AUG 4 1998

SPECIALTY

ULTRAVISION INC.

K980197

510(k) Summary

Submitter Information:

Company: Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, CA 95008

Contact Person: Ivalee Cohen
Director, Regulatory and Clinical Affairs

Telephone: (408) 341-0700
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Date Prepared: January 16, 1998

Device Name:

Common Name: Rigid Gas Permeable Contact Lens

Trade/Proprietary Names: UltraCon (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear
and
UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear

Classification Name: Rigid Gas Permeable Contact Lens

Device Classification: Class II (21 CFR 886.5916)

Predicate Device:

The predicate device is the LifeStyle GP (telefocon B) Rigid Gas Permeable Contact Lens for Daily Wear, which was cleared under 510(k) K963010. This device was selected as the predicate device because of its similarities in intended use (daily wear), Dk value, and material type (FDA Group II: containing silicone but not fluorine).

Description of Devices:

1. **UltraCon (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear**

   The **UltraCon (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear** is available as a hybrid lens design with spherical and aspherical curves on its surfaces. The lens material (carbosilfocon A) is composed of polymethyl methacrylate (PMMA) combined with a proprietary copolymer that contains silicone. D&C Green No. 6 is incorporated into the polymer, resulting in a blue

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handling tint. The **UltraCon Rigid Gas Permeable Contact Lens for Daily Wear** is a hemispherical shell of the following dimensions:

- Chord Diameter: 8.5 to 10.5 mm
- Center Thickness: 0.10 mm to 0.28 mm
- Base Curve: 7.0 to 8.5 mm
- Powers: +12.00 D to-20.00 D

The physical/optical properties of the lens are:

- Specific Gravity 1.105
- Refractive Index: 1.57 at 20°C
- Light Transmittance: 96.5%
- Surface Character: Hydrophobic
- Water Content: 0.5%
- Wetting Angle: 19° (CLMA method)
- Oxygen Permeability (Dk)*: 44 x 10^{-11} (cm^2/sec) (ml O_2 /ml x mm Hg) at 35°C

*[Fatt method used for determination of oxygen permeability]

2. UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear

The **UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear** is available as a hybrid lens design with spherical and aspherical curves on its surfaces. The diameter of the lens is larger than conventional rigid gas permeable lenses, and the UltraCon S lens extends beyond the cornea and onto the limbal region. The lens material (carbosilfocon A) is composed of polymethyl methacrylate (PMMA) combined with a proprietary copolymer that contains silicone. D&C Green No. 6 is incorporated into the polymer, resulting in a blue handling tint. The **UltraCon S Rigid Gas Permeable Contact Lens for Daily Wear** is a hemispherical shell of the following dimensions:

- Chord Diameter: 12.0 mm to 14.0 mm
- Center Thickness: 0.10 mm to 0.28 mm
- Base Curve: 7.0 to 8.5 mm
- Powers: +12.00 D to-20.00 D
- Peripheral Curves: C, D, and E

The physical/optical properties of the lens are:

- Specific Gravity 1.105
- Refractive Index: 1.57 at 20°C
- Light Transmittance: 96.5%
- Surface Character: Hydrophobic
- Water Content: 0.5%
- Wetting Angle: 19° (CLMA method)
- Oxygen Permeability (Dk)*: 44 x 10^{-11} (cm^2/sec) (ml O_2 /ml x mm Hg) at 35°C

*[Fatt method used for determination of oxygen permeability]

Comparison to Predicate Device

PARAMETER	*UltraCon and UltraCon S Rigid Gas Permeable Contact Lens for Daily Wear*	*LifeStyle Gp Rigid Gas Permeable Contact Lens for Daily Wear (K963010)*
material	carbosilfocon A	telefocon B
material classification	Hydrophobic Lens Group 2	Hydrophobic Lens Group 2
indication for use	myopia, hyperopia and astigmatism	myopia, hyperopia and astigmatism
water content	0.5%	less than 0.5%
light transmittance	96.5%	96%
Dk (35° C)	44×10^{-11}	43.5×10^{-11}
powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters
color	blue visibility	blue, green, brown and gray
specific gravity	1.105	1.126
refractive index	1.57 at 20°	1.480 at 20° C
wetting angle	< 19°	< 30°
Method of manufacture	Gel Flow Molding	Lathe cut

Indications for Use:

The **UltraCon and UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 4.00 diopters. The lens may be disinfected using a chemical disinfection system.

Description of Safety and Substantial Equivalence:

A series of non-clinical tests and a clinical study were performed to demonstrate the safety and effectiveness of the UltraCon and UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear, and to establish substantial equivalence to the predicate lens. All testing was conducted in accordance with the May, 1994 FDA guideline titled *Premarket Notification 510(k) Guidance Document for Class II Contact Lenses* and in conformance to applicable device regulations. Results demonstrate the lens is non-toxic and biocompatible, and has material characteristics comparable to or better than other currently marketed RGP lenses. Clinically, the lens has performed satisfactorily in a daily wear investigation. Results from all tests demonstrate the substantial equivalence to the predicate lens.

Non-Clinical Testing:

In vitro and *in vivo* preclinical toxicology and biocompatibility tests were performed to assess the safety of the device. All tests were conducted in accordance with 21 CFR Part 58, GLP regulations. Physicochemical and leachability testing was performed to establish device characteristics.

Results of the testing demonstrate that the lens material and extracts are not toxic and non irritating, and that the lens physical and material properties are consistent with marketed contact lenses.

Clinical Testing:
A three month clinical evaluation of the UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear was performed at six investigational sites in accordance with current Good Clinical Practices and established regulations. The study assessed the safety and effectiveness of the lens, and compared its clinical performance to the predicate lens.

Performance of the UltraCon S lens was substantially equivalent to performance of the predicate lens with respect to safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 1998

Ms. Ivalee I. Cohen
Director, Regulatory and Clinical Affairs
Specialty ULTRAVISION, Inc.
307 Orchard City Drive
Suite 100
Campbell, CA 95008

Re: K980197
Trade Name: UltraCon and UltraCon S (Carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear (Sperical and Aspheric) Visibility tinted with D & C Green No. 6
Regulatory Class: II
Product Code: 86 HQD
Dated: June 5, 1998
Received: June 8, 1998

Dear Ms. Cohen:

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

Device Name:

UltraCon (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear

UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear

Indications for Use:

The UltraCon and UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lenses for Daily Wear are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 4.00 diopters. The lenses may be disinfected using a chemical disinfection system.

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

Prescription Use ✓ OR Over-the-Counter Use _____

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980197