

MAY 21 1997

**510 (k) Summary** K971049**SUBMITTER:****Submitted on behalf of:**

**Company Name:** Aspect Vision Care, Ltd.  
**Address:** South Point, Hamble  
Southampton SO31 4RF  
United Kingdom

**Phone:** 011 44 1703 455 567  
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**CONTACT PERSON:** Martin S. Knopf

**DATE SUMMARY PREPARED:** April 16, 1997

**TRADE NAME:** FREQUENCY 38™ (polymacon) Hydrophilic Contact Lens  
for Daily Wear (clear and tinted)

**COMMON NAME:** contact lens

**SUBSTANTIALLY EQUIVALENT TO:**

FREQUENCY 38™ (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted) are equivalent to The LifeStyle4 Vue (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted) currently marketed in the U.S.

The FREQUENCY 38 (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted) is substantially equivalent to the LifeStyle 4-Vue (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted) manufactured by The LifeStyle Company, Inc. Aspect Vision Care, Ltd. has received from the manufacturer of the LifeStyle 4-Vue (polymacon) Hydrophilic Contact Lens for Daily Wear all manufacturing information including; but not limited to, formulation, manufacturing processes (including polymerization conditions, tinting process, lens parameter tolerances, sterilization and packaging, quality control/quality assurance, established shelf life data, shelf life protocol) necessary to manufacture the devices, which are the subject of K963001 and K950283. Aspect Vision Care, Ltd. has also received from The LifeStyle Company, Inc. the right to reference its premarket notifications, K950283 and K963001. In addition, Aspect Vision Care, Ltd. will manufacture these devices at the same manufacturing location as the predicate devices.

This lens is in Group 1, non-ionic, low water content polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the FREQUENCY 38 (polymacon) Hydrophilic

Contact Lens for Daily Wear (clear and tinted) are equivalent to those of the LifeStyle 4 Vue (polymacon) Soft Contact Lens for Daily Wear (clear and tinted).

#### DESCRIPTION of the DEVICE:

Soft contact lenses are hemispherical shells manufactured of polymerized material of HEMA crosslinked with EGDMA which yield the appearance of lenses which are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves which conform to the shape of the radius of the cornea and center over the apex of the cornea to provide corrective refraction for functional conditions of the eye including myopia (nearsightedness), hyperopia (farsightedness) and astigmatism (multiple foci). Each lens provides corrective power which is to correspond to the refractive power of the eye to which it is being treated. Each lens is designed with a base curve on the internal side of the lens and an optical zone in the center of the lens which is generally of a diameter greater than 6mm. Secondary and tertiary curves as well as beveled edge configurations are built into the lens for the purpose of aiding in lens centration and comfort.

#### INDICATIONS FOR USE:

***Device Name: FREQUENCY 38 (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted)***

The FREQUENCY 38™ (polymacon) Hydrophilic Contact Lens (clear and tinted ) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

Eyecare practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using heat, chemical or hydrogen peroxide disinfection systems.

#### PARAMETERS AVAILABLE:

The FREQUENCY 38™ (polymacon) Hydrophilic Contact Lens (clear and tinted)

Powers:	+20.00 to -20.00D
Center Thickness:	0.07 mm
Diameter:	14.0 mm
Base Curve:	8.6 mm



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 21 1997

Aspect Vision Care, Ltd.  
c/o Mr. Martin S. Knopf  
President and CEO of Knopf  
Associates, Inc.  
84 West Main Street  
Freehold, NJ 07728

Re: K971049  
Trade Name: Frequency™ 38 (Polymacon) Soft (Hydrophilic) Daily Wear  
Contact Lens (Clear and Visibility tint, Spherical and Cast-  
molded)  
Regulatory Class: II  
Product Code: 86 LPL  
Dated: March 20, 1997  
Received: March 21, 1997

Dear Mr. Knopf:

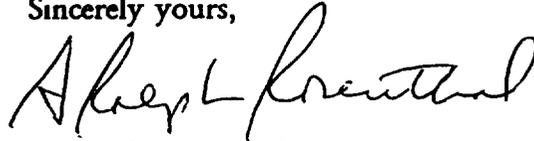
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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 at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# INDICATIONS STATEMENT

**Device Name: FREQUENCY 38™ (polymacon) (Hydrophilic Contact Lens for Daily Wear (clear and tinted))**.....

The FREQUENCY 38™ (polymacon) Hydrophilic Contact Lens (clear and tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

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**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR Over-The-Counter Use

E. S. O. 5/14/97

**(Division Sign-Off)**  
**Division of Ophthalmic Devices**

**SDO(t) Number** K 971049

(Optional Format 1-2-96)