510(k) Summary

K042824

1. **SUBMITTER:**

Submitted on Behalf of:

- Company Name: CooperVision Manufacturing, Ltd.
- Address: Unit 2, South Point
  Hamble SO3 4RF
  Southampton UK
- Phone: 011 44 2380 605200
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2. **CONTACT PERSON:** Bonnie Tsymbal

- Company Name: CooperVision, Inc.
- Address: 711 North Road
  Scottsville, NY 14546
- Phone: (585) 264-3210
- Fax: (585) 889-5688

3. **DATE SUMMARY PREPARED:** September 21st, 2004

4. **DEVICE IDENTIFICATION:**

- Trade Name: Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lens
- Common Name: Hydrophilic Soft Contact Lens
- Classification: Lenses, Soft Contact, Daily Wear 86LPL
- Device Classification: Class II (21 CFR 886.5925)

5. **DEVICE DESCRIPTION:**

The Frequency 38 and Silver 07 (polymacon) Hydrophilic Contact Lens for Daily Wear (tinted) is available as a single vision lens. The lens material, polymacon is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) cross-linked with ethyleneglycol dimethacrylate (62%) and water (38%). Frequency 38 and Silver 07 (polymacon) Hydrophilic Contact Lenses for Daily Wear are tinted for visibility purposes from edge to edge using color additive Blue No. 4.

Frequency 38 is a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera with the following dimensions:

- Diameter: 14.0 mm to 15.0 mm
- Base Curve: 8.4 mm to 9.0 mm
- Center Thickness: 0.03 mm to 0.40 mm (varies with power)
- Powers: -20.00 to +20.00 D

The physical properties of the lens are:

- Refractive Index: 1.43
- Light Transmittance: >97%
- Specific Gravity: 1.17
- Water Content: 38%
- Oxygen Permeability: 8.0×10^{-11} (cm^2/sec)(ml O_2/ml x mmHg) at 35°C (Fatt method for determination of oxygen permeability)

6. INTENDED USE:

Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lenses are 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.

Eye care practitioners may prescribe Frequency 38 (polymacon) Soft (hydrophilic) Contact Lenses for frequent replacement wear, with cleaning, disinfecting, and scheduled replacement.

7. SUBSTANTIAL EQUIVALENCE:

Characteristic	Polymacon In-Monomer Tint (New Device)	Frequency 38 & Silver 07 *Post-Hydration Tint* K971049
Material	Polymacon	Polymacon
Material Classification	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1
Indications for Use	Daily Wear Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lenses are 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. Eye care practitioners may prescribe Frequency 38 (polymacon) Soft (hydrophilic) Contact Lenses for frequent replacement wear, with cleaning, disinfecting, and scheduled replacement.	Daily Wear Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lenses are 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. Eye care practitioners may prescribe Frequency 38 (polymacon) Soft (hydrophilic) Contact Lenses for frequent replacement wear, with cleaning, disinfecting, and scheduled replacement.
Water Content	38%	38%
Light Transmittance	>97%	>97%
Dk (35° C)	8.0×10^{-11}	8.0×10^{-11}
Refractive Index	1.43	1.43
Powers	-20.00 to +20.00 D	-20.00 to +20.00 D
Dye	C.I. Reactive Blue #4	C.I. Reactive Blue #4
Manufacturing Method	Cast Molded	Cast Molded

8. PRECLINICAL INFORMATION:

The results of toxicology testing, including Ocular Irritation, Cytoxicity and Systemic Toxicity have demonstrated that the subject lens is non-toxic.

Our in-house evaluation of the physical properties of the in-monomer tinted polymacon showed the values to be consistent with the post-hydration tinted polymacon. No significant differences were noted.

A leachable study was conducted to assess the color fastness of C.I. Reactive Blue 4 when used for in-monomer tinting of the Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lens.

From the absorbance values obtained from the three extraction solutions it is possible to show that the concentration of:

1. Reactive dye Blue 4 that leached out of the test lenses, if present, was below 1 ppm.

2. The mean absorbance values of the contact lenses prior to and following extraction were not significantly different and suggested that no leaching of the dye had occurred.

As a consequence to this, it is possible to conclude that despite utilizing an in-monomer tint option for the C.I. Reactive Blue 4 dye in Frequency 38 and Silver 07 (polymacon) soft contact lenses, an acceptable level of color fastness is still obtained.

9. CLINICAL DATA:

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lens. This determination was based on the following:

The in-monomer tinted polymacon soft (hydrophilic) contact lens has demonstrated to be substantially equivalent to the predicate post-hydration tinted polymacon soft (hydrophilic) contact lens (K971049).

10. CONCLUSION:

The information provided in this 510(k) establishes that the Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lenses are equivalent in optical, chemical and physical properties of the predicate device and does not raise any questions of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2004

CooperVision
c/o Ms. Bonnie Tsymbal
Manager, Regulatory Affairs
711 North Road
Scottsville, NY 14546

Re: K042824
Trade/Device Name: Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lenses
Regulation Number: 21CFR886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: II
Product Code: LPL
Dated: October 6, 2004
Received: October 13, 2004

Dear Ms. Tsymbal:

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

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Indication for Use Statement

510(k) Number:

Device Name: Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lenses

Indication for Use:

Frequency 38 and Silver 07 (polymacon) Soft (hydrophilic) Contact Lenses are 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.

Eye care practitioners may prescribe Frequency 38 (polymacon) Soft (hydrophilic) Contact Lenses for frequent replacement wear, with cleaning, disinfecting, and scheduled replacement.

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

PLEASE DO NO 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 K042824