ALLERGAN

DEC 18 1998

2525 Dupont Drive, P.O. Box 19534, Irvine, California, USA 92623-9534 Telephone: (714) 246-4500 Website: www.allergan.com

K 984383

December 4, 1998

510(k) SUMMARY

1. Submitter Information

Allergan
2525 Dupont Drive
Irvine, California 92612

Contact Person: Paul J. Nowacki
Manager, Regulatory Affairs

Telephone Number: (714) 246-6761

2. Device Name

Classification Name: Soft (hydrophilic) contact lens care products
Proprietary Name ULTRACARE® Neutralizing Tablets

3. Predicate Device

The predicate device is ULTRACARE® Neutralizing Tablet with Color Indicator.

4. Description of the Device

ULTRACARE Neutralizing Tablets are smooth, round, beige to pale pink tablets that contain catalase, hydroxypropyl methylcellulose, and cyanocobalamin (Vitamin B_{12}) as a color indicator, with buffering and tableting agents.

5. Indications for Use

ULTRACARE Neutralizing Tablets are part of the ULTRACARE® System, a disinfecting, neutralizing and storage system for daily and extended wear soft (hydrophilic) contact lenses in a chemical (not heat) lens care system.

The ULTRACARE Neutralizing Tablets are indicated for use to neutralize the ULTRACARE® Disinfecting Solution in the ULTRACARE System. ULTRACARE Neutralizing Tablets are added at the beginning of the disinfection cycle so that disinfection and neutralization occur without any additional steps.

6. Description of Safety and Substantial Equivalence

A series of preclinical tests and clinical testing was performed to demonstrate the safety and effectiveness of ULTRACARE® Neutralizing Tablets. 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 following is a summary of the test results.

Preclinical Testing

A series of *in-vitro* and *in-vivo* preclinical chemical, microbiological and toxicological studies were performed to assess the safety and effectiveness of ULTRACARE Neutralizing Tablets. The results of these studies indicate that ULTRACARE Neutralizing Tablets are substantially equivalent to the predicate device.

Lens compatibility

A study was conducted to determine the compatibility of hydrogel contact lenses with the ULTRACARE® lens care regimen consisting of ULTRACARE® Disinfecting Solution, ULTRACARE® Neutralizing Tablets and ULTRAZYME® Enzymatic Cleaner. A control regimen using the predicate device was also tested.

Representative lenses from FDA Lens Groups 1 and 4 were monitored for changes in power, diameter, basecurve, spectral transmittance and material surface changes during and after 30 regimen cycles.

The results indicated that ULTRACARE Neutralizing Tablets used in combination with ULTRACARE Disinfecting Solution and ULTRAZYME Enzymatic Cleaner are compatible with hydrogel contact lenses and perform comparably to the predicate device.

Microbiology

The antimicrobial efficacy of the ULTRACARE® System using ULTRACARE Neutralizing Tablets was evaluated, in the presence and absence of ULTRAZYME Enzymatic Cleaner, against FDA's recommended panel of microorganisms.

The test results showed that the disinfection system using ULTRACARE Neutralizing Tablets met the criteria for "stand-alone" contact lens disinfecting products.

Toxicology

A 28-day subacute ocular safety study was performed using ULTRACARE® Neutralizing Tablets in conjunction with ULTRACARE® Disinfecting Solution and ULTRAZYME® Enzymatic Cleaner. The results of this study showed no clinically significant ocular discomfort, irritation or toxicity.

Clinical Testing

A three-month clinical study was conducted to evaluate the safety and acceptability of ULTRACARE Neutralizing Tablets when used with ULTRACARE Disinfecting Solution for hydrogel contact lenses.. The results of the study showed that the ULTRACARE lens care regimen is safe and acceptable for its intended use based on:

- Successful use by 96.7% (55/59) of evaluable subjects
- No apparent difference in the key safety variable of corneal staining compared to the predicate device
- No apparent difference in the key acceptability variable of lens comfort compared to the predicate device.

Results of the clinical study demonstrate the safety, acceptability and substantial equivalence of ULTRACARE Neutralizing Tablets to the predicate device for its intended use.

7. Substantial Equivalence

ULTRACARE Neutralizing Tablets are substantially equivalent in terms of actions, indications for use, safety, and effectiveness to the predicate device: ULTRACARE Neutralizing Tablets with Color Indicator (approved for marketing under PMA P850088/S36).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

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

Re: K984383
Trade Name: ULTRACARE ® Neutralizing Tablets with Color Indicator
Regulatory Class: II
Product Code: 86 LPN
Dated: December 4, 1998
Received: December 8, 1998

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

Attachment 2

Indications for Use Statement

510(k) Number (if known)	The predicate device, ULTRACARE® Neutralizing Tablets with Color Indicator, was approved under **PMA P850088/S36.**
Device Name	**ULTRACARE®** Neutralizing Tablets
Indications For Use	ULTRACARE Neutralizing Tablets are part of the ULTRACARE System, a disinfecting, neutralizing and storage system for daily and extended wear soft (hydrophilic) contact lenses in a chemical (not heat) lens care system. The ULTRACARE Neutralizing Tablets are indicated for use to neutralize the ULTRACARE Disinfecting Solution in the ULTRACARE System. ULTRACARE Neutralizing Tablets are added at the beginning of the disinfection cycle so that disinfection and neutralization occur without any additional steps.

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 K984383

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109