

SEP 25 2003



K032030

510(k) SUMMARY

blink[™] CL Lubricant Eye Drops

This summary uses the format provided in 21 CFR 807.92:

- (a)(1) **Submitter:** Paul J. Nowacki
Manager
Regulatory Affairs
Advanced Medical Optics
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Santa Ana, CA 92799-5162

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EMail: paul.nowacki@amo-inc.com
- Summary Prepared:** June 30, 2003
- (a)(2) **Device Trade Name:** *blink*[™] CL Lubricant Eye Drops
- Device Common Name:** Soft (Hydrophilic) and Rigid Gas Permeable Contact Lens Lubricating and Rewetting Solution
- Device Classification/Panel:** Class II (Special Controls)/Ophthalmic Device
- Device Classification Names:** Accessories to Contact Lenses – Cleaning and Wetting Agents
- (a)(3) **Identification of Predicate Device:** *blink*[™] CL Lubricant Eye Drops is substantially equivalent to other lubricating and rewetting solutions currently marketed or cleared for commercial distribution in the U.S. These include REFRESH[®] CONTACTS[™] Lubricating and Rewetting Drops (Allergan), AQUIFY Lens Comfort Drops (CIBA Vision) and HYLASHIELD[®] CL Lubricating Eye Drop (Biomatrix).
- (a)(4) **Device Description:** *blink*[™] CL Lubricant Eye Drops is a sterile, isotonic, buffered solution containing a lubricant, a preservative, buffers, tonicity agents, and purified water.
- The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

- (a)(5) **Intended Use (Indications for Use):** Use *blink*TM CL Lubricant Eye Drops to lubricate and rewet soft and rigid gas permeable (RGP) contact lenses, to help relieve dryness, irritation and discomfort that maybe associated with lens wear, and to cushion lenses by placing a drop on the lens prior to application on the eye. The intended use is comparable to that of the predicate devices.
- (a)(6) **Comparison of Technological Characteristics:** *blink*TM CL Lubricant Eye Drops has the same intended use and the same technological characteristics as the predicate lubricants/rewetters. The lubricant and preservative are materials which are used in the predicate lubricants/rewetters but not in combination in any one product. The ophthalmic demulcent, while not listed in 21 CFR 349.12, is used in one of the three predicate lubricants/rewetters in which we are requesting a determination of substantial equivalence. Additionally, a chemically similar lubricant is used in another one of the predicate lubricants/rewetters. Both of these lubricants have been cleared for commercial distribution in the U.S. All excipients are commonly recognized and used in ophthalmic and contact lens care products, including the predicate lubricants/rewetters.

Description of Safety and Substantial Equivalence

Nonclinical and clinical studies were performed to demonstrate the substantial equivalence of *blink*TM CL Lubricant Eye Drops to the predicate device(s). Testing was conducted in accordance with and in conformance to applicable device regulations. The following is a discussion of the study results.

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

Lens Compatibility: *In vitro* lens compatibility testing was conducted to establish product compatibility with both soft (hydrophilic) and RGP contact lenses. The results show that the product is compatible with soft (hydrophilic) and RGP contact lenses and substantially equivalent to the control.

Solution Compatibility: A study was conducted to evaluate the compatibility of *blink*TM CL Lubricant Eye Drops when used with leading contact lens care products on the market. The results indicate that the product is compatible with these leading contact lens care products.

Preservative Uptake and Release: A study was conducted with soft (hydrophilic) and RGP contact lenses to determine the uptake and release of the preservative in *blink*TM CL Lubricant Eye Drops. The results show that there is very little, if any, uptake of the preservative in or onto soft or RGP lenses. Any amounts taken up are quickly released. The results indicate that the product is compatible and acceptable for use with soft (hydrophilic) and RGP contact lenses.

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

Contact Lens Wetting Angle: A wetting angle study was conducted to assess the effectiveness of *blink*TM CL Lubricant Eye Drops in enhancing the wettability of RGP lenses compared with predicate lubricating and rewetting products. The results indicate that *blink*TM CL Lubricant Eye Drops is substantially equivalent in wetting properties to the predicate devices.

Microbiological Studies: The product was evaluated for preservative efficacy and sterility:

- The product meets the acceptance criteria for Preservative Effectiveness Testing as outlined in ISO 14730:2000(E), "Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date."
- The product meets USP Sterility test requirements.

Stability: Accelerated testing predicts that the product will remain stable for the labeled shelf-life.

Toxicology: The safety of *blink*TM CL Lubricant Eye Drops was evaluated using cytotoxicity and acute ocular toxicity tests. The results of the testing demonstrate that *blink*TM CL Lubricant Eye Drops is non-cytotoxic, non-irritating and well-tolerated.

(b)(2) Discussion of Clinical Data:

AMO conducted a multi-center, double-masked, randomized, parallel-group, one-month evaluation to assess the safety and acceptability of *blink*TM CL Lubricant Eye Drops. The results of this study indicate that the investigational formulation is safe, acceptable, and substantially equivalent to the control.

(b)(3) Conclusions Drawn from Data Supporting Equivalence Determination: It is concluded that the safety, efficacy and performance of *blink*TM CL Lubricant Eye Drops is substantially equivalent to the predicate products currently on the market or cleared for commercial distribution in the U.S.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Medical Optics, Inc
c/o Paul J. Nowacki
1700 E. St. Andrew Place
P.O. Box 25162
Santa Ana, CA 92799

Re: K032030
Trade/Device Name: *blink*TM CL Lubricant Eye Drops
Regulation Number: 21 CFR 886.5928; 21 CFR 886.5918
Regulation Name: Soft (hydrophilic) contact lens care products;
Rigid gas permeable contact lens care products
Regulatory Class: Class II
Product Code: LPN; MRC
Dated: June 30, 2003
Received: July 1, 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

K032030

510(k) NUMBER:
(IF KNOWN):

blink™ CL Lubricant Eye Drops

DEVICE NAME:

INDICATIONS FOR USE:

- Use *blink™* CL Lubricant Eye Drops to lubricate and rewet soft and rigid gas permeable (RGP) contact lenses; to help relieve dryness, irritation and discomfort that may be associated with lens wear; and to cushion lenses by placing a drop on the lens prior to application on the eye.

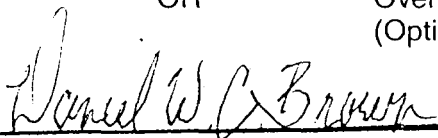
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X
(Optional Format 1-2-96)



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

510(k) Number K032030