

K980147

K980147 Summary

510(k) SUMMARY

1. **SUBMITTER** **Company:** Automatic Liquid Packaging, Inc
 Address: 2200 W. Lake Shore Dr
 Woodstock, IL 60098-7498

2. **CONTACT PERSON** **John Brda**
 Address: 2200 W. Lake Shore Dr
 Woodstock, IL 60098-7498
 Telephone: (815) 338-9500

3. **DEVICE IDENTIFICATION**
 Common Name Multipurpose Contact Lens Solution
 Trade Name **Store Name** Multi-purpose Solution

4. **CLASSIFICATION**
 Class II (Performance Standards)
 21 CFR 886.5928
 Soft (hydrophilic) contact lens solution

5. **PREMARKET NOTIFICATION NUMBER** K980147

6. **INDICATIONS FOR USE**
 The STORE NAME Multi-Purpose Solution is indicated for use in cleaning, rinsing, chemical
 (NOT HEAT) disinfection, and storing of soft (hydrophilic) contact lenses.

7. **DEVICE DESCRIPTION**
 A sterile isotonic, phosphate buffered saline solution containing polyoxyethylene polyoxy-
 propylene block copolymer, preserved with 0.128% EDTA and 0.0001% Cosmocil CQ
 (polyhexamethylene biguanide).
 Contains no chlorhexidine or thimerosal.
 Cleans, loosens and removes accumulations of films, deposits and debris from soft contact lenses.
 Destroys harmful microorganisms on the surface of the lens. Rinses, stores and rewets lenses
 before the lenses are placed on the eye.

8. **SUBSTANTIAL EQUIVALENCE**
 This product is substantially equivalent to the currently marketed product, Complete brand Multi-
 Purpose Solution. The device has the same basic technological characteristics as the predicate
 device, relative to design, packaging and composition.

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9. SAFETY AND EFFICACY

A. Chemistry

STORE NAME Multi-Purpose Solution is a sterile isotonic, phosphate buffered saline solution containing polyoxyethylene polyoxypropylene block copolymer, preserved with 0.128% EDTA and 0.0001% Cosmocil CQ (polyhexamethylene biguanide).

The compatibility of the Store Name Multi-purpose Solution was shown for cleaning, rinsing, disinfecting and storing soft hydrophilic contact lenses.

- a. cycling
- b. critical micelle concentration

B. Toxicology

The solution and bottle were shown to be non-toxic in all tests as listed below.

- a. **Agar Overlay Cytotoxicity (Direct Contact Antisl/Gess Method): non-cytotoxic**
- b. **Systemic Toxicity (USP/ISO Method): no difference, test/control**
- c. **Acute Oral Toxicity (FDA Draft Guidelines for Class III Soft Hydrophilic Contact Lens Solutions, July 1985 revision): no acute oral toxicity.**
- d. **Acute Ocular Irritation (FDA Guidelines for Class III Intraocular and Contact Lenses and Ophthalmic Solutions, Federal Register Volume 50, No. 183): no acute ocular irritation**
- e. **Full USP Class VI Testing for Containers for Ophthalmic Products.**

C. Microbiology

- a. **Sterility: Sterile**
- b. **Preservative efficacy: passed challenge/rechallenge**
- c. **Disinfection Efficacy: passed stand-alone disinfection test**
- d. **Stability: to date, approximately one year**

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10. CLINICAL STUDIES

A. Accountability

	Test	Control	
		Multipurpose	Peroxide
Completed	419*	107	94
Discontinued	72	10	23
Total	491	117	116

*Number of eyes

B. Final Visual Acuity

	Test	Control	
		Multipurpose	Peroxide
20/15	30*	7	8
20/20	344	92	83
20/25	74	13	17
20/30	21	1	0
20/40	5	1	0
20/50 or greater	1	1	0
Not reported	16	3	8

*Number of eyes

C. Adverse Reactions

2 adverse reactions in the test group, both resolved with no sequelae

D. Slit Lamp Findings

	Test	Control	
		Multipurpose	Peroxide
Edema	5/2,990*	6/750	4/672
Neovas	102/2,990	48/750	62/672
Stain	85/2,990	119/750	60/672
Hypertonia	320/2,990	93/750	40/672
Palpebral	335/2,990	199/750	123/672
Other	16/2,990	7/750	3/672

*Number of reports/number of eye examinations at scheduled visits

K980147 Summary**E. Symptoms, Problems and Complaints**

	Test	Control	
		Multipurpose	Peroxide
Total Visits	2,990	750	672
No symptoms	2,503	597	573
1. Discomfort	88	26	28
2. Movement	12	2	6
3. Tearing	10	6	10
4. Photophobia	17	4	4
5. Pain, etc	61	22	18
6. Spectacle blur	15	10	0
7. Secretions	16	12	10
8. Lens awareness	121	25	26
9. Blinking	19	4	3
10. Variable vision	46	34	11
11. Handling	2	2	0
12. Poor dist. Vision	25	19	2
13. Cleaning	55	39	12
14. Reading problems	7	2	5
15. Medications	2	2	2
16. Sol'n sensitivity	32	3	6
17. Other	163	32	29
Total symptoms	691	244	168

F. Lens Cleanliness

	Test	Control	
		Multipurpose	Peroxide
Clinically clean	2,919/2,990	695/750	630/672



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 1998

Mr. John Brda
Regulatory Affairs Manager
Automatic Liquid Packaging
2200 Lake Shore Drive
Woodstock, Illinois 60098-7498

Re: K980147
Trade Name: Store Name Multi-Purpose Soft (hydrophilic) Contact Lens Solution
Regulatory Class: II
Product Code: 86 LPN
Dated: January 14, 1998
Received: January 15, 1998

Dear Mr. Brda:

This letter corrects our substantially equivalent letter of April 13, 1998 regarding the above referenced device to change the addressee.

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

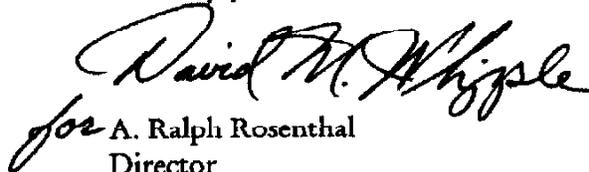
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action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might 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) 594-1744. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "David M. Whipple". The signature is written in dark ink and is positioned above the typed name of the signatory.

for A. Ralph Rosenthal
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER (IF KNOWN) K980147

DEVICE NAME STORE NAME MULTI-PURPOSE SOLUTION

INDICATIONS FOR USE

STORE NAME Multi-Purpose Solution is indicated for use in cleaning, rinsing, chemical (NOT HEAT) disinfection, and storing of soft (hydrophilic) contact lenses.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(21 CFR 801.109)

OR

Over-The-Counter-Use X (Per
(Optional Format 1-2-96)

M. Smith
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980147

JS