K101424

AUG 17 2010

510(k) Summary

14-Jul-10

PharmaCaribe
3513 Di Leuca St.
Punta Gorda, FL 33950

Tel - (941) 505-0793
Fax – (941) 505-0718

Official Contact: W. Randolph Warner

Proprietary or Trade Name: PharmaCaribe inhaled saline solutions

Common/Usual Name: Saline solution

Classification Name: Nebulizer (Direct Patient Interface)
CAF – 868.5630

Device: Inhaled saline solutions – 3%, 3.5%, 6%, 7%, and 10%

Predicate Devices: DEY Laboratories – K972778
Pari – K070498

Device Description:
PharmaCaribe Sodium Chloride Solutions are homogeneous mixtures (complete solutions) and are composed of USP sterile water and sodium chloride only and provided in 3%, 3.5%, 6%, 7%, and 10% concentrations. They are packaged sterile in standard 5ml (4ml fill) flexible material vials. The vials have a tear-off top. They are marked NOT FOR INJECTION.

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 3%, 3.5%, 6%, 7%, and 10%

Patient Population:
Any patient population where sputum specimens are indicated

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

Contraindications:
None

Features	Proposed Inhaled saline solutions	Predicate DEY K972778	Predicate Pari K070498
Indications for use	Used in conjunction with a nebulizer. The contents of these vials are for the induction of sputum production where sputum production is indicated.	Used in conjunction with a nebulizer. For induction of sputum production where specimen collection is indicated.	Used in conjunction with a nebulizer for an induction of sputum production where specimen collection is indicated.
Prescription	Yes	Yes	Yes
Environment of Use	Home, Hospital, Sub-acute Institutions	Same	Same
Patient Population	For those required sputum specimens	Same	Same
Used with a nebulizer	Yes	Yes	Yes
Contraindications	None	None	None
Marked Not for Injection	Yes	Yes	Yes
Packaged sterile in a flexible tear-off top vial	Yes	Similar	Identical
Solutions	3%, 3.5%, 6%, 7% and 10%	3% and 10%	3.5%, 6% and 7%
Manufactured	Per USP monograph	Same	Same
Manufacturing process and formulation per USP	Osmolality, Appearance, Pre-filtration Bioburden, Sterility USP (71), Identification of Sodium and Chloride USP (191), pH USP (791), Bacterial Endotoxin USP (85), Iron Content USP (241), Heavy Metals Content USP (231), Sodium Chloride Assay USP Monograph, 3 month stability of solution	Similar	Identical

Performance Testing Summary:

The PharmaCaribe inhaled saline solutions are manufactured and tested in an identical manner to the predicate Pari (K070498). This includes:

- USP Water
- Filtration – sterility grade filters
- Testing for
    - pH
    - Osmolality
    - Appearance
    - Pre-filtration Bioburden
    - Sterility per USP (71)
    - Identification of Sodium and Chloride per USP (191)
    - pH per USP (791)
    - Bacterial Endotoxin per USP (85)
    - Iron Content per USP (241)
    - Heavy Metals Content per USP (231)
    - Sodium Chloride Assay per USP Monograph
    - Testing for 3 month stability of solution

Differences between Other Legally Marketed Predicate Devices

Based upon formulation requirements as specified by the USP monograph the proposed inhale saline solutions are viewed as substantially equivalent (identical) to the predicates – DEY K972778 and Pari – K070498.

There are no differences and thus there are no new concerns of safety or effectiveness between the intended device and the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Pharmacaribe
C/O Mr. Paul Dryden
Promedic
24301 Woodsage Drive
Bonita Springs, Florida 34134

AUG 17 2010

Re: K101424
Trade/Device Name: PharmaCaribe Inhaled Saline Solutions 3%, 3.5%, 6%, 7% and 10%
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 14, 2010
Received: July 16, 2010

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,

for

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

Enclosure

K101424

Indications for Use Statement

510(k) Number: K101424

Device Name: PharmaCaribe Inhaled saline solutions 3%, 3.5%, 6%, 7%, and 10%

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 3%, 3.5%, 6%, 7%, and 10%

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)

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

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