

MAY 14 2000

K 991550

SECTION III

510(k) Summary

FreshLook® Bifocal UV-absorbing Contact Lenses

A. Product 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: FreshLook® Bifocal UV-absorbing (phemfilcon A) Molded Spherical Handling Tint and Colors Soft (Hydrophilic) Contact Lenses for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lenses for Daily Wear.

Common Name: FreshLook® Bifocal

Proprietary Name: FreshLook® Bifocal UV-absorbing (phemfilcon A) Spherical Soft (Hydrophilic) Contact Lenses.

Facility Registration Number: 1422160

3. Identification of predicate device:

FreshLook® UV (phemfilcon A) Molded Spherical Handling Tint and Colors Soft (Hydrophilic) Contact Lenses. FreshLook® Bifocal is an alternate design to the currently marketed FreshLook® UV (phemfilcon A) Contact Lenses.

4. Description of device:

The FreshLook® Bifocal UV-absorbing (phemfilcon A) Spherical Soft (Hydrophilic) contact lenses in Handling Tint and Colors are hemispherical shells indicated for the correction of visual acuity in presbyopic patients for daily wear. The generic name (USAN) is phemfilcon A. The form in which the device is to be delivered is a contact lens immersed in 0.9% sodium chloride solution. Exclusive of the saline solution, the lens is a hydrophilic polymer swollen with water, in the polymer/water weight ratio of 45/55 respectively.

The components of the FreshLook® Bifocal UV-absorbing lenses are identical to the currently manufactured FreshLook® UV. The lens material (phemfilcon A) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate and a proprietary UV absorbing monomer which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light.

The FreshLook® Bifocal lenses are available in the following parameter range:

Chord Diameter:	12.0 to 15.0 mm
Base Curve:	7.80 to 9.00 mm
Distance Power Zone:	5 mm (colors) 5 mm to 9 mm (Handling Tint - varies with power)
Increments:	0.25 D
Center Thickness:	0.08 to 0.56 mm (Varies with power)
Distance Powers:	-20.00 D to +20.00 D
Bifocal Add Powers:	+0.50 D to +3.00 D
Near Power Zone:	1.00 to 3.80 mm
Progressive Power Zone:	1.40 to 4.80 mm

The physical properties of the FreshLook® Bifocal UV-absorbing lens are identical to the FreshLook® UV lens and are as follows:

Physical Property	FreshLook® Bifocal UV
Specific Gravity	1.152
Refractive Index	1.411 @ 25°C
Light Transmittance	95% (minimum)
Surface Character	Hydrophilic
Water Content	55%
Oxygen Permeability (Dk)	16.1×10^{-11} ml O ₂ cm ² / sec ml mmHg
Oxygen Transmissibility* (Dk/L)	20×10^{-9} ml O ₂ cm / sec ml mmHg

*Dk/L = 20×10^{-9} ml O₂ cm / sec ml mmHg at 35°C (Dr. Irving Fatt Method)

Reference PMA Supplement P830037/S042 Exhibit IV-1, Exhibit IV-2 and subsequent Amendment #1 for a detailed physical description, drawing and center thickness table of the FreshLook Bifocal UV-absorbing Spherical (phemfilcon A) Soft (Hydrophilic) Contact Lenses submitted to the agency for Real Time Review.

B. Statement of Intended Use

FreshLook® Bifocal UV-absorbing Spherical (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity and presbyopia in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 0.75 diopters that does not interfere with visual acuity. The lens ranges in power from -20.00 to +20.00 diopters for daily wear.

The lenses may be prescribed for Daily Wear in aphakic or not aphakic persons. The eye care practitioner may prescribe the lenses in either a single use daily disposable program or in a frequent replacement program with cleaning, disinfection and scheduled replacement. When prescribed in the frequent replacement program, the lenses may be disinfected using a chemical disinfection system.

FreshLook 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

Reference PMA Supplement P830037/S042 for technological device characteristics of the FreshLook® Bifocal UV-absorbing Spherical (phemfilcon A) Soft (Hydrophilic) Contact Lenses submitted to the agency for Real Time Review.

D. Device Manufacturing Section

Reference PMA Supplement P830037/S042 for the manufacturing of the FreshLook® Bifocal UV-absorbing Spherical (phemfilcon A) Soft (Hydrophilic) Contact Lenses. All device-manufacturing information submitted to the FDA in the PMA Supplement P830037/S042 Real Time Review is applicable to this submission.



MAY 14 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991550
Trade Name: FreshLook® Bifocal UV-absorbing (phemfilcon A) Molded Spherical
Handling Tint and Colors Soft (Hydrophilic) Contact Lenses for Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: May 3, 1999
Received: May 4, 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.

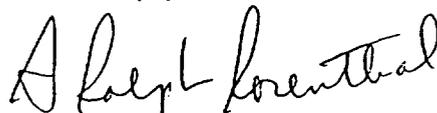
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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

INDICATIONS STATEMENT

510(k) Number (if known) K 991550

Device Name: FreshLook® Bifocal UV-absorbing (phemfilcon A) Molded Spherical Handling Tint and Colors Soft (Hydrophilic) Contact Lenses for non-diseased presbyopic eyes Daily Wear

Indication for Use:

Spherical

FreshLook® Spherical (phemfilcon A) 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.

Toric

FreshLook® Toric (phemfilcon A) 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.

Bifocal

FreshLook® Bifocal UV-absorbing Spherical (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity and presbyopia in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 0.75 diopters that does not interfere with visual acuity.

The lenses may be prescribed for Daily Wear in aphakic or not aphakic persons. The eye care practitioner may prescribe the lenses in either a single use daily disposable program or in a frequent replacement program with cleaning, disinfection and scheduled replacement. When prescribed in the frequent replacement program, the lenses may be disinfected using a chemical disinfection system.

FreshLook Lenses with UV-absorbing monomers help protect against transmission of harmful UV radiation to the cornea and into the eye.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)
Conference of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The Counter

[Signature]
(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K 991550