

FEB 2 2000

K 992187

SPECIALTY

ULTRAVISION
INC.

510(k) Summary

Submitter Information:

Company: Specialty UltraVision, Inc.
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Date Prepared: December 6, 1999

Device Name:

Common Name: Rigid Gas Permeable Contact Lens

Trade/Proprietary Names: EpiCon K (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 UltraCon S (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear, which was cleared under 510(k) K980197. This device was selected as the predicate device because it is manufactured from the same polymer, using similar lens designs, at the same manufacturing facility, under the same Quality System and using the same manufacturing equipment.

Description of Device:

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

- Chord Diameter: 10.5 mm to 14.0 mm
- Center Thickness: 0.10 mm to 0.35 mm
- Base Curve: 6.0 to 8.5 mm
- Powers: Plano to -20.00 D
- Peripheral Curves: A, B, C, D, E, F and G
Step ↔ Flat

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Comparison to Predicate Device

PARAMETER	<i>EpiCon K Rigid Gas Permeable Contact Lens for Daily Wear</i>	<i>UltraCon S Rigid Gas Permeable Contact Lens for Daily Wear</i>
<i>material</i>	carbosilfocon A	carbosilfocon A
<i>material classification</i>	Hydrophobic Lens Group 2	Hydrophobic Lens Group 2
<i>indication for use</i>	myopia, hyperopia and astigmatism	myopia, hyperopia and astigmatism
<i>water content</i>	0.5%	0.5%
<i>light transmittance</i>	96.5%	96.5%
<i>Dk (35° C)</i>	52×10^{-11}	52×10^{-11}
<i>powers</i>	Plano to -20.00 Diopters	+20.00 to -20.00 Diopters
<i>color</i>	blue visibility	blue visibility
<i>specific gravity</i>	1.105	1.105
<i>refractive index</i>	1.49 at 20°	1.49 at 20°
<i>wetting angle</i>	< 19°	< 19°
<i>Method of manufacture</i>	Gel Flow Molding	Gel Flow Molding

Indications for Use:

The EpiCon K (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear is indicated for daily wear in aphakic or not-aphakic persons exhibiting the irregular corneal surface associated with keratoconus and/or requiring keratoconus management with otherwise non-diseased eyes. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism). The lenses may be disinfected using a chemical disinfecting system.

Description of Safety and Substantial Equivalence:

Biocompatibility, toxicology, physicochemical and leachability studies were previously performed on the carbosilfocon A polymer and cleared under K980197. Results of that testing indicate that the lens material is non-toxic and biocompatible.

Clinical Testing:

A four week clinical evaluation of the EpiCon K (carbosilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear was performed at five investigational sites in accordance with current Good Clinical Practices and established regulations. The study assessed the clinical performance of the EpiCon K lens in subjects with bilateral keratoconus. Subjects were seen at an Initial Visit, which was a diagnostic fitting visit. Subjects were seen at a Dispensing Visit, and after 1, 2 and 4 weeks of lens wear. The EpiCon K lens was dispensed to 38 keratoconic subjects, and 18 subjects (47.4%) completed the 4 weeks of the study period while 20 subjects (52.6%) discontinued. Two adverse reactions were reported during the study period, both of which resolved without sequelae upon discontinuation of lens wear.

Based on the clinical data analysis, it was determined that the incidence of positive slit lamp findings, subject symptoms, problems and complaints, keratometry and refractive changes, visual acuity with the lens, lens wearing time and lens comfort were within the expected range for keratoconic eyes wearing RGP lenses.

Clinical performance of the EpiCon K lens was substantially equivalent to the clinical performance of the predicate lens.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gerald L. Edwards, O.D., F.A.A.O.
Vice President, Technical Affairs
Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, California 95008

Re: K992787

Trade Name: EpiCon K (Carbosilifocon A) Rigid Gas Permeable Contact Lens for
Daily Wear (Keratoconus Design)

Regulatory Class: Class II

Product Code: 86HQD

Dated: December 6, 1999

Received: December 7, 1999

Dear Dr. Edwards:

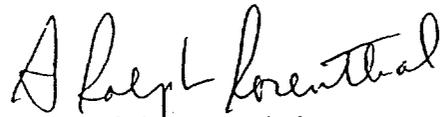
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

