DEY LABORATORIES
2751 Napa Valley Corporate Drive
Napa, CA 94558
TEL.(707) 224-3200 FAX (707) 224-0791

K972778

PREMARKET NOTIFICATION [510(K)] SUMMARY

OCT - 8 1997

Dey Laboratories LP
2751 Napa Valley Corporate Drive
Napa, CA 94558
(707) 224-3200
Fax: (707) 224-0791
Contact Person: Allan S. Kaplan, R.P., Ph.D., Vice President of Technical Affairs
Date Summary Prepared: July 18, 1997

Trade Name: DEY-PAK® Sodium Chloride Solution 3%
DEY-PAK® Sodium Chloride Solution 10%

Common Name: Sodium Chloride Solution 3%
Sodium Chloride Solution 10%

Classification: Class II

Equivalence Claim: DEY-VIAL® Sodium Chloride, USP Sterile 10 mL (K880411)
Arm-A-Vial (Armour, K841988, K841988-A, K841989, K841989-A)
Dis-Pos-Vial (Parke-Davis)
Redipak (Wyeth)

Device Description: DEY-PAK® Sodium Chloride Solution 3% and 10% solutions are contained in a 15 mL polyethylene vial. The vials have a tear-off top and a lower tab for displaying the lot number and expiration date. One side of the vial has pressure sensitive label and the other side is blank. The vials are supplied in cartons of 50 vials.

Intended Use: DEY-PAK® Sodium Chloride Solution 3% and 10% are used in conjunction with a nebulizer. The contents of the vial is to be dispensed, as prescribed, into a nebulizer cup. The solution is then inhaled to induce sputum.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 8 1997

Allan S. Kaplan, R.P., Ph.D.
Dey Laboratories
2751 Napa Valley Corporate Drive
Napa, California 94558

Re: K972778
DEY-PAK® Sodium Chloride Solution, USP, Sterile, 3% and 10%
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: July 24, 1997
Received: July 25, 1997

Dear Dr. Kaplan:

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

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) Number (if known): K972778

Device Name: Dey Vial Sodium Chloride 3% and 10%

Indications For Use:

Dey Vial Sodium Chloride 3% and 10% are used in conjunction with a nebulizer for the induction of sputum production where specimen collection is indicated.

(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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use V OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)