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### SUMMARY OF SAFETY & EFFECTIVENESS

#### General Information

- A. Device Generic Name: DuraSoft 2 FreshLook phemfilcon A hydrophilic contact lens
- B. Device Trade Name: DuraSoft 2 FreshLook COLORS and FreshLook LiteTint Contact Lenses
- 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) 294-3110
- E. Device Common Name: contact lens for daily wear

#### Indications for Use

The DuraSoft 2 FreshLook Colors (phemfilcon A) Soft (hydrophilic) Contact Lenses and the DuraSoft 2 FreshLook LiteTint (phemfilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear in the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit astigmatism of 0.75 diopters (D) or less that does not interfere with visual acuity.

The lenses indicated are for Daily Wear (for available powers see Lens Description Section). Eye care practitioner may prescribe the lens for either single-use disposable daily wear or for frequent replacement wear for daily use, with cleaning, rinsing, disinfection and scheduled replacement from one to 14 days of use. (See Wear Schedule Section for additional information.) When prescribed for frequent replacement wear, the lens must be disinfected using either chemical or heat disinfection systems.

#### Substantial Equivalence

DuraSoft 2 FreshLook Colors and DuraSoft 2 FreshLook LiteTint Soft (hydrophilic) Contact Lenses are substantially equivalent to other DuraSoft 2 clear and tinted lathe cut soft (hydrophilic) contact lenses previously marketed in the United States. Additionally, the subject contact lenses have the same characteristics and properties as the DuraSoft 2 clear and tinted lenses, as approved under NDA N17-852. The DuraSoft 2 FreshLook Colors and FreshLook LiteTint Contact Lenses (the subject lens) is manufactured using the identical manufacturing process as the DuraSoft 3 FreshLook Colors and LiteTint Contact Lenses, as approved under PMA P830037/S33 approved

January 31, 1994. In 1994 the FDA reclassified all daily wear soft (hydrophilic) contact lenses from Class III, Premarket Approval to Class II, Premarket notification. Class II calls for establishing devices as substantially equivalent to previously marketed devices of the same class. DuraSoft 2 FreshLook Colors and DuraSoft 2 FreshLook LiteTint Soft (hydrophilic) Contact Lenses have the same physical, optical and chemical characteristics of their predicate devices. Preclinical testing including testing for cytotoxicity using the agarose overlay method; systemic toxicity in mice; and a primary ocular irritation study in the rabbit have established that minor changes in formulation to enhance molding characteristics have no detrimental affect on the lens material as manufactured.

#### Device Description

The DuraSoft 2 FreshLook Colors (phemfilcon A) Soft (hydrophilic) Contact Lenses and DuraSoft 2 FreshLook LiteTint (phemfilcon A) Soft (hydrophilic) Contact Lenses are hemispherical shells of the following dimensions:

Chord Diameter:	12.0 to 15.0 mm
Center Thickness:	0.08 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 methylacrylate and 2-ethoxyethyl methacrylate. The DuraSoft 2 FreshLook Colors (phemfilcon A) Soft (hydrophilic) Contact Lenses are made by modifying the clear lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the iris. The colored pigments consist of the following color additives listed in the Color Additive Provisions of the Code of Federal Regulations 21 CFR Section 706. All colored lenses contain iron oxides, titanium dioxide and [phthalocyaninato (2-1)] copper. In addition, the green lens contains chromium oxide and the violet lens contains carbazole violet. The DuraSoft 2 FreshLook Colors (phemfilcon A) Soft (hydrophilic) Contact Lenses are available in the following opaque colors: Blue, Green, Hazel and Violet. The DuraSoft 2 FreshLook LiteTint (phemfilcon A) Soft (hydrophilic) Contact Lenses is tinted green with the color additive, phthalocyanine green for easy visibility for handling.

The physical properties of the lenses are:

Specific Gravity:	1.176
Refractive Index:	1.440
Light Transmittance:	
FreshLook LiteTint:	95% minimum
FreshLook Colors:	97% minimum
Surface Characteristics:	Hydrophilic
Water Content:	38%
Optical Zone (FreshLook Colors):	5 mm
(FreshLook LiteTint):	5 mm to 9 mm (Varies with power)
Oxygen Transmissibility:	$Dk/L = 12.9 \times 10^{-9} \text{ ml O}_2 \text{ cm} @ 35^\circ \text{C}$ sec ml mm Hg

#### General Use Instructions

The DuraSoft 2 FreshLook Colors (phemfilcon A) Soft (hydrophilic) Contact Lenses and the DuraSoft 2 FreshLook LiteTint (phemfilcon A) Soft (hydrophilic) Contact Lenses are available as Spherical Contact Lenses. The lens wearing schedule may be prescribed for either Disposable Daily Wear or Frequent Replacement Wear for daily use.

In the Disposable program, patients should be instructed to dispose of the lenses at each daily removal and to use lens care products only on an emergency basis.

In the Frequent Replacement Program, the lens wearing time prescribed by the eye care practitioner is for daily wear from 1 to 14 days. Each time the lens needs to be removed before the replacement time has elapsed, the lens must be cleaned, rinsed, and disinfected prior to placing it back on the eye. Wesley-Jessen recommends that the lens be discarded and replaced with a new lens every 2 weeks, or as recommended by the eye care practitioner. The eye care practitioner is encouraged to determine the wearing schedule based on the response of the patient.