JUN 2 1998

Steripak

510(k) Summary

"This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92".

"The assigned 510 (k) number is K980829 ".

1. Submitter Information

Steripak Limited
Goddard Road, Astmoor
Runcorn , Cheshire WA7 1QF
England

Contact Person: Steve Forrester-Coles
Site Operations Director

Phone: 44-1-928-579110
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2. Name of Device

Trade/Proprietary Name:	3mL Steri-Neb Saline, 0.9% $^{W}/_{V}$ Sodium Chloride Inhalation Solution USP
Common/Usual Name:	Pre-filled Vial for Respiratory Therapy, 0.9% $^{W}/_{V}$ Sodium Chloride Inhalation Solution USP
Classified Name:	Accessory for Nebulizer, Direct Patient Interface

3. Predicate Device

The predicate device identified for the substantial equivalence claim is Dey's 3 mL 0.9% Sodium Chloride Inhalation Solution USP. This product is distributed by Dey under Automatic Liquid Packaging, Incorporated's 510 (k) K840943, Pre-filled Respiratory Therapy Vial, cleared on April 24, 1983. Dey's Sodium Chloride Inhalation Solution USP 0.9% product is a plastic single-use vial containing sterile preservative-free solution for respiratory therapy and tracheal lavage.

4. Description of the Subject Device

The subject device is 3 mL Steri-Neb Saline, 0.9% $^{W}/_{V}$ Sodium Chloride Inhalation Solution USP. Steri-Neb Saline is used for respiratory therapy and tracheal lavage. For respiratory therapy, Steri-Neb Saline is used for dilution of solutions used in nebulizers. Steri-Neb Saline is a unit dose low density polyethylene vial containing sterile, preservative-free, clear, colourless, aqueous solution. The Steri-Neb Saline product contains 0.9% w/v Sodium Chloride USP in Water for Injection USP. The formulation contains no additives.

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5. Intended Use of the Subject Device

The Steri-Neb Saline product is 0.9% Sodium Chloride Inhalation Solution USP in a plastic unit-dose vial. The Steri-Neb Saline plastic unit-dose vial is first separated from the strip of vials and then opened by twisting off the top of the vial. The Steri-Neb Saline is used for respiratory therapy and tracheal lavage. For respiratory therapy, the Steri-Neb Saline vial is emptied into the nebulizer reservoir by squeezing the solution from the opened vial. The Steri-Neb Saline product is a sterile single use product. Any solution remaining in the plastic unit-dose vial should be discarded.

6. Technological Characteristics of the Subject Device Compared to the Predicate Device

The predicate device identified for the substantial equivalence claim is Dey's 3 mL 0.9% w/v Sodium Chloride Inhalation Solution USP. Dey's product is substantially equivalent to the Steri-Neb Saline product in that both products are plastic unit-dose vials containing 0.9% Sodium Chloride Inhalation Solution USP for single-use in respiratory therapy and tracheal lavage. The solution for both the predicate and subject device is sterile and preservative-free. Comparison of the predicate device and the subject device indicate that there are no technological differences between the two products that raise new questions of safety and effectiveness. Details of the substantial equivalence claim are included in Attachments 3 through 8.

7. Signature of Applicant

Steripak Limited,

John William Holloway BSc. CChem MRSC MBIRA
Head of Product Development and Regulatory Affairs

Signature

03/03/98

Date

Steripak Limited,
Goddard Road, Astmoor, Runcorn, Cheshire WA7 1QF (Registered Office)
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1998

Mr. Jason A. Gross
Zenith Goldline Pharmaceuticals Inc.
140 Legrand Avenue
Northvale, NY 07647

Re: K980829
0.9% w/v Sodium Chloride Inhalation Solution USP
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: March 3, 1998
Received: March 4, 1998

Dear Mr. Gross:

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

510 (K) Notification
3rd March 1998

Indications For Use Statement

510(k) Number (if known): K980829

Device Name : 0.9%w/v Sodium Chloride Inhalation Solution USP

Indications For Use:

For respiratory therapy and tracheal lavage

(Please Do Not Write Below This Line - Continue On another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980829

Prescription Use ✓ Over-The-Counter Use_____

(Per 21 CFR § 801.109)