April 10, 2024

Mankind Pharma Limited
% Parimal Upadhyay
Senior Vice President - Business Development & Portfolio
Lifestar Pharma LLC (a Mankind Group Company)
1200 MacArthur Blvd.
Mahwah, New Jersey 07430

Re: K232523
Trade/Device Name: Sodium Chloride Inhalation Solution, USP 0.9%, 3% & 7%
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: March 11, 2024
Received: March 11, 2024

Dear Parimal Upadhyay:

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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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)*
K232523

Device Name

Sodium Chloride Inhalation Solution, USP, 0.9%, 3%, and 7%

Indications for Use *(Describe)*

Sodium Chloride Inhalation Solution, USP 3% and 7%
The Sodium Chloride Inhalation Solution, USP is used in conjunction with a nebulizer. The contents of these vials are for the induction of sputum production where sputum production is indicated.

Sodium Chloride Inhalation Solution, USP 0.9%
The intended use of this sterile device is as accessories to medicinal non-ventilatory nebulizers in respiratory therapy and for tracheal irrigation or lavage.

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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510(k) Summary

I. SUBMITTER

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Submission Correspondent:
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Summary Preparation Date: April 05, 2024

II. DEVICE

Name of Device: Sodium Chloride Inhalation Solution, USP, 0.9%, 3%, and 7%.
Common or Usual Name:
- Sodium Chloride Inhalation Solution, USP, 0.9%, 3%, and 7%.
- Saline Solution

Classification Name: Nebulizer (21 CFR 868.5630)
Regulatory Class: II
Product Code: CAF

III. PREDICATE DEVICE

- PharmaCaribe Inhaled saline solutions 3%, 3.5%, 6%, 7%, and 10%, K101424
- Sodium Chloride Inhalation Solution USP 0.45%; 0.9%, K972466

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The proposed device is a sterile, preservative-free Sodium Chloride Inhalation Solution, USP, provided in concentrations of 0.9%, 3% and 7% with a nominal fill volume of 3 mL & 5 mL (0.9%), 4 mL (3%) and 4 mL (7%) and supplied in single-use low density polyethylene (LDPE) vials.

V. INDICATIONS FOR USE

Sodium Chloride Inhalation Solution, USP 3% and 7%

The Sodium Chloride Inhalation Solution, USP is used in conjunction with a nebulizer. The contents of these vials are for the induction of sputum production where sputum production is indicated.

Sodium Chloride Inhalation Solution, USP 0.9%

The intended use of this sterile device is as accessories to medicinal non-ventilatory nebulizers in respiratory therapy and for tracheal irrigation or lavage.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The induction of sputum production is the technological principle for both the proposed and predicate devices when used in conjunction with a nebulizer. The technological characteristics when compared to the predicate device are detailed below.

Technological Characteristics Compared to the Predicate Device	Proposed Device	Predicate Device	Predicate Device	Comparison
		PharmaCaribe (K101424)	Sodium Chloride Inhalation Solutions, USP 0.45%; 0.9% (K972466)	
Product Name	Sodium Chloride Inhalation Solution USP 0.9%, 3% and 7%.	PharmaCaribe Inhaled saline solutions 3%, 3.5%, 6%, 7%, and 10%.	Sodium Chloride Inhalation Solution USP 0.45%; 0.9%.	The proposed device follows the established name provided in the USP Monograph; whereas, the predicate device uses a proprietary name.
Design	Sterile, preservative-free Sodium Chloride Inhalation Solutions supplied in single use vials.	Sterile, preservative-free Sodium Chloride Inhalation Solutions supplied in single use vials.	Sterile, preservative-free Sodium Chloride Inhalation Solutions supplied in single use vials.	Similar (Proposed device design is equivalent and no change as that of the predicate device)
Material/Chemical Composition	Water for Injection, USP Sodium Chloride, USP	Sterile Water for Injection, USP Sodium Chloride, USP	Water for Injection, USP Sodium Chloride, USP	Similar (Proposed device material/chemical composition is equivalent to the predicate device)
Concentrations	0.9%, 3% and 7%	3%, 3.5%, 6%, 7%, and 10%	0.45%; 0.9%	Similar (Proposed device 0.9% is equivalent to the

Technological Characteristics Compared to the Predicate Device	Proposed Device	Predicate Device PharmaCaribe (K101424)	Predicate Device Sodium Chloride Inhalation Solutions, USP 0.45%; 0.9% (K972466)	Comparison
				predicate device (K972466) and proposed device 3% and 7% concentration is equivalent to the predicate device (K101424)
Indications for Use	<u>3% and 7%</u> Sodium Chloride Inhalation Solution, USP is used in conjunction with a nebulizer. The contents of these vials are for the induction of sputum production where sputum production is indicated. Concentrations of 3% and 7%. <u>0.9%</u> The intended use of this sterile device is as accessories to medicinal non-ventilatory nebulizers in respiratory therapy and for tracheal irrigation or lavage.	PharmaCaribe inhaled saline solutions are used in conjunction with a nebulizer. The contents of these vials are for the induction of sputum production where sputum production is indicated. Concentrations of 3%, 3.5%, 6%, 7% and 10%. --	-- The intended use of these sterile device is as accessories to medicinal non-ventilatory nebulizers in respiratory therapy or for tracheal irrigation or lavage.	Similar (Proposed device Indications for Use is equivalent to the individual predicate devices)
Prescription	Yes	Yes	Yes	Similar (No Change)

Technological Characteristics Compared to the Predicate Device	Proposed Device	Predicate Device	Predicate Device	Comparison
		PharmaCaribe (K101424)	Sodium Chloride Inhalation Solutions, USP 0.45%; 0.9% (K972466)	
Environment of Use	Hospital, sub-acute care or home	Hospital, sub-acute care or home	Hospital, sub-acute care or home	Similar (No Change)
Patient Population	3% and 7% Any patient population where sputum production is indicated. 0.9% Any patient population requiring lavage therapy or tracheal irrigation.	Any patient population where sputum production is indicated. --	-- Any patient population requiring lavage therapy or tracheal irrigation.	Similar (Proposed device Patient Population is equivalent to the individual predicate devices)
Used with a Nebulizer	Yes	Yes	Yes	Similar (Proposed device and the predicate device is Used with a Nebulizer)
Contraindications	None	None	None	Similar (Proposed device Contraindications is equivalent to the predicate device)
Vial Labeling	3% and 7% Embossed with identifying product text, lot number, and expiration date. 0.9%	Embossed with identifying product text, lot number, and expiration date.	--	Similar (Proposed device Vial Labeling is equivalent to the predicate device)

Technological Characteristics Compared to the Predicate Device	Proposed Device	Predicate Device	Predicate Device	Comparison
		PharmaCaribe (K101424)	Sodium Chloride Inhalation Solutions, USP 0.45%; 0.9% (K972466)	
	Embossed with identifying product text, lot number, expiration date and Level markings.	--	Embossed with identifying product text, lot number, expiration date and Level markings.	
Shelf Carton Labeling	Includes instructions for use and UDI requirements.	Includes instructions for use and UDI requirements.	Includes instructions for use and UDI requirements.	Similar (Proposed device Shelf Carton Labeling is equivalent to the predicate device)
Sterility	Contents are sterile	Contents are sterile	Contents are sterile	Similar (Proposed device and predicate device contents are sterile)
Primary Container Closure System	LDPE vial with twist-off cap	LDPE vial with twist-off cap	LDPE vial with twist-off cap	Similar (Proposed device primary container closure system is equivalent to the predicate device)
Fill Volume	0.9%: 3 mL and 5 mL 3%: 4 mL 7%: 4 mL	4 mL	3 mL and 5 mL	Similar (Proposed device 0.9% fill volume i.e. 3 mL and 5 mL is equivalent to the predicate device (K972466) and proposed device 3% and 7% fill volume i.e.

Technological Characteristics Compared to the Predicate Device	Proposed Device	Predicate Device	Predicate Device	Comparison
		PharmaCaribe (K101424)	Sodium Chloride Inhalation Solutions, USP 0.45%; 0.9% (K972466)	
				4 mL is equivalent to the predicate device (K101424)
Compliance with Compendia	United States Pharmacopeia	United States Pharmacopeia	United States Pharmacopeia	Similar (Proposed device and predicate device complies with United States Pharmacopeia)
Manufacturing Process	Aseptic Processing using Blow-Fill-Seal Technology	Aseptic Processing using Blow-Fill-Seal Technology	Aseptic Processing using Blow-Fill-Seal Technology	Similar (Proposed device Manufacturing Process (Aseptic) is equivalent as the predicate device)
Shelf Life	24 months	Unknown	unknown	-

Summary: The proposed device is Similar in both indications for use and technological characteristics when compared to the predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

- Design Verification: Design verification testing was conducted to ensure the device met the predetermined acceptance criteria for the following tests: Identity, Assay, pH, endotoxin, sterility, fill weight, vial attributes, and vial function (i.e., vial separation, cap removal, occluded orifice, etc.). All results met the predetermined acceptance criteria.

- Biocompatibility: A biocompatibility risk assessment was performed in accordance with the FDA Guidance Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process." Chemical characterization was performed on the final LDPE containers per ISO 10993-18, "Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process" and assessed extractable constituents based on the principles of ISO 10993-17:2002, "Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances." The extraction solvent was selected in alignment with the recommendations of ISO 10993-12:2021, "Biological evaluation of medical devices — Part 12: Sample preparation and reference materials."

- A validated, equivalent bacterial endotoxin test has been used in place of the in vivo rabbit pyrogen test in accordance with USP <151>, met the requirements for the absence of pyrogens.

Summary

The safety and effectiveness of the proposed device is demonstrated to be equivalent to the predicate device based on the results of the design verification testing, biocompatibility risk assessment and met the requirements for the absence of pyrogens in accordance with USP <151>.

Performance Testing Summary

Performance characteristics of proposed device that is the subject of this notification are equivalent to the predicate devices.

The Sodium Chloride Inhalation Solution USP 0.9%, 3% and 7% are manufactured and tested in an identical manner to the Predicate Device. This includes:

- USP Water for Injection
- Filtration – sterility grade filters
- USP Sodium Chloride
- Testing for
    - Description
    - Identification for Sodium and Chloride per USP (191)
    - Minimum fill per USP (755)
    - pH per USP (791)
    - Osmolality per USP (785)
    - Iron content
    - Uniformity of Dosage Unit per USP (905)
    - Container closure integrity USP (1207)
    - Sodium Chloride Assay per USP Monograph
    - Sterility per USP (71)
    - Particulate matter USP (789)
    - Foreign matter USP (790)
    - Bacterial Endotoxin Test per USP (85)
    - Testing for 3 Months stability of solution
    - Extractable study of the LDPE respule and manufacturing components
    - Leachable study for 3 Months stability of solution
    - Vial Attributes and Vial Functionality Testing (Vial separation, Cap removal, Occluded orifice)

VIII. CONCLUSIONS

Based on a comparison of composition, technological characteristics, intended use, design verification testing, performance testing, biocompatibility risk assessment and met the requirements for absence of pyrogens in accordance with USP <151>, it is concluded that the proposed device is substantially equivalent to the predicate device.