

JUN 28 1999

K 991000

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 F. Foos
Vice President
Scientific Affairs
Phone: (847) 294-3306
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2. Name of the Device:

Proprietary Name: GentleTouch™ UV (netrafilcon A)

Device Classification: As per 21 CFR Section 886.5925 Soft (hydrophilic) daily wear contact lenses are classified as Class II device.

Product Code: 86 LPL

B. Indication for use:

The Gentle Touch UV (netrafilcon A) soft (hydrophilic) contact lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity. The lens is to be disinfected using a recommended chemical (not heat) disinfection system or hydrogen peroxide disinfection system. Gentle Touch UV (netrafilcon A) lenses help to protect against transmission of harmful UV radiation to the cornea and into the eye.

C. Description of device:

The GentleTouch UV (netrafilcon A) soft (hydrophilic) contact lenses are available as handling tinted hemispherical lenses with base curves of 8.2 mm and 8.5 mm and a diameter of 14.5 mm. The lens may be worn by persons that require a spherical lens in the power range from -20.00 to +20.00 Diopters (D) for daily wear. The lens material, netrafilcon A, is a hydrophilic copolymer of N,N-dimethyl acrylamide, methyl methacrylate, with a UV absorbing monomer (UVAM) and in-monomer tint. It consists of 65% water and 35% netrafilcon A. The lenses are manufactured by injecting a small amount of netrafilcon A monomer into a polypropylene mold and then thermally cured.

Physical Properties

Physical Test	GentleTouch UV
Refractive Index (21 °C)	1.394
Light Transmittance	95% min.
Water Content	65%
Oxygen Permeability*	31

*Note: Permeability Coefficient $Dk \times 10^{-10}$ (ccO₂,mm)/(cm² sec mmHg), measured by the OX-Tran(R) "H" technology embodied in the new ASTM method F-1927.

Mechanical Properties

The GentleTouch UV contact lenses were compared to the current lathed GentleTouch lenses for tensile properties. The measured tensile properties show that the molded lenses are equivalent to the lathed lenses.

Toxicology

The safety of GentleTouch (netrafilcon A) has been established (PMA P890012). The preclinical studies on GentleTouch UV with the In-monomer-tint, UV absorbing monomer and new molding process were conducted to assure that the safety of this material, netrafilcon A, has not been altered by these changes. The studies are summarized below:

a. Cytotoxicity:

The negative controls and positive controls performed as anticipated. Under the condition of this study, the test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the USP.

b. Systemic Injection:

Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts. Each test article extract met the USP requirements.

c. Ocular irritation:

Under the conditions of this study, the SC (sodium chloride) and CSO (cottonseed oil) test article extracts would not be considered irritants to the ocular tissue of the rabbit.

Residual Analysis

Samples of lenses were extracted in saline and the extracts analyzed by high performance liquid chromatography and spectrophotometric method to determine if extractables from the material would be detected. There were no extractables detected.

Lens Compatibility with the Recommended Lens Care Regimen

Any changes in parameters through 30 cycles were within manufacturing tolerances. Cycling in the ReNu Multipurpose System, in heat disinfection or in the AOSep System did not adversely affect measured lens parameters relative to the uncycled control lenses. Tint color was still evident after 30 cycles and is still effective as a handling tint.

Light Transmittance:

The ultraviolet spectra of cycled lenses was individually measured before and after cycling. All variances were within the experimental tolerance. It can be considered that there was no significant difference between the light transmittance before and after cycling.

D. Safety & Effectiveness:

GentleTouch UV Soft (Hydrophilic) Contact Lenses are comparable to the previously marketed GentleTouch lenses of the same material as approved under PMA (P890012).

The approval of 510(k) K961299, marketed as Precision UV™ (vasurfilcon A) substantiates the safe and efficacious use of the IMT (D&C Green No.6 dye) as a handling tint and the UV absorbing monomer, UVAM, is also the same UV absorber utilized in Precision UV (K944722 & K982988). The use of the IMT (D&C Green No. 6, C.I. No. 61565) for tinting GentleTouch UV (netrafilcon A) hydrophilic soft contact lenses will be in accordance with the color additive listing provisions of 21 Code of Federal Regulations § 74.3206.

E. Conclusion

A thorough series of pre-clinical, toxicology and compatibility studies demonstrates that all physical, optical and chemical properties for the handling tint (IMT), UV absorbing monomer (UVAM) and molding process are equivalent to the original lathe process and the final lens specifications are substantially equivalent to the prior approved lathed process.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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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: K991000

Trade Name: Gentle Touch™ UV (netrafilcon A) Soft (hydrophilic) Contact Lens for Daily
Wear (visitint with D & C Green #6, cast-molded)

Regulatory Class: II

Product Code: 86 LPL

Dated: May 27, 1999

Received: June 1, 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.

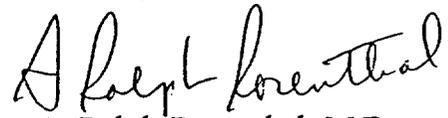
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

