nephron pharmaceuticals corporation

APR 2 0 2012

Section 5: 510(k) Summary k 120051

Date Premarket Notification Summary was Prepared
This 510(k) premarket notification summary was prepared January 02, 2012 in conjunction with the notification.

Applicant Name & Address
Nephron Pharmaceuticals Corporation
4121 SW 34th Street
Orlando, FL 32811
Phone: (407) 246-1389
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Contact Persons:
Lou Kennedy
President/CEO

Marcus Juliano
Vice President, Quality Assurance & Regulatory Affairs (regulatory contact)

Kimberly Grevera
Manager, Regulatory Affairs (regulatory contact)

Proprietary or Trade Name:	Sodium Chloride Inhalation Solution USP, 3%, 7% and 10%
Common/Usual Name:	Saline Solution
Classification Name:	Nebulizer (Direct Patient Interface) – Accessory CAF – 868.5630 Class II
Device:	Inhaled saline solution
Predicated Devices:	Pari Innovative – K070498 PharmaCaribe – K101424 Dey-Laboratories – K972778

Device Description
The subject devices are 4mL Sodium Chloride Inhalation Solution USP, 3%, 7% or 10%. The single-use devices are a clear blow-fill-sealed, low density polyethylene (LDPE) vials containing sterile, preservative-free, clear, colorless, aqueous solution as labeled for induction of sputum production where specimen collection is indicated. Sodium Chloride Inhalation Solution USP, 3%, 7% or 10% are used in conjunction with a nebulizer. The product contains 3%, 7% or 10% w/v Sodium Chloride USP in Water for Injection USP. The formulation contains no additives.

Contents	Volume	Container
3% Sodium Chloride Inhalation Solution, USP	4mL Fill	Clear, Embossed Label
7% Sodium Chloride Inhalation Solution, USP	4mL Fill	Clear, Embossed Label
10% Sodium Chloride Inhalation Solution, USP	4mL Fill	Clear, Embossed Label

Indications for Use
To be used in conjunction with a nebulizer, the contents of these vials are for the induction of sputum production where sputum production is indicated.

Limitations for Use
These devices are not intended for parenteral use or for preparations intended for parenteral use. The use of this device requires a prescription.

Technological Characteristics of the Subject Devices and Predicate Devices
The subject unit-dose devices of this premarket notification are formed of polyethylene resins meeting the direct food and drug contact criteria. The formed units meet the criteria for direct food and drug contact as prefilled unit containers. The solution component, at the stated concentration of Sodium Chloride Inhalation Solution, meets the USP monograph requirements.

The single-use containers are embossed with identifying product text.

The finished device product configuration characteristics of this inhalation device are similar to those of the predicate devices.

The Blow/Fill/Seal system on which these devices are manufactured represents technological advances in the production of these devices for inhalation therapy and in the control of the manufacturing environment. These devices are manufactured under conditions of current Good Manufacturing Practices (cGMP).

There are no technological differences between the subject devices and predicate devices that raise new questions of safety and effectiveness. Performance characteristics of these devices that are the subject of this notification are equal to or greater than the predicate devices.

Section 5: 510(k) Summary

Nonclinical and Clinical Testing

The component materials of the accessory device container have been substantiated to each meet the criteria for direct food and drug contact or additive respectively. The formulation components of the filled device solution have been substantiated to each meet their respective USP monograph criteria. The finished device undergoes testing to meet the stated USP monograph and container criteria.

Clinical testing is not necessary to show substantial equivalence for either safety or efficacy of intended use to the predicate devices as there are several various in vitro analytical methods (assay; fill uniformity; sterility; container integrity) and physical-chemical characteristics (solution properties; unit configuration) available which demonstrate this equivalence.

Summary Conclusions

The subject devices:

3% Sodium Chloride Inhalation Solution, USP
7% Sodium Chloride Inhalation Solution, USP
10% Sodium Chloride Inhalation Solution, USP

as manufactured by Nephron Pharmaceuticals Corporation of Orlando, FL claims substantial equivalence, with the same intended use, to several devices which have received market clearance through established equivalence.

These devices are designed to meet current USP specifications. The device containers have embossed unit identification and shelf carton labeling so that label requirements are met.

Analytical testing to the stated specifications demonstrates that these devices will have comparable safety and efficacy in use.

The devices, as manufactured by Nephron, are produced using Blow Fill Seal technology specifically designed for aseptic filling operations. These manufacturing systems represent a technological advance for the production of these types of devices.

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

Mr. Marcus Juliano
Vice President, Quality Assurance & Regulatory Affairs
Nephron Pharmaceuticals Corporation
4121 SW 34th Street
Orlando, Florida 32811

APR 2 0 2012

Re: K120051
Trade/Device Name: Sodium Chloride Inhalation Solution USP, 3%, 7%, AND 10%
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: March 30, 2012
Received: April 2, 2012

Dear Mr. Juliano:

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.

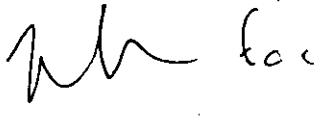
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

nephron pharmaceuticals corporation

Section 4: Indications for Use Statement

510(k) Number: **Not Known**

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

Indications for Use:

To be used in conjunction with a nebulizer, the contents of these vials are for the induction of sputum production where sputum production is indicated.

Prescription Use __X___ (21 CFR 801 Subpart D) and/or Over-The-Counter Use_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

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