1. Applicant Name & Address:

Holopack International, LP
Carolina Research Park
1 Technology Circle
Columbia, SC 29203

JAN 21 1998

Contact Persons:

Walter Zahn
President
Phone: 803-806-3300
Fax: 803-806-3301

Marianna Cronrath
Regulatory Agent
Phone: 732-888-6278
Fax: 732-888-2917

This 510(k) premarket notification summary was prepared October, 1997 in conjunction with the notification.

2. Device Name and Classification:

- Trade Name of Device:

  2.1 0.9% Sodium Chloride Inhalation Solution, USP
  [labeled concentration at 0.9%]

- Common Name of the Device:

  2.2 0.9% Sodium Chloride Inhalation Solution

- Classification: Class II, Anesthesiology
  514 Compliance: Standard

  2.3 Class Code: 73 CAF

3. The Predicate Devices to which Equivalence is Claimed

There are several comparable devices manufactured prior to 1976 and/or those to which Substantial Equivalence is claimed.

K884359 Unit Dose 0.45%; 0.9% ; 3% Sodium Chloride Solution for Inhalation in 3, 5 and 15mL containers

K870332 Automatic Liquid Packaging, Inc.
2200 W. Lake Shore Drive
Woodstock, IL 60096

K8703320 Travenol Laboratories (pre-1976)
Wyeth Laboratories, Inc. (pre-1976)
Respiratory Therapy Vials

Sodium Chloride Inhalation Solution
Dey Laboratories, Inc.
Concord, CA 94518

4. Description of the Devices

The single-use device is in a color-coded unit blow-fill-sealed container with liquid contents as labeled for inhalation therapy. The device contains no preservative and is sterile and pyrogen-free.

CONTENTS	VOLUME	CONTAINER
0.9% Sodium Chloride Inhalation Solution, USP	15mL fill	Pink Embossed label

5. Intended Use

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

The intended use indication is identical to those devices to which substantial equivalence is claimed. The use of these devices as respiratory therapy accessories and for inhalation therapy is well-established.

5.1 Limitations

These devices are not for parenteral use nor for preparations intended for parenteral use. The use of these devices is on order of physician or licensed practitioner.

6. Technological Characteristics of the Device and the Predicate Devices

The subject unit dose device containers of this premarket notification are formed of polyethylene resins meeting the direct food and drug contact criteria. The formed units likewise meet the criteria for direct food and drug contact as prefilled unit containers. The solution component at the stated concentration in Sodium Chloride Inhalation Solution meets the current USP monograph requirements.

The single-use containers are embossed with identifying product text and level markings. The finished device product configuration characteristics of these inhalation devices are similar to those of the predicate devices.

The technological improvements relate to the method of manufacture of the devices which are the subject of this premarket notification. The blow-fill-seal systems used by Holopack International, LP in the production of these devices for inhalation therapy utilize dark-side/white-side machine technology. The blow-fill-seal systems on which the devices are manufactured represent technological advances in this type of production and in the control of the manufacturing environment. The devices are manufactured under conditions of current Good Manufacturing Practices (cGMP).

Performance characteristics of the devices that are the subject of this notification are identical or better than the predicate devices. Proprietary details of the aseptic manufacturing environment and blow-fill-seal technology are referenced under confidentiality.

7. Non-Clinical and Clinical Testing

The component materials of the accessory device container have each been substantiated to meet criteria for direct food and drug contact or additive respectively and to comply with USP container testing. The formulation components of the filled device solution have been substantiated to each meet their respective USP monograph criteria. Each of the finished devices 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 various *in vitro* analytical methods (assay; fill uniformity; sterility; container integrity) and physical-chemical characteristics (solution properties; unit configuration) available which demonstrate this equivalence.

8. Summary Conclusions

The subject device:

0.9% Sodium Chloride Inhalation Solution, USP

as manufactured by Holopack International, LP of Columbia, SC claims substantial equivalence, with the same intended use, to several devices which were manufactured prior to 1976 or which have received market clearance through established equivalence.

This device is designed to meet the current USP specifications. The device containers have embossed unit identification and shelf carton labeling.

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

The devices, as manufactured by Holopack, are produced using dark-side/white-side blow-fill-seal technology on rommeLag® machines specifically designed for aseptic filling operations. These manufacturing systems represent a technological advance for the production of this type of device. The details of the aseptic manufacturing processes and environment are referenced under confidentiality.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1998

Mr. Walter Zahn
Holopack International, L.P.
Carolina Research Park
1 Technology Circle
Columbia, SC 29203

Re: K974056
0.9% Sodium Chloride Solution for Inhalation, USP
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: October 20, 1997
Received: October 27, 1997

Dear Mr. Zahn:

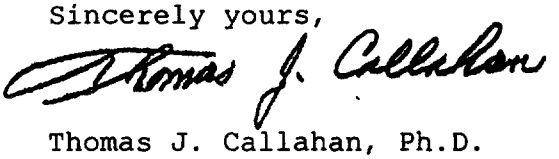
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

Devices: **Sodium Chloride Inhalation Solution, USP**
[labeled concentration at]
0.9%

Intended Use

The intended use of these sterile single use devices is as accessories to medicinal non-ventilatory nebulizers in respiratory therapy or for tracheal irrigation or lavage.

The intended use indication is identical to those devices to which substantial equivalence is claimed. The use of these devices for inhalation therapy is well-established.

Limitations

These devices are not for parenteral use nor for preparations intended for parenteral use.

The use of these devices is on order of physician or licensed practictioner.

Prescription Device

M. Ryan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974056