

DEC 21 1999

K993935

SECTION III

510(k) Product Summary

**DuraSoft® 3 and DuraSoft® 3 UV  
Spherical, and OptiFit® Toric Soft Contact Lenses**

**A. Device Summary**

**1. Name and Address of Applicant:**

Wesley-Jessen Corporation  
333 East Howard Avenue  
Des Plaines, IL 60018

**Contact Person:**

Joseph Foos  
Vice President  
Scientific Affairs  
Phone: (847) 294-3306  
Fax: (847) 294-3853

**2. Name of the Device:**

**Trade Name:**

DuraSoft® 3 and DuraSoft® 3 UV (phemfilcon A)  
Spherical Clear, Handling Tint, Colors,  
Complements and ColorBlends Soft (Hydrophilic)  
Contact Lenses (Lathe Cut) for Daily Wear.

DuraSoft® 3 and DuraSoft® 3 UV (phemfilcon A)  
OptiFit Toric Clear, Handling Tint, Colors  
Complements and ColorBlends Soft (Hydrophilic)  
Contact Lenses (Lathe Cut) for Daily Wear.

**Classification Name:**

Soft (Hydrophilic) Contact Lenses for Daily Wear.

**Common Name:**

D 3 and D 3 UV Contact Lenses.

**Proprietary Name:**

DuraSoft® 3 and DuraSoft® 3 UV (phemfilcon A)  
Spherical Soft (Hydrophilic) Contact Lenses.

DuraSoft® 3 and DuraSoft® 3 UV (phemfilcon A)  
OptiFit Toric Soft (Hydrophilic) Contact Lenses.

**3. Identification of predicate device:**

Same as above. The addition of intended use  
to include cosmetic correction of disfigured  
eyes does not change the name of the device.

4. Description of device:

The dimensions of DuraSoft® 3 and DuraSoft® 3 UV (phemfilcon A) Spherical and OptiFit Toric hydrophilic contact lenses in Clear, Colors, Complements, ColorBlends and Handling Tint are the same as approved in PMA 830037/S41 and K982344.

The lens material (phemfilcon A) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate. The DuraSoft® 3 UV (phemfilcon A) contact lenses are made by adding the UV absorber to the monomer mixture. The physical properties of the lenses are listed below. The light transmittance table has been added as approved for the Supplement No. 42 PMA P830037 and 510(k) K991550 (FreshLook® Bifocal UV-absorbing (phemfilcon A) contact lenses). The data to support this table is available in Section X, Exhibit -3.

Physical properties of the lenses:

Specific Gravity:	1.178
Refractive Index:	1.411
Light Transmittance:	
Handling Tint:	95% minimum
Color:	95% minimum
Surface Characteristics:	Lathed and polished
Water Content:	55%
Optical Zone:	
Handling Tint:	5 mm to 9 mm (varies with power)
Colors:	5 mm
Oxygen Transmissibility (Dk/L):	$32.2 \times 10^{-9} \text{ ml O}_2 \text{ cm at } 35^\circ \text{ C}$ sec ml mm Hg

Light Transmittance	a) Visible (600 nm) ≥ 95%			
	b) UV (250-400 nm) †			
DuraSoft® 3UV with Handling Tint	UVA (315-380 nm)		UVB (280-315 nm)	
	+2.00	0.6	+2.00	3.1
	-4.00	4.0	-4.00	10.7
	-3.00*	2.3	-3.00*	7.3
DuraSoft® 3UV with Carbazole violet in-monomer tint	UVA (315-380 nm)		UVB (280-315 nm)	
	+2.00	0.7	+2.00	1.7
	-4.00	2.7	-4.00	5.2
	-3.00*	2.9	-3.00*	5.6

† The referenced data was determined from "Methods for Determining Ultraviolet Transmission of UV-blocking Contact Lenses," by Dr. H. Faubl, International Contact Lens Clinic, Vol. 25, no.5, 1998.

\* Representative of the thinnest lens design.

## **B. Statement of Intended Use**

### **Spherical**

DuraSoft® 3 Spherical (phemfilcon A) Clear, Colored, Complements ColorBlends and Handling Tint Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2.0 diopters that does not interfere with visual acuity. The lens range in power from -20.00 to +20.00 diopters for daily wear.

### **OptiFit Toric**

DuraSoft® 3 OptiFit Toric (phemfilcon A) Clear, Colored, Complements ColorBlends and Handling Tint Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6.0 diopters. The lens range in power from -20.00 to +20.00 diopters for daily wear.

### **Prosthetic**

DuraSoft® 3 Prosthetic (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for Daily Wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) or for occlusive therapy conditions such as diplopia, amblyopia or extreme photophobia.

The lenses may be prescribed for Daily Wear in not-aphakic and/or aphakic persons. The eye care practitioner may prescribe the lens for daily use with routine cleaning, rinsing and disinfection. The lens may be disinfected using a chemical (not heat) disinfection system only.

DuraSoft 3 Contact Lenses with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye.

## **C. Technological Characteristics of the Device and Comparison**

The physical properties of the device have not changed. Reference PMA Supplement P830037/S40 and S041 for technological device characteristics of the DuraSoft® 3 and DuraSoft® 3 UV (phemfilcon A) Spherical and OptiFit Toric Soft (Hydrophilic) Contact Lenses submitted and approved by the agency.

**D. Device Manufacturing Section**

**1. Facility:**

The manufacturing of the DuraSoft® 3 and DuraSoft® 3 UV Clear, Handling Tint, Colors, Complements and ColorBlends Spherical and OptiFit Toric Contact Lenses is at the following facility:

Wesley Jessen - Cidra Operation  
Road 173, KM 1.1  
Cidra, PR 00739

Establishment Registration No.: 2648694

Reference PMA Supplement P830037/S041 for the manufacturing of the DuraSoft® 3 and DuraSoft® 3 UV Spherical and OptiFit Toric (phemfilcon A) Soft (Hydrophilic) Contact Lenses. All device-manufacturing information submitted to the FDA in the PMA Supplement P830037/S40 & S41 is applicable to this submission.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Joseph F. Foos  
Vice President, Scientific Affairs  
Wesley Jessen Corporation  
333 East Howard Avenue  
Des Plaines, IL 60018-5903

Re: K993935

Trade Name: DuraSoft® 3 and DuraSoft® 3 UV (phemfilcon A) Spherical, and OptiFit® Toric Clear, Handling Tint, Colors, Colors Complements® and ColorBlends Soft (Hydrophilic) Contact Lenses (Lathe Cut) for Daily Wear (Prosthetic Use)

Regulatory Class: II

Product Code: 86 LPL

Dated: November 18, 1999

Received: November 19, 1999

Dear Mr. Foos:

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.

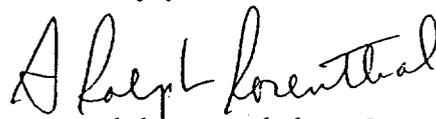
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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

