K973829

510(k) Summary
Automatic Liquid Packaging Inc.
Sterile Water and Saline Bottle for Irrigation

FEB 2 3 1998

Submitter:

Automatic Liquid Packaging Inc.
2200 W. Lake Shore Drive
Woodstock, IL 60098

Device Name:

- Common Name: Sterile Water and Saline Bottle for Irrigation
- Classification Name: Unclassified

Predicate Device:

ALP's Prefilled Saline Solution for Irrigation USP

Description of the Device:

Automatic Liquid Packaging, Inc. Sterile Water and Saline Solutions are products that have been used in the medical community for decades. These products have not experienced or been associated with toxic or undesirable effects that relate to the ingredients used in their production. The only ingredient in the two solutions other than water is Sodium Chloride; there are no preservatives or stabilizers.

The irrigation bottle is manufactured of 100% virgin low density polyethylene (LDPE) and contains no regrind, color or chemical additives.

The two solutions are sterile, aseptically filled, and are hermetically sealed for Single Use Only.

Intended Use:

The intended use of the Sterile Water and Saline Irrigation Bottle is to irrigate:

- Nasal suctioning and tracheostomy catheters to lubricate these and aid in their use
- Body cavities

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Automatic Liquid Packaging, Inc.
c/o Mr. Eduardo March
Senior Consultant
AAC Consultant Group
7475 Wisconsin Avenue, Suite 850
Bethesda, MD 20814

FEB 23 1998

Re: K973829
Irrigation Bottle
Regulatory Class: II (Two)
Product Code: 73 JOH
Dated: January 21, 1998
Received: January 23, 1998

Dear Mr. March:

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) Number (if known): K973829

Device Name: Sterile Water and Saline Solution Irrigation Bottle

Indications for Use:

This solution is indicated for use as a tracheal lavage, nasal irrigation solution or as an irrigation solution for flushing a body cavity.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONIINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **OR** **Over-the-Counter Use:**
(Per 21 CFR 80.109)

M. Pugsley

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____