

JAN 6 1999

K 982988

## Attachment C

### Summary of 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:

Proprietary Name:

Precision UV™ (vasurfilcon A)

3. Identification of  
Predicate Device:

Same as above

#### B. Indication for use:

Precision UV™ (vasurfilcon A) Hydrophilic Contact Lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may have 2.00 diopters(D) or less of corneal astigmatism that does not interfere with visual acuity. The contact lenses may be prescribed for daily wear. The eye care practitioner may prescribe the contact lens for either single-use disposable wear or for frequent replacement wear, with cleaning, disinfecting and scheduled replacement. When prescribed for frequent replacement wear, the contact lens may be disinfected using a chemical, heat or hydrogen peroxide disinfecting system. Precision UV lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

#### C. Description of device:

Precision UV™ (vasurfilcon A) Hydrophilic Contact Lenses are available as clear and locator tinted spherical lenses in the power range from -16.00 to + 10.00 diopters, center thickness from 0.09 - 0.17 mm (minus lenses) and 0.22 - 0.41 mm (plus lenses) with base curves of 8.4 and 8.7mm and a diameter of 14.4mm. The lens material, vasurfilcon A, is a hydrophilic random copolymer of N-vinyl-pyrrolidone (NVP), Methyl methacrylate (MMA), Allyl methacrylate (AMA), Ultraviolet absorbing monomer (UVAM) and AIBN (Azo-Iso-butyronitrile) as an initiator. It consists of 74% water and 26% vasurfilcon A.

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Precision UV™ (vasurfilcon A) Hydrophilic Contact Lenses are currently marketed domestically and internationally by Wesley Jessen Corporation under PMA P940013. Previously, they were marketed by Pilkington Barnes Hind under Allergan Medical Optic's PMA P790020.

**D. Substantial Equivalence/Safety & Effectiveness:**

Precision UV™ (vasurfilcon A) Hydrophilic Contact Lenses are identical to previously marketed Precision UV™ (vasurfilcon A) Hydrophilic Contact Lenses of the same material as approved under 510(k) premarket notification, K961299, and PMA P940013 for all properties (physical, optical, chemical, biocompatible, microbiological, and clinical). There were no changes to the lens material or design; however, the associated labeling and indications were changed.

**E. Summary:**

Wesley Jessen considers the study, data and referenced literature (epidemiological studies, non-clinical research reports, studies on the nature of UV energy, etc.) submitted under 510(k) premarket notification, K982988, and PMA Supplement, P940013/S6, evidence supporting the additional intended use and associated modified labeling.



JAN 6 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K982988  
Trade Name: Precision UV™ (vasurfilcon A) Hydrophilic Contact Lens for Daily Wear  
(clear and visibility tinted)  
(Labeling modifications)  
Regulatory Class: II  
Product Code: LPL  
Dated: November 20, 1998  
Received: November 23, 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 legally marketed predicate 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.

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

# Attachment B

## INDICATIONS STATEMENT

510(k) Number (if known): K982988

Device Name: Precision UV™ clear and tinted (74% water) Daily Wear  
Soft Contact Lens

### Indication for Use:

Precision UV™ (vasurfilcon A) Hydrophilic Contact Lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may have 2.00 diopters(D) or less of corneal astigmatism that does not interfere with visual acuity. The contact lenses may be prescribed for daily wear. The eye care practitioner may prescribe the contact lens for either single-use disposable wear or for frequent replacement wear, with cleaning, disinfecting and scheduled replacement. When prescribed for frequent replacement wear, the contact lens may be disinfected using a chemical, heat or hydrogen peroxide disinfecting system. Precision UV lenses 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 \_\_\_\_\_

Karen Warburton   
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K982988

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