510(k) SUMMARY K062332

APR 25 2007

This summary follows the requirements of SMDA 1990 and 21 CFR 807.92, upon which the substantial equivalence determination is based.

510(k) Summary
for
Altaire Pharmaceuticals Multipurpose Solution

1. **Submitter information**

Altaire Pharmaceuticals Inc.
P.O. Box 849
311 West Lane
Aquebogue, NY 11931
Contact Person: Michael S. Sawaya
Phone number: (631) 722-5988

2. **Device Name**

Regulation name #1:	**Soft Lens Products, Contact Lens Solution**
Product Code #1:	**LPN**
Regulation name #2:	**Rigid Gas Permeable, Contact lens care products**
Product Code #2:	**MRC**
Propriety Name	**Altaire MPS#1 Multipurpose Contact Lens Solution**

3. **Predicate Device**

SOLO-care, and SOLO-Care Plus Multipurpose Solution; K991403 & K012731. This product was selected because the formulation and indications for use are identical to the device proposed in this submission.

4. **Description of Device**

Altaire MPS#1 Multipurpose Contact Lens Solution is a sterile aqueous solution containing sodium chloride, bis-tris propane, pluronic F127, cremophor RH40and preserved with edetate disodium dehydrate 0.025% and polyhexanide 0.0001%

5. **Indications for Use**

Altaire MPS#1 Multipurpose Contact Lens Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, daily protein removal, and storing of soft (hydrophilic) contact lenses, and rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.

6. **Description of Safety and Substantial Equivalence**

Altaire MPS#1 Multipurpose Contact Lens Solution is substantially equivalent in terms of its actions and indications for use, to SOLO-Care Plus Multipurpose Solution cleared for marketing under 510(k) K012731. Altaire Pharmaceuticals Multipurpose Solution meets guidelines as set forth in FDA's May 1, 1997 Guidance for Industry, Premarket Notification 510(K) Guidance Document for Contact Lens Care Products.

Cleaning Studies

The Critical Micelle Concentration was performed. Results of the study showed that Altaire MPS#1 Multipurpose Contact Lens Solution satisfies the requirements for daily cleaner of lens care products as per the FDA's Guidance for Industry Premarket Notification 510(k) Guidance Document for Contact Lens Care Products (May 1, 1997).

Lens Compatibility Data

No lens compatibility data is required to be submitted herein this submission.

Cytotoxicity

A series of Cytotoxicity studies were conducted to demonstrate the safety of Altaire MPS#1 Multipurpose Contact Lens Solution. Results of the testing demonstrated that Altaire MPS#1 Multipurpose Contact Lens Solution is non-toxic and a non-irritant.

Microbiological

Microbiological studies were conducted to demonstrate the microbial efficacy of Altaire MPS#1 Multipurpose Contact Lens Solution. Two studies evaluated the disinfection properties of the product under stand alone with and without soil. Another study evaluated disinfection properties using a no rub regime. All three studies showed that the Altaire MPS#1 Multipurpose Contact Lens Solution met acceptance criteria. Preservative Efficacy testing with 14-day re-challenge was evaluated, and the Altaire MPS#1 Multipurpose Contact Lens Solution met acceptance criteria.

Clinical testing

Altaire MPS#1 Multipurpose Contact Lens Solution possess the same active and inactive ingredients within marketed concentrations as that of the Solo-Care Plus Multipurpose Solution and utilizes the same manufacturing processes, and therefore clinical performance data was not performed, nor is it a requirement for the purpose of this pre-market notification.

7. **Substantial Equivalence**

The data provided in this 510(k) submission concludes that Altaire MPS#1 Multipurpose Contact Lens Solution is substantially equivalent to SOLO-Care Plus Multipurpose solution for cleaning, rinsing, chemical (not heat) disinfecting, protein removal, and storing soft (hydrophilic) contact lenses, and rigid gas permeable (flouro silicon acrylate and silicon acrylate) contact lenses as recommended by your eye care practitioner.

SUBSTANTIAL EQUIVALENCY CHART

Substantial Equivalency	**Altaire MPS#1 Multipurpose Contact Lens Solution**	**SOLO-Care Plus Multipurpose Solution**
Manufacture	**Altaire Pharmaceuticals**	**CIBA Vision Corp**
INTENDED USE	The **Altaire MPS#1 Multipurpose Contact Lens Solution** is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfecting, and storage of soft (hydrophilic) contact lenses, rigid gas permeable (fluorosilicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.	The **SOLO-Care Plus Multipurpose Solution** is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfecting, and storage of soft (hydrophilic) contact lenses, rigid gas permeable (fluorosilicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.
Ingredient Action Benefits	**Ingredient**	**Ingredient**
Surfactant, daily protein deposit remover	Pluronic F127	Pluronic F127
Preservative, kills bacteria that can cause eye infections	PHMB, Polyhexanide 0.0001%,	PHMB, Polyhexanide 0.0001%,
Chelating Agent, breaks down calcium bridges	Disodium edetate	Disodium edetate
Biological Buffer, maintain pH close to that of natural tears	Bis-tris Propane	Bis-tris Propane
Lubricate, dual comfort action; a.cushioning affect b. reduce protein deposition	Cremophor RH40	Cremophor RH40
Tears Simulation Additive, comfort	Sodium chloride	Sodium chloride

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Altaire Pharmaceuticals, Inc.
c/o Mr. Martin Dalsing
Medvice Consulting, Inc.
Grand Valley Business Plaza
2214 Sanford Drive, Suite #B7
Grand Junction, CO 81505

APR 25 2007

Re: K062332
Trade/Device Name: Altaire MPS#1 Multipurpose Contact Lens Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: March 23, 2007
Received: March 29, 2007

Dear Mr. Dalsing:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, 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: K062332

Device Name: **Altaire MPS#1 Multipurpose Contact Lens Solution**

INDICATIONS FOR USE:

The Altaire MPS#1 Multipurpose Contact Lens Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, daily protein removal, and storing of soft (hydrophilic) contact lenses, rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.

Prescription Use ____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062332