AUG 26

K973063

510 (k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name:	Aspect Vision Care, Ltd.
Address:	South Point, Hamble Southampton S031 4RF United Kingdom
Phone:	011 44 1703 455 567
Fax:	011 44 1703 455 523

CONTACT PERSON: **Martin S. Knopf**

DATE SUMMARY PREPARED: **August 14, 1997**

TRADE NAME: **FREQUENCY 55™ (methafilcon A) Hydrophilic Contact Lens for Daily Wear**

COMMON NAME: **contact lens**

SUBSTANTIALLY EQUIVALENT TO:

FREQUENCY 55™ (methafilcon A) Hydrophilic Contact Lens for Daily Wear are equivalent to the FREQUENCY 55™ (methafilcon A) Hydrophilic Contact Lens for Daily Wear cleared pursuant to K971164.

FREQUENCY 55 (methafilcon A) Hydrophilic Contact Lens for Daily Wear are substantially equivalent to the indications for use, method of manufacture and packaging to the company's predicate device, FREQUENCY 55™ (methafilcon A) Hydrophilic Contact Lens for Daily Wear. This predicate device received marketing clearance pursuant to K971164. The purpose of this premarket notification is to request clearance to tint FREQUENCY 55™ (methafilcon A) Hydrophilic Contact Lens for Daily Wear using Reactive Blue No. 4 in an alternative, in-monomer tinting process. The lens molding manufacturing process will otherwise remain the same as that currently cleared pursuant to K971164. In addition, Aspect Vision Care, Ltd. will continue to manufacture these devices at the same manufacturing location as the predicate devices.

This lens is in Group 4, Ionic, high 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 55 (methafilcon A) Hydrophilic Contact Lens for Daily Wear are equivalent to those of the LifeStyle FREQUENCY Progressive (methafilcon A) Soft Contact Lens for Daily Wear.

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 aiding in lens centration and comfort.

INDICATIONS FOR USE:

Device Name: FREQUENCY 55 (methafilcon A) Hydrophilic Contact Lens for Daily Wear

The FREQUENCY 55™ (methafilcon A) 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 chemical or hydrogen peroxide disinfection systems.

PARAMETERS AVAILABLE:

The FREQUENCY 55™ (methafilcon A) Hydrophilic Contact Lens

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 26 1997

Re: K973063
Trade Name: Frequency™55 (Methafilcon A) Soft (Hydrophilic) Daily Wear Contact Lens (Clear and Visibility tint, Spherical and Cost-molded)
Regulatory Class: II
Product Code: 86 LPL
Dated: August 14, 1997
Received: August 18, 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 (Premarket 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.

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

INDICATIONS STATEMENT

Device Name: FREQUENCY™ 55 (methafilcon A) (Hydrophilic Contact Lens for Daily Wear (clear and tinted)

The FREQUENCY 55 (methafilcon A) 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 chemical or hydrogen peroxide disinfection systems.

(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** _____

8/21/97

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973063

(Optional Format 1-2-96)