JAN 20 1999

K982997

510 (k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name:	Aspect Vision Care Ltd.
Address:	South Point, Hamble Southampton SO31 4RF United Kingdom
Phone:	00 1 44 1703 605 200
Fax:	00 1 44 1703 605 299
CONTACT PERSON:	Ivor Atkinson

DATE SUMMARY PREPARED: August 24, 1998

TRADE NAME: FREQUENCY 55 UV (methafilcon A) Hydrophilic Contact Lens for Daily Wear (clear and tinted)

COMMON NAME: Contact Lens

SUBSTANTIALLY EQUIVALENT TO:

FREQUENCY 55 UV (methafilcon A) Hydrophilic Contact Lenses for Daily Wear (clear and tinted) are substantially equivalent to FREQUENCY 55 (methafilcon A) Hydrophilic Contact Lenses for Daily Wear (clear and tinted) that received marketing clearance pursuant to K973063, currently marketed in the US. A comparison of properties is found in the chart below.

Preclinical Testing

The results of toxicology testing (cytotoxicity, acute systemic toxicity and acute ocular irritation) have demonstrated that the subject lens in non toxic. Furthermore, the results of residual monomer and colour leachability testing demonstrate that the respective extracts did not contain leachable colour or significant levels of residual monomers.

The physical optical, and chemical properties of the FREQUENCY 55 UV (methafilcon A) Hydrophilic Contact Lens for Daily Wear (clear and tinted) are equivalent to those of the FREQUENCY 55 (methafilcon A) Hydrophilic Contact Lens for Daily Wear (clear and tinted). 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 lens will be sterilised and packaged in the same manner as previously cleared in K973063 and K971164. This lens will also be sterility released by parametric release, as cleared in K971164.

COMPARISON OF PHYSICAL/OPTICAL PROPERTIES:

PARAMETER	*FREQUENCY 55 UV™ Hydrophilic Contact Lens for Daily Wear (clear and tinted with UV Blocker)*	*FREQUENCY 55 Hydrophilic Contact Lens for Daily Wear (clear and tinted)*
material	methafilcon A	methafilcon A
indication for use	myopia, hyperopia and astigmatism	myopia, hyperopia and astigmatism
water content	55%	55%
% transmittance @ 590nm	93.58%	95.47%
% transmittance @ 280-315 nm	6.00	82.47
% transmittance @ 316-380 nm	4.09	95.30
Dk (35 °C) (Edge Corrected)	14.00×10^{-11}	15.50×10^{-11}
powers	-20.00 to+20.00 D	-20.00 to+20.00 D
color	clear and aqua visibility	clear and blue visibility
refractive index	1.4027	1.4052
tensile strength	1.26	0.66
Modulus	0.32	0.48
Elongation at Break	287	179
Toughness	1.27	0.38
manufacturing method	cast molding	cast molding

DESCRIPTION of the DEVICE:

The FREQUENCY 55 UV (methafilcon A) Hydrophilic Contact Lens is available as a spherical lens in both clear and an aqua visibility tint. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) which is cross-linked with ethyleneglycol dimethacrylate. When hydrated, the lens consists of 45.0% HEMA and 55.0% water by weight when immersed in normal saline. The lens is visibility tinted aqua with Reactive Blue Dye No. 4 and Reactive Yellow Dye # 86. A benzotriazole UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 10% in the UVB range of 280 to 315 nm and less than 10% in the UVA range of 315 to 380 nm. The FREQUENCY 55 UV (methafilcon A) Hydrophilic Contact Lens for Daily Wear is a hemispherical flexible shell which cover the cornea and a portion of the adjacent sclera with the following dimensions:

- Chord Diameter: 14.0mm to 15.0mm
- Center Thickness: 0.03mm to 0.40mm
- Base Curve: 8.40mm to 9.30mm
- Spherical Powers: -20.00 Diopters to +20.00 Diopters

The physical/optical properties of the lens are:

- Refractive Index: 1.40
- % Transmittance @590nm: >90%
- % Transmittance @ 280-315nm <10%
- % Transmittance @ 316-380nm <10%
- Specific Gravity (calculated): 1.09
- Surface Character: clear

- Water Content: 55%
- Oxygen Permeability (Dk)*: 14.0×10^{-11} (cm^2 /sec) (ml O_2 /ml x mm Hg) at 35°C

*[Fatt Method for determination of oxygen permeability, edge corrected]

INDICATIONS FOR USE:

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

The FREQUENCY™ 55 UV (methafilcon A) Hydrophilic Contact Lens (clear and tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and astigmatism in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Dioptres 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 UV (methafilcon A) Hydrophilic Contact Lens (clear and tinted)

Powers:	+10.00 to -10.00D
Center Thickness:	0.07mm
Diameter:	14.2mm
Base Curve:	8.6, 8.9mm (minus lenses) and 8.8mm (plus lense)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1999

Aspect Vision Care Ltd.
Mr. Ivor Atkinson
Scientific Director
South Point, Hamble
Southhampton SO 31 4RF, Engand

Re: K982997
Trade Name: FREQUENCY 55 UV (methafilcon A) Hydrophilic Contact Lens
for Daily Wear (clear and tinted)
Regulatory Class: II
Product Code: LPL
Dated: November 12, 1998
Received: November 23, 1998

Dear Mr. Atkinson:

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 UV (methafilcon A) Hydrophilic Contact Lens for Daily Wear (clear and tinted)

The FREQUENCY™ 55 UV (methafilcon A) Hydrophilic Contact Lens (clear and tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and astigmatism 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 X OR Over-the-Counter Use _____

Daniel W.C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K982997

(Optional Format 1-2-96)