

OCT 25 2000

K994321

SMDA REQUIREMENTS

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Sterile Water and Saline Bottles for Irrigation, USP**

Manufacturer: Automated Liquid Packaging, Inc.
2200 West Lake Shore Drive
Woodstock, IL 60098

Regulatory Affairs Contact: John Brda

Telephone: 815/338-9500

Date Summary Prepared: December, 1999

Common Name: Sterile Water and Saline Bottle for Irrigation, USP

Classification: Class II per 21CFR § 868.

Predicate Device: Sterile Water and Saline for Irrigation

Description: Automated Liquid Packaging, Inc. Sterile Water and Saline Solutions are products that have been used in the medical community for decades. 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% low density polyethylene (LDPE) and contains no color or chemical additives.

The two solutions are sterile, aseptically filled and are hermetically sealed for single use only.

SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS Sterile Water and Saline Bottles for Irrigation

- Intended Use:** Sterile Water and Saline Solutions are defined as an accessory to a device that is intended For Device Cleaning and Irrigation.
- Substantial Equivalence:** The Sterile Water and Saline Solutions are substantially equivalent to the Sterile Water and Saline Solutions in that:
- the intended use is the same
 - the performance attributes are the same
- Summary of testing:** All materials used in the fabrication of Sterile Water and Saline Solutions were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.



OCT 25 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Brda
Regulatory Affairs Manager
Automatic Liquid Packaging, Incorporated
2200 Lake Shore Drive
Woodstock, Illinois 60098

Re: K994321
Trade Name: Sterile Water and Saline Solutions
Regulatory Class: II
Product Code: JOL
Dated: July 27, 2000
Received: July 31, 2000

Dear Mr. Brda:

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 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). 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.

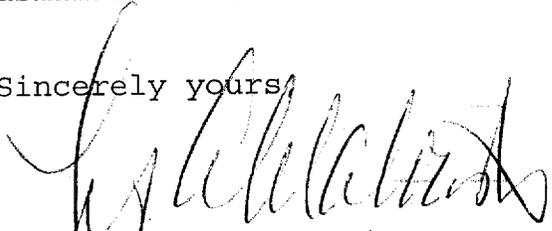
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: Sterile Water and Saline Solutions

Indications For Use: Sterile Water and Saline Solutions are defined as an accessory to a device that is intended For Device Cleaning and Irrigation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use

(Per 21 CFR 801.109)

(Division Sign-Off) James R. Shell for Pat Criscuti
Division of Cardiovascular, ~~Respiratory,~~
and Neurological Devices
510(k) Number 994321