NOV - 4 2003

K 032481

510(k) Summary of Safety and Effectiveness

Applicant's Name and Address: Advanced Vision Research, Inc.
12 Alfred Street, Suite 200
Woburn, MA 01801

Contact Person: Jeffrey P. Gilbard, M.D.
Phone (781) 932-8327
Fax (781) 935-5075

Summary Prepared: October, 2003

Trade Name:

TheraTears Contact Lens Comfort Drops

Classification Name:

Soft (hydrophilic) contact lens care products (886.5928)
Rigid gas permeable contact lens care products (886.5918)

Predicate Device:

Allergan Refresh Contacts™ (K992928)
AQuify lens Comfort Drops (K013204)

Device Description:

TheraTears® brand Contact Lens Comfort Drops *contains carmellose sodium in purified water as a lubricant. It is a sterile, hypotonic, borate buffered solution containing the following essential electrolytes found in natural tears: sodium chloride, potassium chloride, sodium chloride, sodium bicarbonate, calcium chloride, magnesium chloride, and sodium phosphate. The gentle patented preservative system consists of sodium perborate stabilized with phosphonic acid. This solution contains no chlorhexidine, no thimerosal and no other mercury-containing ingredients, and it contains no detergents.*

Indication for Use:

TheraTears Contact Lens Comfort Drops is indicated

- to lubricate and rewet soft (hydrophilic) and RGP* (rigid gas permeable) contact lenses,
- to help relieve dryness, discomfort and irritation that may be associated with lens wear and,
- to cushion lenses and ease insertion.

* RGP lenses include silicone acrylate and fluoro silicone acrylate rigid gas permeable lenses. Consult with your eye care practitioner to identify your RGP material.

Safety, Performance and Substantial Equivalence

Non-clinical Testing

The applicant performed stability, compatibility, toxicology and microbiology testing based the requirements of the May 1, 1997 Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products. The results support the claim of substantial equivalence.

Clinical Testing

A one month clinical study was conducted to evaluate the safety and efficacy of **TheraTears Contact Lens Comfort Drops**. The results of the study demonstrate that **TheraTears Contact Lens Comfort Drops** is equivalent in performance, safety and efficacy to the Bausch & Lomb ReNu MultiPlus® Lubricating and Wetting Drops.

This conclusion is based upon and supported by:

- The relative frequency and severity of positive slit lamp findings
- The stability of the contact lens visual acuities as well as the stability of the best spectacle-corrected visual acuities
- The relative incidence and severity of symptoms, problems and complaints
- The lack of solution-associated complications

The claim of substantial equivalence to Allergan Refresh Contacts and AQuify lens Comfort Drops is based on the indication for use as a lubricating and rewetting solution for soft (hydrophilic) and RGP contact lenses. **TheraTears Contact Lens Comfort Drops** contains the same active ingredient as Allergan Refresh Contacts and the same preservative system as AQuify lens Comfort Drops.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2003

Advanced Vision Research, Inc.
c/o Beverley D. Venuti, Ph.D. R.A.C.
Foresight Regulatory Strategies
269A Ballardvale Street
Wilmington, MA 01887

Re: K032481
Trade/Device Name: TheraTears Contact Lens Comfort 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: August 11, 2003
Received: August 12, 2003

Dear Dr. Venuti:

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. 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

Indications for Use

510(k) Number (if known):

Device Name: TheraTears Contact Lens Comfort Drops

Indications for Use:

TheraTears Contact Lens Comfort Drops is indicated

- to lubricate and rewet soft (hydrophilic) and RGP* (rigid gas permeable) contact lenses,
- to help relieve dryness, discomfort and irritation that may be associated with lens wear and,
- to cushion lenses and ease insertion.

* RGP lenses include silicone acrylate and fluoro silicone acrylate rigid gas permeable lenses. Consult with your eye care practitioner to identify your RGP material.

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C Brown PH. D.

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

510(k) Number K032481

Prescription Use
(Per 21 CFR 80.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)