

JUL 6 1998

K 980775

510(k) SUMMARY

Submitted by:

Paul J. Nowacki
Manager, Regulatory Affairs
Allergan, Inc.
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534
(714) 246-6761 (Voice)
(714) 246-5457 (Fax)

Device Name:

Common Name: Contact Lens Care Multi-Purpose Solution

Proprietary Name: COMPLETE® brand Multi-Purpose Solution (8772X)
Private label brand Multi-Purpose Solution (8474X)

Indications for Use:

COMPLETE® (and Private Label) 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.

Description:

COMPLETE® brand Multi-Purpose Solution is a sterile, isotonic solution containing hydroxypropyl methylcellulose as a lubricant, preserved with TrisChem™ (polyhexamethylene biguanide) 0.0001%, buffered with tromethamine, tyloxapol as a surfactant, edetate disodium as a chelating agent, sodium chloride, and purified water. COMPLETE® brand Multi-Purpose Disinfecting Solution contains no chlorhexidine or thimerosal.

Private label brand Multi-Purpose Solution is a sterile, isotonic solution containing purified water, sodium chloride, preserved with TrisChem™ (polyhexamethylene biguanide) 0.0001%, buffered with tromethamine, tyloxapol as a surfactant, and edetate disodium as a chelating agent. Private label brand Multi-Purpose Disinfecting Solution contains no chlorhexidine or thimerosal.

Substantial Equivalence:

COMPLETE® brand Multi-Purpose Solution and private label brand Multi-Purpose Solution are identical to the products that were approved under P910075 and are substantially equivalent to Bausch & Lomb's ReNu® Multi-Plus Multi-Purpose Solution (P860023/S12).

Safety and Effectiveness:

K980775

A. Non-Clinical Data

Microbiological Studies

COMPLETE® brand Multi-Purpose Solution and private label brand Multi-Purpose Solution were previously evaluated and approved under P910075.

- Both products meet the current FDA criteria for disinfection of contact lenses against bacteria, yeast, and molds
- Both products are effectively preserved by FDA standards.
- Both products conform to USP sterility requirements.

Preclinical

COMPLETE® brand Multi-Purpose Solution and private label brand Multi-Purpose Solution were previously evaluated under P910075. These products are safe for use in cleaning, rinsing, chemical disinfection and up to 30 day storage of all soft contact lenses.

COMPLETE® brand Multi-Purpose Solution and private label brand should not present an ocular hazard to the contact lens wearer when used as directed in the labeling for soft contact lenses.

Compatibility/Cleaning Efficacy

COMPLETE® brand Multi-Purpose Solution and private label brand Multi-Purpose Solution were demonstrated previously under P910075 to be compatible with all soft contact lenses and able to remove non-protein deposits from the surface of the contact lens. An additional study was performed that demonstrated the ability of COMPLETE® brand Multi-Purpose Disinfecting Solution and private label brand Multi-Purpose Solution to remove protein deposits on the contact lens surface and in the lens matrix during disinfection compared to Bausch & Lomb's ReNu® MultiPlus Multi-Purpose Solution..

B. Clinical

COMPLETE® brand Multi-Purpose Solution and private label brand Multi-purpose Solution were proven clinically safe and effective under P910075 and are substantially equivalent to Bausch & Lomb's ReNu® Multi-Plus Multi-Purpose Solution (P860023/S12).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K980775
Trade Name: Complete [®] brand Multi-Purpose Solution and
Private Label brand Multi-Purpose Solution
Regulatory Class: II
Product Code: 86 LPN
Dated: May 20, 1998
Received: May 21, 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 (Pre-market 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.

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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):

K980775

DEVICE NAME:

COMPLETE® brand Multi-Purpose Solution and
Private Label brand Multi-Purpose Solution

INDICATIONS FOR USE:

COMPLETE® (and Private Label) 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 X
(Optional Format 1-2-96)

Evo
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 980775

JS