



K030092

APR 04 2003

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
Advanced Medical Optics, Inc.
1700 E. St. Andrew Place
P.O. Box 25162
Santa Ana, CA 92799-5162

Phone: (714) 247-8601
Fax: (714) 247-8677
- Summary Prepared:** December 16, 2002
- (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 other contact lens care multi-purpose solutions.
- (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.

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COMPLETE® brand Multi-Purpose Solution
December 16, 2002
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- (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:** No changes have been made to the product formulation subject to this application.

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

In Vitro Studies were conducted to compare the physical and chemical properties of COMPLETE® Solution with other multi-purpose solutions in order to evaluate the effects of adding hydroxypropyl methylcellulose (HPMC). They were as follows:

- Compare viscosity of COMPLETE® Solution with HPMC to COMPLETE® without HPMC, and to 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 OPTI-FREE® Express on surface fluid retention.
- Examine the effect of various multipurpose solutions on receding contact angle as a measure of wetting.

The studies show uptake of HPMC onto the lens surface during the soak period, and its subsequent release, over time, in saline. This layer of adsorbed HPMC appears to enhance the lens' ability to retain moisture and remain more wettable.

(b)(2) Discussion of Clinical Data:

Study subjects in three clinical studies received questionnaires asking them to rate the comfort and acceptability of two COMPLETE® formulations with hydroxypropyl methylcellulose (HPMC) demulcent/lubricant, vs. original COMPLETE® without HPMC and other Advanced Medical Optics and competitor regimens. This subjective data shows that COMPLETE® Solution, used with a rub regimen, has comfort substantially equivalent to other marketed contact lens care multipurpose solutions.

Objective data from an additional clinical study demonstrate the substantial equivalence of COMPLETE® Solution used in a "no-rub" regimen, with COMPLETE® Solution used in a "rub" regimen.

(b)(3) Conclusions Drawn from Data Supporting Equivalence Determination:

In view of the *in vitro* and clinical studies supporting this application, we believe the safety, efficacy and comfort of COMPLETE® brand Multi-Purpose Solution is substantially equivalent to other marketed contact lens care multipurpose solutions.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Medical Optics
c/o Paul J. Nowacki
Manager, Regulatory Affairs
1700 E. St. Andrew Place
P.O. Box 25162
Santa Ana, CA 97299-5162

APR 04 2003

Re: K030092

Trade/Device Name: COMPLETE® brand Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: January 10, 2003
Received: January 10, 2003

Dear Mr. Nowacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

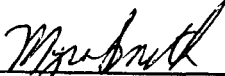
510(k) NUMBER: K030092
(IF KNOWN):

DEVICE NAME: COMPLETE® brand Multi-Purpose Solution

INDICATIONS FOR USE:

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- Clean
- Rinse
- Store
- Remove Protein
- Condition



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

(k) Number K030092

(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)