JUN - 2 2000

ALLERGAN

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50 years GROWTH & INNOVATION

K000164

510(k) SUMMARY
COMPLETE® brand Multi-Purpose Solution

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

Paul J. Nowacki
Manager
Regulatory Affairs
Allergan
2525 Dupont Drive
Irvine CA 92612

Phone: (714) 246-6761
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Summary Prepared: May 25, 2000

(a)(2) **Device Trade Name:** COMPLETE® brand Multi-Purpose Solution

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:** COMPLETE® brand Multi-Purpose Solution is substantially equivalent to formulations of these products marketed now and to other contact lens multi-purpose solutions. The purpose of this application is to add conditioning and enhanced comfort claims.

(a)(4) **Device Description:** COMPLETE® brand MULTI-PURPOSE Solution is a sterile, isotonic, buffered, solution containing hydroxypropyl methylcellulose as a lubricant, preserved with polyhexamethylene biguanide 0.0001%, a phosphate buffer, Poloxamer 237 as a surfactant, edetate disodium as a chelating agent, sodium chloride, potassium chloride, and purified water. COMPLETE® brand MULTI-PURPOSE Solution contains no chlorhexidine or thimerosal.

The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):** COMPLETE® brand Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein
- Condition

(a)(6) **Comparison of Technological Characteristics:** Labeling indications have been expanded. No changes have been made to the current product formulation.

(b)(1) **Discussion of Nonclinical:**

In Vitro Studies were conducted to:

- Compare viscosity of COMPLETE® Solution with HPMC to COMPLETE® without HPMC and other multipurpose solutions.
- Investigate the uptake of HPMC onto the lens surface during the soak period, and its subsequent release, over time, in a saline solution.
- Compare the effect of three COMPLETE® Solution formulations to B&L's ReNu® MultiPlus® and Alcon's OptiFree® Express on surface fluid retention.
- Examine the effect of various multipurpose solutions on receding contact angle as a measure of wetting.

These studies demonstrate the physical and chemical properties behind patient preference for the new formulation. For example, only COMPLETE® Solution contains a recognized ophthalmic demulcent/lubricant. This substance, hydroxypropyl methylcellulose (HPMC) and others like it, are used in ophthalmic preparations to increase eye comfort by providing viscosity, lubricity and cushioning.

Other studies show uptake of HPMC onto the lens surface during the soak period, and its subsequent release, over time, in a saline solution. This layer of adsorbed HPMC not only allows the lens surface to retain moisture and remain more wettable, but also results in the release of this generally-regarded-as-safe (GRAS) demulcent/lubricant to the cornea and other eye tissues. This is the mechanism of action for the improved comfort afforded by the reformulated COMPLETE® product. When this data is correlated to the amount released over time, all day long, between the lens and cornea, it's easy to understand why the lens wearer experiences greater comfort than other lens care regimens.

(b)(2) **Discussion of Clinical Data:**

Study subjects in three clinical studies received questionnaires asking them to rate the comfort and acceptability of COMPLETE® formulations with hydroxypropyl methylcellulose (HPMC) demulcent/lubricant, vs. original COMPLETE® without HPMC and other Allergan and competitor regimens. These studies support overall patient preference for the current COMPLETE® All-In-One Solution.

On the basis of comfort and efficacy, subjects rated current COMPLETE® superior in.

- Overall preference
- In hand feel
- In eye feel
- Comfort in eyes
- Keeps contacts moist/wet in eyes
- Keeps contacts lubricated in eyes
- Soothing in eyes

Other findings were:

- COMPLETE® is more comfortable when inserting lenses.
- COMPLETE® is more comfortable at the end of the day.
- COMPLETE® use results in less dryness at the end of the day.
- A majority expressed a willingness to switch to COMPLETE®.

We believe the high positive scores given to COMPLETE® All-In-One Solution over previous care regimens, is the result of the comfort afforded by HPMC in synergy with other ingredients in the formulation.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:**
We conclude that the safety, efficacy and performance of COMPLETE® brand All-In-One is substantially equivalent to multipurpose solutions currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2000

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

Re: K000164
Trade Name: COMPLETE[R] brand Multi-Purpose Solution
Regulatory Class: II
Product Code: 86 LPN
Dated: April 28, 2000
Received: May 1, 2000

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) 594-6413. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER: (IF KNOWN): K000164

DEVICE NAME: COMPLETE® brand Multi-Purpose Solution

INDICATIONS FOR USE:

COMPLETE® brand Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

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

_____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109 OR Over-The-Counter-Use X (Optional Format 1-2-96)

Zhi Qi, Ph.D

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000164