

DEC 22 1998

SECTION VI

**510 (k) Summary
Safety and Effectiveness****A. General Information****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 UV (phemfilcon A) Optifit Toric
Clear, Handling Tint, Colors and Complements
Soft (Hydrophilic) Contact Lenses (Lathe Cut)
for Daily Wear.

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

Classification Name:

Soft (Hydrophilic) Contact Lenses for Daily
Wear.

Common Name:

D® 3 UV Optifit Toric.
D® 3 UV Spherical.

Proprietary Name:

DuraSoft® 3 UV (phemfilcon A) Optifit Toric
(Hydrophilic) Contact Lenses.

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

B. Indication for use:

The DuraSoft® 3 UV Optifit Toric (phemfilcon A) Clear, Colored, Complements and Handling Tint Soft (Hydrophilic) contact lenses are indicated for daily wear in the correction of vision acuity in aphakic and /or not-aphakic person with non-diseased eyes that are 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 for daily wear.

The DuraSoft® 3 UV Spherical (phemfilcon A) Clear, Colored, Complements and Handling Tint Soft (Hydrophilic) contact lenses are 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 diopter (D) or less that does not interfere with visual acuity. The lens ranges in power from -20.00 to +20.00 diopters for daily wear.

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. Additional information is available in the Wearing Schedule Section of the package insert, patient instruction and fitting guide. The lenses may be disinfected using a chemical disinfection system.

C. Description of device:

The DuraSoft® 3 UV (phemfilcon A) Spherical and Optifit Toric hydrophilic contact lenses in Clear, Colors, Complements and Handling Tint are hemispherical shells of the lens material (phemfilcon A). A hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate.

The DuraSoft® 3 UV Optifit Toric Contact lenses and DuraSoft® 3 UV (phemfilcon A) Spherical Contact Lenses are made by adding the UV absorber and carbazole violet in-monomer tint to the monomer mixture. Once cured the rods are cut to buttons and then lathed to the proper correction for toric or spherical configuration.

D. Substantial Equivalence/Safety & Effectiveness:

DuraSoft® 3UV (with carbazole violet in-monomer tint) Optifit Toric and Spherical Soft (Hydrophilic) Contact Lenses are substantially equivalent to previously marketed DuraSoft® 3UV lenses of the same material (phemfilcon A) as approved under 510(k) premarket notification, K965052 for daily wear and PMA 830037/S40 for extended wear.

Carbazole violet has been listed as a color additive under 21 CFR 73.3107 approved October 21, 1988 (53 FR 41322) as part of an approval of the sponsors opaque series of tints under P830037/S19 approved November 30, 1988.

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The opaque series of tints was approved as a surface entrapment tinting process of which carbazole violet was a part. In this supplement the addition of carbazole violet is intended to be incorporated as an in-monomer tint by entrapment. The violet pigment will be incorporated under the Handling Tint program of tints which follows the approval of DuraSoft® 3 Spherical and Toric Soft Hydrophilic Lenses for Extended Wear as approved under P830037/S21 on October 27, 1987.

Please note that the tint as referenced is a listed tint, has been approved as an opaque surface tint with an amount which exceeds the amount of tint required to be incorporated into the monomer mix as a handling tint.

E. Conclusion

A thorough series of pre-clinical toxicology and compatibility studies demonstrates that all physical, optical and chemical properties for the handling tint are identical to the original opaque tint process and the final lens specifications are equivalent to the lenses approved for the opaque tinting process.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1998

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

Re: K982344/S1

Trade Name: DuraSoft ® 3 UV (phemfilcon A) Spherical and OptiFit ® Toric Clear, Handling
Tint, Color and Color Complements Soft (Hydrophilic) Contact Lenses
for Daily Wear (lathe cut with carbazole violet in monomer tint)

Regulatory Class: II

Product Code: 86 LPL

Dated: October 20, 1998

Received: October 21, 1998

Dear Mr. Foos:

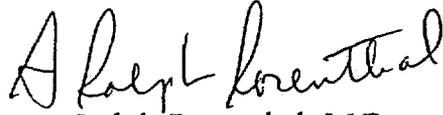
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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

510(k) Number (if known) K 98 2344

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

Indication for Use:

The DuraSoft® 3 UV Optifit Toric (phemfilcon A) Clear, Colored, Complements and Handling Tint 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) Clear, Colored, Complements and Handling Tint hydrophilic contact lenses are 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 diopter (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.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Conference of CDRH, Office of Device Evaluation (ODE)

Mig - Owen Sher
(Division Sign-Off)

Division of Ophthalmic Devices

Prescription Use 510(k) Number OR Over-The Counter

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