January 4, 2024

Medline Industries, LP
Phyllis Kondor
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K231058
Trade/Device Name: Hudson RCI® AddiPak® Unit Dose Vial
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: December 5, 2023
Received: December 6, 2023

Dear Phyllis Kondor:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231058

Device Name
AddiPak® Unit Dose Vial

Indications for Use *(Describe)*

The AddiPak® Unit Dose Vial may be used in conjunction with a non-ventilator nebulizer for lavage therapy, or for tracheal irrigation.

These products are single-use, disposable, and intended for inhalation only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter / 510(k) Sponsor
Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Submission Correspondent
Phyllis Kondor
Regulatory Affairs Specialist
pkondor@medline.com
1-800-633-5463

Summary Preparation Date
January 3, 2024

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: AddiPak® Unit Dose Vials
Classification Name: Nebulizer (Direct Patient Interface)
Product Code: CAF
Classification Panel: Anesthesiology (Respiratory)
Regulatory Class: Class II
Regulation Number: 21 CFR 868.5630

Predicate Device
Hudson RCI® AddiPak® Unit Dose Vials
K142153

Reference Devices
Holopack
K972466 – Sodium Chloride Inhalation Solution
K972467 – Sterile Water for Inhalation

Device Description
AddiPak® unit dose solutions are pre-filled vials of bland liquids for inhalation therapy.

Contents of these products may be sterile water or a 0.45% sodium chloride solution (half-normal saline). Vials are factory-sealed, made of translucent, color-coded polyethylene, and are available in two sizes (3mL and 5mL). These products are single-use, disposable, and intended for inhalation only. Color-coded vials identify contents as sterile

water (blue) and half-normal 0.45% saline (green).
The pre-filled vials have a perforated, break-away twist cap for dispensing solution. When twisted by the user, cap breaks away and open a small hole for solution to pass through.Vials are designed with inverted graduations to allow the clinician to read volume while dispensing solution. Addipak unit dose vials conforms to the specifications of United States Pharmacopeia – National Formulary, Sterile Water for Inhalation and Sterile Sodium Chloride for Inhalation monograph.

Indications for Use
The AddiPak® Unit Dose Vial may be used in conjunction with a non-ventilator nebulizer for lavage therapy, or for tracheal irrigation.

These products are single-use, disposable, and intended for inhalation only.

Principle of Operation
These products are used with a nebulizer for lavage and tracheal lavage.

Environment of Use
The AddiPak® Unit Dose Vials are intended for use in home, hospital, and sub-acute facilities.

Patient Population
The AddiPak® Unit Dose Vials are intended for any patients requiring lavage therapy or tracheal irrigation. This includes infants (weighing ≥ 10kg), children, adolescents, and adults.

Summary of Technological Characteristics

TABLE 9-1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device Addipak®	Primary Predicate Device Addipak® K142153	References Holopack K972466 K972467	Comparison Analysis
Manufacturer	Medline Industries (formerly Teleflex)	Teleflex	Holopack	
Product Code	CAF	CAF	CAF	Same
Indications for Use	The AddiPak® Unit Dose Vial may be used in conjunction with a non-ventilator nebulizer for lavage therapy, or for tracheal irrigation.	The Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal saline Solution may be used in conjunction with a non-ventilator nebulizer for lavage therapy, or for tracheal irrigation.	The intended use of these sterile single use devices is as accessories to medicinal nonventilatory nebulizers in respiratory therapy or for tracheal irrigation or lavage.	Same
Regulation Number	21 CFR 868.5630	21 CFR 868.5630	21 CFR 868.5630	Same

Solutions	Sterile water 0.45% Half Normal Saline	- - 0.9% Full Normal Saline	Sterile water (K972467) 0.45% Half Normal Saline (K972466)	Same as references
Packaging Size	3 mL, 5 mL	3 mL, 5 mL, 15 mL	3 mL, 5 mL	Same size as references
Shelf Life	2 years from date of manufacture	2 years from date of manufacture	Not specified	Same
Materials in fluid contact	Vial LDPE	Vial LDPE	Vial LDPE	Same
Prescription vs. OTC	Prescription	Prescription	Prescription	Same
Contraindications	No known contraindications	No known contraindications	No known contraindications	Same
Sterile vs. Non-Sterile	Sterile – Reverse Osmosis per USP <71>	Sterile – Reverse Osmosis per USP <71>	Sterile – Reverse Osmosis per USP <71>	Same
Vial Design	Pinched seam between vial and cap for opening Nozzle opening design to keep contents within when inverted Raised inverted graduations	Pinched seam between vial and cap for opening Nozzle opening design to keep contents within when inverted Raised inverted graduations	Pinched seam between vial and cap for opening Nozzle opening design to keep contents within when inverted Raised inverted graduations	Same
Single Use vs. Reusable	Single Use	Single Use	Single Use	Same
Biocompatibility	• Cytotoxicity • Sensitization • Intracutaneous Reactivity • Material Mediated Pyrogenicity • Chemical Characterization with Toxicological Risk Assessment • USP 661 • USP 788	• Cytotoxicity • Sensitization • Intracutaneous Reactivity • Material Mediated Pyrogenicity • Chemical Characterization with Toxicological Risk Assessment • USP 661 • USP 788	• Not specified	Same
Patient Population	Any patients requiring lavage therapy or tracheal irrigation.	Any patients requiring lavage therapy or tracheal irrigation.	Any patients requiring lavage therapy or tracheal irrigation.	Same
Used with Nebulizers	Yes	Yes	Yes	Same
Environment of	Home, hospital, and sub-acute	Home, hospital, and sub-	Not specified	Similar

Use	facilities	acute facilities		
Inhalation Only	Yes	Yes	Yes	Same
Manufacturing Process	Per USP Monograph Blow-Fill-Seal aseptic process	Per USP Monograph Blow-Fill-Seal aseptic process	Per USP Monograph Blow-Fill-Seal aseptic process	Same

Summary of Non-Clinical Testing

Biocompatibility Testing

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Material Mediated Pyrogenicity
- Chemical Characterization with Toxicological Risk Assessment
- USP 661
- USP 788

Performance Testing (Bench)

- Stability
- Sterility

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Summary of Clinical Testing

Not applicable.

Conclusion

The proposed AddiPak® Unit Dose Vial, Sterile Water and 0.45% Half Normal Saline Solution is substantially equivalent in

- Intended use for adding sterile water or saline solution with a nebulizer for tracheal irrigation or lavage
- Design – used with a nebulizer and disposable prefilled container
- Principles of operation and solutions similar to the predicate and the same as the references

The differences between the AddiPak® Unit Dose Vial, Sterile Water and 0.45% Half Normal Saline Solution and the predicate devices are:

- Solution type – sterile water and 0.45% saline
- Size of the packaged solution
- Provided nebulizer - the proposed device does not include a nebulizer
- Predicate can provide supplemental oxygen during aerosol therapy

The reference devices address each difference of the predicate namely, the indications for use, solutions, technological characteristics, and principle of operation to support substantial equivalence.