer**	**Predicate** **AirLife Misty Finity Large Volume Continuous Nebulizer (K041418)**	**Reference Device** **Hudson RCI® AquaPak® Prefilled Nebulizer (K141214)**
Device Description	The large volume nebulizer is a non-prefilled reservoir nebulizer for supplying humidity for inhalation therapy. The device features a wing nut style connector that fits standard flow metered medical gas sources and includes a 500mL capacity jar with minimum and maximum fill lines. Large volume nebulizers utilize an internal venturi nozzle to draw the solution up from the jar through a small plastic pickup tube and into the gas stream to be aerosolized. A rotating collar sets the delivered oxygen concentration by controlling the size of the room air opening around the venturi. A bull-nose style output connector is used to connect 22mm aerosol tubing for delivery to the patient.	The nebulizer is a single patient use device, which is filled with a fluid, typically respiratory medication and connected to an air source via flexible tubing. The nebulizer works by having the fluid come into contact with the steam of gas. The gas shatters the liquid into small particles. These particles then impact a baffle that further reduces the size of the particles. The majority of the 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 particles are then administered as the patient inhales. The treatment is completed when the majority of fluid is nebulized.	The Hudson RCI® AquaPak® Prefilled Nebulizers provide sterile water or sterile saline for inhalation therapy. Nebulizers generate aerosol, a fine mist of liquid water (or sodium chloride solution) that is suspended in the gas to be inhaled by the patient. The Hudson RCI® AquaPak® Prefilled Nebulizers are designed to aerosolize and provide a fine mist of sterile water or saline solution to inspired gas during aerosol therapy. Prefilled sterile reservoirs for AquaPak® Nebulizers come in three sizes: 440ml, 760ml, and 1070ml. Each reservoir must be used with a suitable adaptor component, which connects the system to a flow-metered gas source and provides nebulizer functionality.

Product Features	**Proposed** **Hudson RCI Variable Concentration Large Volume Nebulizer**	**Predicate** **AirLife Misty Finity Large Volume Continuous Nebulizer (K041418)**	**Reference Device** **Hudson RCI® AquaPak® Prefilled Nebulizer (K141214)**
Accessories	Masks (not included), tubing (not included)	Masks (not included), tubing (not included)	Nebulizer Adaptors, masks (no included), tubing (not included)
Environment	Hospital or home care setting.	Hospitals, nursing homes, extended care facilities or outpatient clinics.	Hospital or home care setting.
Patient Population	Pediatric (ages 2 years and above) and adults.	Infant, pediatric, and adult	Pediatric (ages 2 years and above) and adults.
Principle of Operation	Jet nebulizer with adjustable air entrainment	Jet nebulizer with adjustable air entrainment	Jet nebulizer with adjustable air entrainment
Sterilization Method	Non-sterile	Non-sterile	Sterile
Patient Contacting Materials	Polypropylene, polyethylene, LDPE, polystyrene, acrylic, dye	Thermoplastics	Thermoplastics
Single Use	Single patient use, disposable	Single patient use, disposable	Single patient use, disposable
Adjustable Oxygen Settings	FIO_2 28-98%	FIO_2 28-98%	FIO_2 28-98%
Biocompatibility	• External communicating, prolonged/permanent contact device that indirectly contacts tissue/bone/dentin • Indirect gas pathway	• Unknown from publicly available summary what biocompatibility endpoints were assessed.	• External communicating, prolonged/permanent contact device that indirectly contacts tissue/bone/dentin. • Indirect gas pathway

Product Features	**Proposed** **Hudson RCI Variable Concentration Large Volume Nebulizer**	**Predicate** **AirLife Misty Finity Large Volume Continuous Nebulizer (K041418)**	**Reference Device** **Hudson RCI® AquaPak® Prefilled Nebulizer (K141214)**
Standards Utilized	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-18 ISO 18562-1 ISO 18562-2 ISO 18562-3	ISO 10993-1	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-18
Non-Clinical Testing	• Packaging • Environmental Conditioning (high and low humidity) • Aging • Oxygen entrainment • Lift testing • Humidity output • Useful life testing • Cleaning process	"Performance evaluation of the proposed and predicated devices consisted of cascade impaction and output rate testing."	• Packaging • Environmental Conditioning (high and low humidity) • Aging

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Hudson RCI Variable Concentration Large Volume Nebulizer. The following tests were performed to demonstrate safety based on current industry standards:

- Biocompatibility
- Packaging
- Environmental Conditioning (high and low humidity)
- Aging
- Oxygen entrainment
- Lift testing
- Humidity output
- Useful life testing
- Cleaning process

The results of these tests indicate that the Hudson RCI Variable Concentration Large Volume Nebulizer is substantially equivalent to the predicate devices.

CONCLUSION

Based on the testing performed, including additional gas pathway biocompatibility according to ISO 18562, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Hudson RCI Variable Concentration Large Volume Nebulizer are assessed to be substantially equivalent to the predicate devices.