MAR 20 2000

K994335

SECTION VI

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
Fax: (847) 294-3853

2. Name of the Device:

Common Name: Daily wear soft (hydrophilic) contact lens

Trade Name: ProSoft (phemfilcon A)

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

Classification Number: LPL; Ophthalmic Devices Panel

B. Indications for use:

Spherical
ProSoft™ 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 2.00 diopters that does not interfere with visual acuity. The lens range in power from -20.00 to +20.00 diopters for daily wear.

Toric
ProSoft™ 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 6.00 diopters. The lens ranges in power from -20.00 to +20.00 diopters for daily wear.

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

ProSoft Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

C. Description of device:

ProSoft Spherical and Toric (phemfilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear are hemispherical shells of the lens material (phemfilcon A), which is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate.

Once cured the rods are cut to buttons and then lathed to the proper spherical or toric configuration. The ProSoft contact lenses are made by adding Vat Green #1 dye to the finished lens using the CTL (custom tinting) process.

Prosoft lenses enhance perception of colored objects relative to other background colors. This enables the wearer to see a ball or selected objects with greater clarity than with the naked eye, on the tennis court, golf course or other background.

Physical and Mechanical Properties

The ProSoft contact lenses were compared to the current lathed DuraSoft 3 UV lenses for physical and mechanical properties. The measured properties show that the lathed lenses are equivalent to predicate lenses.

Toxicology

The safety of phemfilcon A is well established (PMA P830037). The preclinical studies on ProSoft with the CTL tinting process using Vat Green #1 were conducted to assure that the safety of this material, phemfilcon 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 to determine if dye extractables from the material would be detected. There were no dye 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® did not adversely affect measured lens parameters relative to the uncycled control lenses. Tint color was still evident after 30 cycles.

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.

Microbiology:

Lens manufacturing, packaging and sterilization are identical to the sterilization described for the predicate device, DuraSoft 3 UV, therefore sterilization validation is not required.

D. Conclusion:

ProSoft (phemfilcon A) contact lenses are substantially equivalent to marketed DuraSoft® 3UV lenses of the same material as approved under 510(k) premarket notification, K965052, and the tinting process is substantially equivalent to the approved process for CustomEyes (bufilcon A) contact lenses under PMA P850057.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2000

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

Re: K994335
Trade Name: ProSoft Spherical and Toric (phemfilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: December 21, 1999
Received: December 23, 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.

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) K994335

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Indications for Use:

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

Prescription Use X OR Over-The-Counter _____

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K994335