12/3/2021

The Ritedose Corporation
Linda Valentine
Director of Regulatory Affairs
1 Technology Circle
Columbia, South Carolina 29203

Re: K210126
Trade/Device Name: Sodium Chloride Inhalation Solutions, 3%, 3.5%, 7% and 10%
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: November 4, 2021
Received: November 5, 2021

Dear Linda Valentine:

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,

Brandon Blakely, 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)*
210126

Device Name
Sodium Chloride Inhalation Solution, USP 3%, 3.5%, 7% and 10%

Indications for Use *(Describe)*
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%, 3.5%, 7%, and 10%.

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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The Ritedose Corporation

510(k) Summary

I. SUBMITTER

The Ritedose Corporation
1 Technology Circle
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Phone: (803) 806-3300
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Contact Person: Linda Valentine, Director of Regulatory Affairs
Date Prepared: March 3, 2021

II. DEVICE

Name of Device: Sodium Chloride Inhalation Solution, USP, 3%, 3.5%, 7%, and 10%
Common or Usual Name:

- Sodium Chloride Inhalation Solution, USP, 3%, 3.5%, 7%, and 10%
- 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

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 3%, 3.5%, 7%, and 10% with a nominal fill volume of 4 mL and supplied in single-use low density polyethylene (LDPE) vials.

V. INDICATIONS FOR USE

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.

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** **PharmaCaribe (K101424)**	**Comparison**
Product Name:	Sodium Chloride Inhalation Solution, USP, 3%, 3.5%, 7%, and 10%	PharmaCaribe Inhaled saline solutions 3%, 3.5%, 6%, 7%, and 10%.	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.	Same
Material/Chemical Composition:	Water for Injection, USP Sodium Chloride, USP	Sterile Water for Injection, USP Sodium Chloride, USP	Sterile Water for Injection is used for the PharmaCaribe device. No impact as the final solution is sterilized via filtration.
Concentrations	3%, 3.5%, 7%, and 10%	3%, 3.5%, 6%, 7%, and 10%	The concentrations of the proposed device are within the range of the predicate.

Technological Characteristics Compared to the Predicate Device:	**Proposed Device**	**Predicate Device** **PharmaCaribe (K101424)**	Comparison
Indications for Use:	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%, 3.5%, 7%, and 10%	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 proposed device uses the established name and uses "is" instead of "are."
Prescription:	Yes	Yes	Same
Environment of Use:	Hospital, sub-acute care or home	Hospital, sub-acute care or home	Same
Patient Population:	Any patient population where sputum production is indicated.	Any patient population where sputum production is indicated.	Same
Used with a Nebulizer:	Yes	Yes	Same
Contraindications:	None	None	Same
Vial Labeling:	Embossed with identifying product text, lot number, and expiration date	Embossed with identifying product text, lot number, and expiration date	Same
Shelf Carton Labeling:	Includes instructions for use and UDI requirements.	Includes instructions for use and UDI requirements.	Same

Technological Characteristics Compared to the Predicate Device:	**Proposed Device**	**Predicate Device** **PharmaCaribe (K101424)**	Comparison
Sterility:	Contents are sterile	Contents are sterile	Same
Primary Container Closure System:	LDPE vial with twist-off cap	LDPE vial with twist-off cap	Same
Fill Volume:	4 mL	4 mL	Same
Compliance with Compendia:	United States Pharmacopeia	United States Pharmacopeia	Same
Manufacturing Process:	Aseptic Processing using Blow-Fill-Seal Technology	Aseptic Processing using Blow-Fill-Seal Technology	Same
Shelf Life:	24 months	unknown	-

Summary

The proposed device is identical 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 toxicological risk assessment was performed on the chemicals observed during the chemical characterization study. The organic chemicals extracted above the threshold of 1.5 µg/day, are considered to have a low potential for toxicity (low potency) and the calculated margin of safety is acceptable. Therefore, the chemicals observed do not pose significant systemic, genotoxic, or carcinogenic toxicological safety risks to all patients (adult and child). Additionally, material-mediated pyrogenicity testing was performed in accordance with USP <151> and met the requirements for the absence of material-mediated pyrogens under the conditions employed.

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 material-mediated pyrogenicity testing.

VIII. CONCLUSION

Based on a comparison of composition, technological characteristics, intended use, design verification testing, biocompatibility risk assessment, and material-mediated pyrogenicity testing, it is concluded that the proposed device is as safe and effective and is substantially equivalent to the predicate device.