



WESLEY JESSEN

MAY 14 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

K 965052

General Information

- A. Device Generic Name: DuraSoft 3 UV (phemfilcon A) hydrophilic contact lens
- B. Device Trade Name: DURASOFT® 3 Spherical: Clear, LiteTint™, Colors, Colors Complements
DURASOFT® 3 OptiFit® Toric: Clear, LiteTint™, Colors, Colors Complements
DURASOFT® 3 UV Spherical: Clear, LiteTint™, Colors, Colors Complements
DURASOFT® 3 UV OptiFit®: Clear, LiteTint™, Colors, Colors Complements
- C. Manufacturer's Name: Wesley Jessen Corporation
333 East Howard Avenue
Des Plaines, IL 60018
- D. Contact Person: Mr. Richard Main
Regulatory Affairs
Phone: 847 294-3342
Fax: 847 294-3434
- E. Device Common Name: contact lens for daily wear

Indications for Use

The DuraSoft 3 UV Optifit Toric (phemfilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear in the correction of vision in aphakic and/or not-aphakic persons with non-diseased eyes that are of myopic (nearsighted) or hyperopic (farsighted) and for the correction of astigmatism from 0.75 to 6.00 diopters. The lens ranges in power from -20.00 to +20.00 diopters.

The DuraSoft 3 UV Spherical (phemfilcon A) Soft (hydrophilic) Contact Lenses as indicated for daily wear in the correction of visual acuity in aphakic and/or not-aphakic persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit astigmatism of 2.00 diopters (D) or less that does not interfere with visual acuity. The lens ranges in power from -20.00 to +20.00 diopters.

The lenses indicated are for Daily Wear. The eye care practitioner may prescribe the lenses for daily use with routine daily cleaning, rinsing and disinfection. The lenses may be disinfected using a chemical disinfection system.

Substantial Equivalence

Substantial equivalence is being claimed for the addition of the UV absorber into the D3 Optifit Toric and D3 Spherical Soft lenses on the basis of the sponsor's prior approval of D3 FreshLook LiteTint UV lenses. The primary change occurring with the daily wear versions is that the UV absorber is being added to polymerized rods for lathed cut lenses while the previous approval was for the addition of the same UV absorber in the molding process as an in-molding process. Test data demonstrates the equivalence of the two processes and that the processes have no effect on the physical, optical or chemical properties of the finished lenses, and that the final finished specifications of the lenses are not adversely affected.

The process of incorporating the UV absorber into the polymer rods has been adjusted as an additive before polymerization which differs little from the previously approved in-process molding technique for molding lenses.

The sponsor will add appropriate UV absorption curves and standard claims statements to its labeling, and will continue to extend the current shelf life expiration date of two years, based on a reference to an approved shelf life protocol under the sponsor's PMA P830037/S31 approved March 5, 1990.

Device Description

The DuraSoft 3 UV Optifit Toric (phemfilcon A) Soft (hydrophilic) Contact Lenses and DuraSoft 3 UV Spherical (phemfilcon A) Soft (hydrophilic) Contact Lenses are hemispherical shells of the following dimensions:

DuraSoft 3 UV Optifit Toric

| | |
|-------------------|-------------------------------------|
| Chord Diameter: | 12.0 to 15.0 mm |
| Center Thickness: | 0.07 to 0.56 mm (varies with power) |
| Base Curves: | 7.80 to 9.00 mm |
| Powers: | -20.00 Diopters to +20.00 Diopters |

DuraSoft 3 UV Spherical Lenses

| | |
|-------------------|-------------------------------------|
| Chord Diameter: | 12.0 to 15.0 mm |
| Center Thickness: | 0.05 to 0.56 mm (varies with power) |
| Base Curves: | 7.80 to 9.00 mm |
| Powers: | -20.00 Diopters to +20.00 Diopters |

The lens material (phemfilcon A) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate. The DuraSoft 3 UV Optifit Toric (phemfilcon A) Soft (hydrophilic) Contact Lenses and the DuraSoft 3 UV Spherical (phemfilcon A) Soft (hydrophilic) Contact Lenses are made by adding the UV absorber to the polymerized rods. Once cured the rods are cut to buttons and then lathed to the proper correction for toric or spherical configurations.

The physical properties of the lenses are:

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|--------------------------|---|
| Specific Gravity: | 1.152 |
| Refractive Index: | 1.412 |
| Light Transmittance: | |
| LiteTint: | 95% minimum |
| Colors: | 97% minimum |
| Surface Characteristics: | Hydrophilic |
| Water Content: | 55% |
| Optical Zone: (Colors): | 5 mm |
| (LiteTint): | 5 mm to 9 mm (varies with power) |
| Oxygen Transmissibility: | $Dk/L = 32.2 \times \frac{10^{-9} \text{ ml } O_2 \text{ cm}}{\text{sec ml mm Hg}}$ at 35°C |

General Use Instructions

The DuraSoft 3 UV Optifit Toric (phemfilcon A) Soft (hydrophilic) Contact Lenses and the DuraSoft 3 UV Spherical (phemfilcon A) Soft (hydrophilic) Contact Lenses are available as astigmatic or spherical lenses, respectively. The lens wearing schedule may be prescribed for daily use at the direction of the eye care practitioner.