OCT 7 1999 K992028

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
REFRESH® CONTACTS™ Lubricating and Rewetting Drops

1. **Submitter Information:**

Allergan, Inc.
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Contact Person: Paul J. Nowacki
Manager, Regulatory Affairs
Telephone: (714) 246-6761 (voice)
(714) 246-5457 (fax)

2. **Device Name:**

Common Name:	In-Eye Soft (Hydrophilic) Contact Lens and Rigid Gas Permeable Contact Lens Lubricating and Rewetting Solution
Trade Name:	REFRESH® CONTACTS™ Lubricating & Rewetting Drops
Device Classification:	Accessories to Contact Lenses – Cleaning and Wetting Agents (86LPN)

3. **Predicate Device:**

The Allergan products, REFRESH® CL Lubricating and Rewetting Drops, COMPLETE® Lubricating and Rewetting Drops and CLARIS® Rewetting Drops were selected as the predicate device for REFRESH® CONTACTS™ Lubricating and Rewetting Drops.

4. **Device Description:**

REFRESH® CONTACTS™ Lubricating and Rewetting Drops is a sterile, buffered, isotonic preserved solution containing sodium carboxymethylcellulose as the demulcent and preserved with PURITE® (stabilized oxychloro complex 0.005%). Boric acid, sodium chloride, potassium chloride, calcium chloride and magnesium chloride act as buffering and tonicity agents.

REFRESH® CONTACTS™ Lubricating and Rewetting Drops is supplied sterile, packaged in plastic bottles with controlled dropper tips and labeled with lot number and 24 month expiration date.

5. Indications for Use:

- Use REFRESH® CONTACTS™ Lubricating and Rewetting Drops to lubricate and rewet soft and rigid gas permeable contact lenses (silicone acrylate lenses and fluorosilicone acrylate lenses).
- Use REFRESH® CONTACTS™ Lubricating and Rewetting Drops to help relieve dryness, discomfort and irritation that may be associated with lens wear.
- Use REFRESH® CONTACTS™ Lubricating and Rewetting Drops to cushion lenses by placing a drop on the lens prior to application on to the eye.

6. Description of Safety and Substantial Equivalence:

A series of preclinical tests and clinical testing was performed to demonstrate the safety and effectiveness of REFRESH® CONTACTS™ Lubricating and Rewetting Drops. The following is a summary of the test results.

Preclinical Testing

A series of in-vitro and in-vivo preclinical chemical, toxicological and microbiological studies were performed to assess the safety and effectiveness of REFRESH® CONTACTS™ Lubricating and Rewetting Drops. The tests were designed and performed in accordance with the guidelines set forth in FDA's May 1, 1997 **Guidance for Industry – Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products.**

The results of these studies indicate that the physical, chemical and microbiological properties of REFRESH® CONTACTS™ Lubricating and Rewetting Drops are substantially equivalent to the predicate devices REFRESH® CL Lubricating and Rewetting Drops, COMPLETE® Lubricating and Rewetting Drops and CLARIS® Rewetting Drops.

The solution is non-toxic to the ocular tissue as demonstrated by in-vivo preclinical testing in laboratory animals. In-vitro lens compatibility testing was conducted to establish product compatibility with both soft (hydrophilic) contact lenses and RGP contact lenses.

Clinical Testing

A one month clinical study was conducted to evaluate the safety and acceptability of REFRESH® CONTACTS™ Lubricating and Rewetting Drops for both hydrogel and rigid gas permeable (RGP) contact lenses. The results of the study showed that the product is safe and acceptable for its intended use based on:

- One month successful use by 100% of subjects- (25/25) hydrogel lens wearers and (25/25) RGP lens wearers.
- Safety comparable to COMPLETE® Lubricating and Rewetting Drops (hydrogel lens wearers) or CLARIS® Rewetting Drops (RGP lens wearers) as measured by slit lamp findings.
- Acceptability comparable to COMPLETE® Lubricating and Rewetting Drops (hydrogel lens wearers) or CLARIS® Rewetting Drops (RGP lens wearers) as measured by symptoms of discomfort.

Results of the clinical study demonstrate the safety, acceptability and substantial equivalence of REFRESH® CONTACTS™ Lubricating and Rewetting Drops to the predicate devices for lubricating and rewetting both soft (hydrophilic) and RGP contact lenses.

Substantial Equivalence

REFRESH® CONTACTS™ Lubricating and Rewetting Drops are substantially equivalent in terms of action, indications for use, safety and effectiveness to the predicate devices, REFRESH® CL Lubricating and Rewetting Drops (approved for marketing under PMA P960012), COMPLETE® Lubricating and Rewetting Drops (approved for marketing under P910075/S7) and CLARIS® Rewetting Drops (approved for marketing under P900047/S5). Any differences between the new device and its predicates do not effect the use of this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1999

Mr. Paul J. Nowacki
Manager, Regulatory Affairs
Allergan
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Re: K992028
Trade Name: REFRESH® CONTACTS™ Lubricating and Rewetting Drops
Regulatory Class: II
Product Code: 86 LPN
Dated: September 10, 1999
Received: September 13, 1999

Dear Mr. Nowacki:

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) 594-4613. 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)	**K992028**
Device Name	**REFRESH® CONTACTS™ Lubricating and Rewetting Drops**
Indications for Use	• Use REFRESH® CONTACTS™ Lubricating and Rewetting Drops to lubricate and rewet soft and rigid gas permeable contact lenses (silicone acrylate lenses and fluorosilicone acrylate lenses). • Use REFRESH® CONTACTS™ Lubricating and Rewetting Drops to help relieve dryness, discomfort and irritation that may be associated with lens wear. • Use REFRESH® CONTACTS™ Lubricating and Rewetting Drops to cushion lenses by placing a drop on the lens prior to application on to the eye.

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 Ophthalmic Devices
510(k) Number K992028

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109