K130091

510(k) Summary
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21-Feb-13

MAR 13 2013

PharmaCaribe
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Punta Gorda, FL 33950

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Official Contact: W. Randolph Warner, Managing Partner

Trade Name: ***PulmoSal***™ inhaled saline solution

Common/Usual Name: Saline solution

Classification Name: CAF – Nebulizer (Direct Patient Interface)
CFR – 868.5630, Class 2

Device: Inhaled saline solutions – 0.9%, 3%, 3.5%, 6%, 7%, and 10% with a pH of 7.4

Predicate Device: PharmaCaribe – Sodium Inhalation solutions - K101424

Device Description:
The proposed inhaled saline solutions are in 0.9%, 3%, 3.5%, 6%, 7%, and 10% concentrations with a pH of 7.4. They are packaged sterile in 4 ml vials for use as indicated.

Indications for Use:
PharmaCaribe inhaled saline solutions are used in conjunction with a nebulizer. The contents of these vials are for the induction of sputum production when used in conjunction with a nebulizer.

Concentrations of 0.9%, 3%, 3.5%, 6%, 7%, and 10% with a pH of 7.4

Patient Population:
Any patient requiring induction of sputum production.

Environment of Use:
Hospital, sub-acute care or home

Contraindications:
None

Predicate Device Comparison:

The ***PulmoSal***™ inhaled saline solution is viewed as substantially equivalent to the predicate devices because:

Indications –

- Intended to be in conjunction with a nebulizer for sputum production is identical to the predicate PharmaCaribe Inhaled Saline Solutions (K101424)

Discussion – identical to the predicate PharmaCaribe Inhaled Saline Solutions (K101424) except the addition of 0.9% saline and a pH of 7.4.

Technology of Manufacturing–

- A homogeneous aqueous mixtures of sterile water and saline

Discussion – identical to the predicate PharmaCaribe Inhaled Saline Solutions (K101424)

Mode of Action –

- Used with a nebulizer to increase sputum production

Discussion – identical to the predicate PharmaCaribe Inhaled Saline Solutions (K101424)

Formulation –

- Based upon USP specification except pH of 7.4 which matches the pH of the lungs
- 3%, 3.5%, 6%, 7% and 10% solutions identical to the predicate PharmaCaribe Inhaled Saline Solutions (K101424)
- 0.9% solution is identical to the predicate Nephron Pharma – Sodium Chloride Inhalation solution (K113033)

Discussion – the concentrations are identical to the predicates PharmaCaribe Inhaled Saline Solutions (K101424) and Nephron Pharma – Sodium Chloride Inhalation solution (K113033). The pH of 7.4 is identical pH *Pulmicort Respules"* (budesonide) AstraZeneca, which has a 7.4 pH, was approved under (NDA # N020929 an inhaled drug.

Materials –

- Blow-fill-sealed low density polyethylene (LDPE) vial containing sterile, preservative-free, clear, colorless, aqueous solution of sodium chloride in various concentrations by weight / volume. The formulation contains no additives.

Discussion – identical to the predicate PharmaCaribe Inhaled Saline Solutions (K101424)

Environment of Use –

- Hospital, home, sub-acute care settings

Discussion – identical to the predicate PharmaCaribe Inhaled Saline Solutions (K101424)

Patient Population –

- Any patient requiring induction of sputum production.

Discussion – identical to the predicate PharmaCaribe Inhaled Saline Solutions (K101424)

Features	Proposed *PulmoSal*™ Inhaled saline solution	Predicate PharmaCaribe K101424
Indications for use	PharmaCaribe inhaled saline solutions are used in conjunction with a nebulizer. The contents of these vials are for the induction of sputum production.	PharmaCaribe inhaled saline solutions are used in conjunction with a nebulizer. The contents of these vials are for the induction of sputum production when used in conjunction with a nebulizer.
Prescription	Yes	Yes
Environment of Use	Home, Hospital, Sub-acute Institutions	Home, Hospital, Sub-acute Institutions
Patient Population	Any patient requiring induction of sputum production.	Any patient requiring induction of sputum production.
Contraindications	None	None
Materials in fluid contact	Vial LDPE	Vial LDPE
Sterile water	Yes	Yes
Solutions	3%, 3.5%, 6%, 7% and 10%	3%, 3.5%, 6%, 7% and 10%
	0.9%	0.9% - K113033 – Nephron Pharma – USP pH
pH	7.4	USP 4.5 to 7.0
Manufactured	Per USP monograph except pH	Per USP monograph
Supplied	Sterile	Sterile
Used with a nebulizer	Yes	Yes

Non-clinical Testing Summary -

Asept Pak will perform Lot Release testing. The concentrations meet the USP Specifications with exception having a pH of 7.4, which is a normal physiological value. Additional performance testing includes:

In Process testing includes:

- Incoming resin certification and testing
- Current USP water testing
- pH as per USP <791>
- Appearance
- Salinity
- Environmental monitoring per Asept SOPs
- Container Fill weight monitoring
- Visual 100% inspection

Finished Product Tests

- Salinity
- Identification of Sodium per USP (191)
- Sodium Chloride Assay per USP Monograph
- Sterility as per USP <71>

The above demonstrates that the proposed devices are substantially equivalent to the predicate devices.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

PharmaCaribe
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
BONITA SPRINGS FL 34134

Re: K130091
Trade/Device Name: PulmoSal™ Inhaled Saline Solution
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 21, 2013
Received: February 22, 2013

Dear Mr. Dryden:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K130091 (To be assigned)

Device Name: ***PulmoSal™*** Inhaled saline solution

Indications for Use: 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 0.9%, 3%, 3.5%, 6%, 7%, and 10% with a pH of 7.4

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal -S

c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000059331, cn=Albert E. Moyal -S 2013.03.07 16:55:28 -05'00'

for LS

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130091