K981168

SEP 1 1998

510(k) SUMMARY

COMPLETE® brand Multi-Purpose Solution

This summary formatted as directed by 21 CFR 807.92:

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

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Summary Prepared: June 30, 1998

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

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification Names: Contact Lens Solution (86LPM)

(a)(3) **Identification of Predicate Device:** COMPLETE® brand Multi-Purpose Solution is substantially equivalent to the formulations of this product marketed now and to other contact lens multi-purpose solutions.

(a)(4) **Device Description:** COMPLETE® brand Multi-Purpose Solution is a sterile, isotonic, buffered, preserved solution. This aqueous formulation includes purified water, sodium chloride, hydroxypropyl methylcellulose as a lubricant, preserved with polyhexamethylene biguanide 0.0001%, Poloxamer 237 as a surfactant, a phosphate buffer, and edetate disodium as a chelating agent. This preparation contains no chlorhexidine, no thimerosal and no other mercury containing ingredients.

Both current and reformulated products are clear, colorless solutions packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use:** COMPLETE® brand Multi-Purpose Solution is indicated for use in the chemical (NOT HEAT) disinfection, cleaning, rinsing, protein removal and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

Except for protein removal, these uses are identical to the predicate, currently marketed products.

(a)(6) **Comparison of Technological Characteristics:** The technological characteristics of the new formulation remain essentially the same as the current product.

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

Solution Compatibility and Cleaning Effectiveness: The product was tested with the same protocol used to test the prior (substantially equivalent) formulation. Results show that the product is compatible with, and an effective cleaner for, all soft (hydrophilic) contact lenses.

Critical Micelle Concentration of Poloxamer 237: Using data provided by the manufacturer of this surfactant, we show that the aggregation concentration range (pseudo critical micelle concentration) of this surfactant is reached at a concentration >0.01% which is well below the amount found in our product. Surface tension of our product is approximately 45 dynes/cm, which is in the same range as the current and competitor multi-purpose solutions.

Passive Protein Cleaning: We compared the ability of four formulations/products to passively remove lysozyme protein adsorbed to contact lens surfaces and within the lens matrix. The results of the study show that both current and proposed COMPLETE® formulation have significantly (2.8 times) better passive protein cleaning ability than the competitive product.

Microbiological Studies The product was evaluated for microbiological efficacy using studies outlined in FDA's Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products, issued May 1, 1997.

- The product meets current FDA requirements for disinfection of contact lenses against bacteria, yeast and mold.
- The product meets the USP Modified criteria for Preservative Effectiveness Testing.
- The product meets USP Sterility test requirements.

Toxicology Product safety was evaluated using the following tests:

- Cytotoxicity: The new formulation compares favorably with the old formulation.
- Sensitization: No dermal reactions were observed in either test or control groups. The new formulation is comparable to the marketed formulation.
- Acute Oral Toxicity: The product caused no adverse effects when administered to rats at a single oral dose.
- 28-Day Ocular Safety Study: All animals remained healthy throughout the test with no clinically significant ocular discomfort or conjunctival irritation.

Stability: Accelerated testing predicts that the product will remain stable for at least 24 months.

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

Six clinical investigators enrolled a total of 124 subjects, of whom 62 were assigned to the Investigational MPS group and 62 to the COMPLETE® MPS group. Two subjects in the Investigational MPS group were disqualified, leaving 60 evaluable subjects in the Investigational MPS group and 62 evaluable subjects in the COMPLETE® MPS group. Of these:

- 90.3% (56/62) in the Investigational MPS group and 90.3% (56/62) in the COMPLETE® MPS group completed the study.
- No subjects in the Investigational MPS group and 4.8% (3/62) in the COMPLETE® MPS group were discontinued for non-regimen related reasons.
- 1.6% (1/62) in the Investigational MPS group and 1.6% (1/62) in the COMPLETE® MPS group were discontinued for findings of uncertain etiology.
- 4.8% (3/62) in the Investigational MPS group and 3.2% (2/62) in the COMPLETE® MPS group were discontinued for regimen related reasons.

Safety:

- No adverse device effects were reported during this study.
- There were no statistically significant differences in the number of examinations with clinically significant slit lamp findings.
- There were statistically significant differences between the Investigational MPS and COMPLETE® MPS groups in the maximum severity grades for injection and tarsal anomaly, with more severe findings in the COMPLETE® MPS group than in the Investigational MPS group.
- The incidence of clinically significant changes in subjective spherical refraction, best-corrected visual acuity, keratometry, and mire distortion was similar for both the Investigational MPS and COMPLETE® MPS groups, with no findings directly attributed to the study regimens.

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

Acceptability:

- There was a statistically significant difference between the Investigational MPS and COMPLETE® MPS groups with higher maximum severity score for symptoms of discomfort in the Investigational MPS group. The overall incidence of these selected symptoms were low. The severe symptoms reported were not regimen related and therefore not clinically relevant to the performance of the investigational regimen. There was no statistically significant difference between the Investigational MPS and COMPLETE® MPS groups in the number of examinations with clinically significant ocular symptoms of discomfort.

- There was no statistically significant difference between the Investigational MPS and COMPLETE® MPS for average lens comfort scores

- There was no statistically significant difference between the Investigational MPS and COMPLETE® MPS for lens wearing time

- There was no statistically significant difference between the groups in investigators' analysis of lens cleanliness.

- The incidence of lens discoloration of untinted lenses was low in both groups, and no lens discoloration or atypical tint of tinted lenses was reported in either group.

- Lens fit was well-maintained in both groups throughout the study, and unscheduled replacement of lenses was similar between the groups.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** It is concluded that the safety, efficacy and performance of the investigational COMPLETE® brand Multi-Purpose Solution formulation is substantially equivalent to formulations of these products currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1998

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

Re: K981168
Trade Name: COMPLETE ® brand Multi-Purpose Solution (Revised)
Regulatory Class: II
Product Code: 86 LPN
Dated: July 1, 1998
Received: July 2, 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

510(k) NUMBER: (IF KNOWN): K981168

DEVICE NAME: COMPLETE® brand Multi-Purpose Solution

INDICATIONS FOR USE:

COMPLETE® brand Multi-Purpose Solution is indicated for use in the chemical (NOT HEAT) disinfection, cleaning, rinsing, protein removal and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

(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 ✓ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981168