October 26, 2023

Medline Industries, Inc.
% Joy Gutermuth
Consultant
Rqm+
2790 Mosside Blvd.
Suite 800
Monroeville, Pennsylvania 15146

Re: K230559
Trade/Device Name: Hudson RCI® Disposable Humidifier with 4 PSI Pressure Relief Valve (3230), Hudson RCI® Disposable Humidifier with 6 PSI Pressure Relief Valve (3260)
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: September 27, 2023
Received: September 27, 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 (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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230559

Device Name
Hudson RCI® Disposable Humidifier with 4 PSI Pressure Relief Valve
Hudson RCI® Disposable Humidifier with 6 PSI Pressure Relief Valve

Indications for Use *(Describe)*
Intended to add moisture to breathing gases for administration to pediatric through adult patients weighing ≥ 10 kg >1 month in homecare, hospital, extended care and hospice.

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
October 25, 2023

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Hudson RCI® Disposable Humidifier with 4 PSI Pressure Relief Valve (3230) Hudson RCI® Disposable Humidifier with 6 PSI Pressure Relief Valve (3260)
Common Name:	Bubble Humidifier
Regulation Number:	§868.5450
Class:	II
Product Code:	BTT

PREDICATE DEVICE IDENTIFICATION
The Hudson RCI Bubble Humidifiers are substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K161719	Salter Labs Bubble Humidifier	✓

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

DEVICE DESCRIPTION

There are two models of the Hudson RCI Disposable Humidifier. Both models have identical intended uses and modes of operation. One model has a 4 PSI pressure relief valve (referred to as model 3230) and the other has a 6 PSI pressure relief valve (referred to as model 3260). Regardless of device model, the disposable humidifier delivers humidified gases to the patient. Both models of the non-prefilled disposable humidifier add humidity in water vapor form to respiratory gases delivered to patients to make the gases more comfortable to breathe. The disposable humidifier incorporates a pressure relief valve with an audible alarm at 4 psi or 6 psi, depending on the model selected.

In both models, air is channeled through the water-containing bottle where it becomes humidified before exiting the device and being administered to the patient.

The patient can influence the use of these devices by occluding or loosening secure connections. In cases where the patient is also the user, over or under filling the device and selection of incorrect oxygen percent concentration and gas input pressures may influence the use of the device.

INDICATIONS FOR USE

Intended to add moisture to breathing gases for administration to pediatric through adult patients weighing ≥ 10 kg >1 month in homecare, hospital, extended care and hospice.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Medline Industries believes that the Hudson RCI Bubble Humidifiers are substantially equivalent to the predicate device based on the information summarized here:

The subject devices have a similar design and dimensions and use similar or identical materials as the device cleared in K161719. The subject devices have the same intended use and similar technological characteristics to the devices cleared in K161719. The devices have similar instrumentation to the device cleared in K161719. These technological characteristics have undergone testing to ensure the subject devices are substantially equivalent to the predicate.

Product Features	Proposed Bubble Humidifiers	Predicate Salter Labs Bubble Humidifier (K161719)	Assessment of Equivalence
Classification	Class II	Class II	Same
Product Code	BTT	BTT	Same
Regulation Number	§868.5450	§868.5450	Same
Regulation Name	Respiratory gas humidifier	Respiratory gas humidifier	Same

Product Features	Proposed Bubble Humidifiers	Predicate Salter Labs Bubble Humidifier (K161719)	Assessment of Equivalence
Intended Use	Intended to add moisture to breathing gases for administration to pediatric through adult patients weighing ≥ 10 kg >1 month in homecare, hospital, extended care and hospice.	Intended to add moisture to breathing gases for administration to patients >1 month in homecare, hospital, extended care and hospice.	Similar
Indications for Use	Intended to add moisture to breathing gases for administration to pediatric through adult patients weighing ≥ 10 kg >1 month in homecare, hospital, extended care and hospice.	The bubble humidifier is intended to add moisture to breathing gases for administration to patients >1 month in homecare, hospital, extended care and hospice. The bubble humidifier is a non-sterile device indicated for single-patient usage. The device is indicated for patients who require humidification of high flow supplemental breathing gases.	Similar
Representative Image			Similar

Device Description	The Proposed Hudson RCI® Disposable Humidifier with 4 PSI or 6PSI Pressure Relief Valve is an empty, disposable, non-sterile, not made with natural rubber latex, device intended to humidify breathing gas prior to delivery to a patient. It is provided in two configurations with either a 4 PSI or 6 PSI safety valve and can operate within flow rates of 2-12 LPM (model 3230) or 2-15 LPM (model 3260). The device is used with various breathing gas sources (i.e., oxygen concentrators, gas cylinders, and wall outlets) and provides connection for delivery of humidified breathing gas via face masks or cannulas and use of optional oxygen tubing and water traps (sold separately). This device is a passive device and is not a cascade humidifier, is not heated, and is not prefilled.	humidify breathing gas prior to delivery to a patient. The Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve is provided with a 6 pounds per square inch (PSI) safety valve and can operate within flow rates of 6 to 15 liters per minute (LPM). The device is used with various breathing gas sources (i.e., oxygen concentrators, gas cylinders and wall outlets) and provides connection for delivery of humidified breathing gas via face masks or cannulas, and use of optional oxygen tubing and water traps (face masks, 21 CFR 868.5580; nasal cannulas, 21 CFR 868.5340; oxygen tubing, 21 CFR 868.5860 and water traps, 21 CFR 868.5995 are 510(k) exempt). This device is a passive device and is not a cascade humidifier, is not heated and is not prefilled. The device is made of a humidifier bottle which is used to hold water during use, a lid which seals the humidifier bottle, an audible pressure relief mechanism to notify the user of a downstream occlusion and a diffuser located at the end of a PVC diffuser tube inside the humidifier bottle. The diffusor is designed to uniformly disperse the gas throughout the water. Both the bottle and lid are constructed to be easy to grip and reduce the chance of cross threading. The bottle is permanently	Similar

Product Features	Proposed Bubble Humidifiers	Predicate Salter Labs Bubble Humidifier (K161719)	Assessment of Equivalence
		marked with "minimum/maximum" water levels. The lid is marked with minimum source pressure, flow ranges and pressure value of the safety valve.	
Environment of Use	Hospital, hospice, or home care setting.	Hospital or home care setting.	Similar
Principle of Operation	This device is a passive device and is not a cascade humidifier, is not heated and is not prefilled. It is used with oxygen concentrators or gas sources. Air is channeled through a water-contained jar. The air then becomes humidified before exiting to the patient.	This device is a passive device and is not a cascade humidifier, is not heated and is not prefilled. It is used with oxygen concentrators or gas sources. Air is channeled through a water-contained jar. The air then becomes humidified before exiting to the patient.	Same
Sterilization Method	Non-sterile	Non-sterile -	Same
Patient Contacting Materials	Polystyrene, polypropylene, PVC (DOHP)	Polyethylene, polystyrene, PVC (DHOP)	Same
Prescription	Prescription only	Prescription only	Same
Single Use	Single patient use	Single patient use	Same
Cleaning	No preparations required prior to use; cleaning process only. Cleaning instructions validated per useful life of device.	No preparations required prior to use; cleaning process only. Cleaning instructions validated per useful life of device.	Same
Power Source	None- passive device, non-heated	None- passive device, non-heated	Same
Accessories (not included)	Face mask, nasal cannula, oxygen tubing, water traps	Face mask, nasal cannula, oxygen tubing, water traps	Same
Biocompatibility	• External communicating, limited contact device that indirectly contacts tissue/bone/dentin. • Indirect gas pathway	• "Device does not touch the patient"	Similar

Product Features	Proposed Bubble Humidifiers	Predicate Salter Labs Bubble Humidifier (K161719)	Assessment of Equivalence
	ISO 18562-1 ISO 18562-2 ISO 18562-3 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-18	ISO 10993-1 ISO 10993-5 ISO 10993-10	Similar
Humidification Output Specification	10mg/l	10mg/l	Same
Flow Rate	**Finished Good 3230:** 2-12 LPM **Finished Good 3260:** 2-15 LPM	6-15 LPM	Similar
Alarm	**Finished Good 3230:** 4 PSI **Finished Good 3260:** 6 PSI	6 PSI	Similar
Pull Test Specification (tubing assembly to diffuser and tubing to lid)	Minimum 5lbs at 7in/min	Not stated	Unknown as predicate does not state value

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

- Biocompatibility
- Packaging
- Environmental Conditioning (high and low humidity)
- Aging
- ISO 80601-2-74 Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
    - Humidification Output
    - Flow Rate
    - Alarm
- Pull Test
- Useful life testing

The results of these tests indicate that the Hudson RCI Bubble Humidifiers are substantially equivalent to the predicate devices.

BIOCOMPATIBILITY

Requirements for biological evaluation were based on the FDA Guidance Document "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The expected contact category, type and duration for the proposed Bubble Humidifiers is as follows:

The Bubble Humidifiers are considered external communicating, permanent devices that indirectly contact tissue/bone/dentin per ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."

Testing has been conducted per a biological evaluation and the applicable endpoints are summarized below.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic toxicity
- Material Mediated Pyrogenicity
- Particulate Matter
- Volatile Organic Compounds

The following standards have been utilized:

- ISO 18562-1, Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
- ISO 18562-2, Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- ISO 18562-3, Biocompatibility evaluation of breathing gas pathways in healthcare application – Part 3: Tests for emissions of volatile organic compounds
- ISO 10993-1, Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process
- 10993-5 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-18, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process

CONCLUSION

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