NOV 25 1998

# 510(k) SUMMARY

K983150

## COMPLETE® brand Lubricating and Rewetting Drops

This summary uses the format provided in 21 CFR 807.92:

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

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Regulatory Affairs
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**Summary Prepared:** November, 1998

(a)(2) **Device Trade Name:** COMPLETE® brand Lubricating and Rewetting Drops

**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 Lubricating and Rewetting Drops are substantially equivalent to the formulation of this product marketed now and to other contact lens multi-purpose, lubricating and rewetting solutions.

(a)(4) **Device Description:** COMPLETE® brand Lubricating and Rewetting Drops are 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 Lubricating and Rewetting Drops contain no chlorhexidine or 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 Lubricating and Rewetting Drops are indicated to lubricate and rewet soft (hydrophilic) contact lenses during lens wear.

These uses are identical to the predicate, currently marketed product.

(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:**

With one exception, new COMPLETE® brand Lubricating and Rewetting Drops were evaluated for safety and efficacy using recommendations outlined in FDA's Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products, issued May 1, 1997. A 28-day, ocular safety study in rabbits with repeated (4X/day) instillations, was completed to support product safety in lieu of a clinical study in humans. This product meets the suggested microbiological and toxicological criteria.

Microbiological Studies These studies are referenced from K981168 for COMPLETE® brand Multi-Purpose Solution.

- The product meets USP Modified criteria for Preservative Effectiveness.
- The product meets USP Sterility test requirements.

Toxicology Product safety was evaluated using the following tests:

- Cytotoxicity:
  Neutral Red Retention Assay: In an evaluation of ReNu MultiPlus vs. the old and new COMPLETE® solutions, using benzalkonium chloride (BAK) as a control, both new COMPLETE® and ReNu MultiPlus exhibited better neutral red retention than BAK. Old COMPLETE was better until the 2 hour time point, but dropped to approximately the same level as BAK after 3 hours of direct exposure. This indicates that new COMPLETE® may be less damaging to cells than old COMPLETE®.

  CHO Clonal Growth Assay: In this comparison of ReNu MultiPlus vs. old COMPLETE® and new COMPLETE® Lubricating and Rewetting Drops, Chinese hamster ovary cells showed a significantly better survival rate with new COMPLETE® than the other two formulations. Relative survival was higher than the negative control at almost all concentration levels. Overall, new COMPLETE® showed the best relative survival in this assay. This indicates that new COMPLETE® solution may be less damaging to eye cells than the other products tested.

- Sensitization: The potential contact sensitization (Maximization Test) of new COMPLETE® brand Lubricating and Rewetting Drops was evaluated in 25 female Hartley guinea pigs using a maximization test conducted following methods adapted from the procedure described by Magnusson and Kligman, 1970. The marketed COMPLETE® formulation was used as a control.

  No dermal reactions were observed in either test or control groups, indicating that new COMPLETE® is comparable to the marketed formulation.

  This study is referenced from K981168 for COMPLETE® brand Multi-Purpose Solution.

Toxicology (Continued)

- Acute Oral Toxicity: The acute oral toxicity of new COMPLETE® Lubricating and Rewetting Drops was evaluated in forty (20 male and 20 female) CD albino rats following a single oral administration and 14 days of observation. Test animals received new COMPLETE® while control animals received sterile water for injection, both at a dose of 20 mL/kg. All rats were sacrificed at the end of the 14-day observation period.

  There were no treatment-related effects or deaths. New COMPLETE® caused no adverse effects when administered to rats at a single oral dose of 20 mL/kg.

  This study is referenced from K981168 for COMPLETE® brand Multi-Purpose Solution.

- 28-Day Ocular Safety Study: The ocular safety of new COMPLETE® Lubricating and Rewetting Drops in conjunction with COMPLETE® Weekly Enzymatic Cleaner, using SOFLENS® soft contact lenses was evaluated in twelve female New Zealand white rabbits.

  Lenses were soaked overnight in approximately 4 mL of either the new or old formulation. Once a week, one COMPLETE® enzyme tablet was added to the overnight soak (1 tablet/4 mL). The test also involved topical instillations of new or old COMPLETE® solution at approximate 2 hour intervals (4X/day) for the entire study period. Lenses were worn for approximately 8 hours a day for 28 consecutive days.

  Rabbits were observed daily at lens application and at each instillation for ocular discomfort. Observations for gross ocular irritation were made at each topical instillation and at lens removal. Pachometry, slit lamp examinations, and body weights were performed weekly. Ophthalmoscopy was performed prior to the start and at the end of the study. Histopathological evaluation was performed on both eyes of all rabbits at the conclusion of the study.

  All animals remained healthy and growth was normal throughout the study. No clinically significant ocular discomfort or conjunctival irritation was observed at lens application or removal. No clinically significant changes in corneal thickness were detected by pachometry examinations. No clinically significant conjunctival, uveal or corneal abnormalities were noted at any slit lamp examination. No apparent ocular changes were observed by direct ophthalmoscopy. Histopathological examinations revealed no treatment related changes in ocular tissue.

  The results of this study indicate that frequent eye contact with new COMPLETE® brand Lubricating and Rewetting Drops, in conjunction with COMPLETE® Weekly Enzymatic Cleaner, is safe for use with hydrophilic contact lenses.

Stability Testing using the protocol approved in K981168, to establish an expiration date, will be completed prior to marketing this product.

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

This clinical investigation involved use of the new COMPLETE® formulation as a multi-purpose solution. Although the product was not used as a lubricating and rewetting drop, its use as a multi-purpose solution involved indirect instillation. Subjects were instructed to either put the lens into the eye directly from soaking in the lens case, or to rinse the lens with multi-purpose solution prior to wearing. The 28-Day toxicology study summarized on the previous page provides the principal safety support for use as a lubricating and rewetting drop.

Six clinical investigators enrolled a total of 124 subjects, of whom 62 were assigned to the Investigational multi-purpose solution (MPS) group and 62 to the approved (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% in the Investigational MPS group and 90.3% in the COMPLETE® MPS group completed the study.

Safety:

No adverse device effects were reported during this study and 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. Other safety variables were similar for both groups, with no findings directly attributed to the study regimens.

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. However, the overall incidence of these selected symptoms were low and 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 other findings which were unremarkable.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** It is concluded that the safety, efficacy and performance of the Investigational product is substantially equivalent to the approved formulation currently on the market.

This study is referenced from K981168 for COMPLETE® brand Multi-Purpose Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

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

Re: K983150
Trade Name: Complete ® brand Lubricating and Rewetting Drops
Regulatory Class: II
Product Code: 86 LPN
Dated: September 8, 1998
Received: September 9, 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): _____

DEVICE NAME: COMPLETE® brand Lubricating and Rewetting Drops

INDICATIONS FOR USE:

COMPLETE® brand Lubricating and Rewetting Drops are used to lubricate and rewet soft (hydrophilic) contact lenses before application and during lens wear.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Myra Smith
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983150