FEB 2 2000

SPECIALTY
ULTRAVISION INC.

K 993580

510(k) Summary

Submitter Information:

Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, CA 95008
Contact Person: Garold Edwards, O.D., F.A.A.O.
Vice President, Technical Affairs
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Date Prepared: October 19, 1999

Device Name:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Names:	**Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear**
Classification Name:	Soft (Hydrophilic) Contact Lens
Device Classification:	Class II (21 CFR 886.5925)

Predicate Devices:

The Specialty 55 (methafilcon A) Soft Single Vision Contact Lens for Daily Wear was selected as the predicate device. This device, which was cleared under 510(k) K984090, is manufactured from the same polymer and the same lens design.

Description of Devices:

The **Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear** is a hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera. The **Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear** is available as a single vision lens. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). The **Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear** is tinted using D & C Green #6 in an in-monomer tinting process.

Comparison to Predicate Device

PARAMETER	**Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear**	**Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear**
material	methafilcon A	methafilcon A
material classification	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4
indication for use	myopia, hyperopia	myopia, hyperopia
water content	55%	55%
light transmittance	Approximately 98%	Approximately 98%
Dk (35° C)	18.8×10^{-11}	18.8×10^{-11}
powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters
color	blue visibility	blue visibility
refractive index	1.42	1.42
specific gravity	1.06	1.06
Method of manufacture	Molded	Molded
Tint	D&C Green #6	Vat Blue #6
Tint process	Entrapment process during polymerization	Entrapment process during polymerization

Indications for Use:
The **Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia, and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The lenses may be disinfected using a chemical or hydrogen peroxide disinfection system. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

Description of Safety and Substantial Equivalence:
Non-clinical testing was performed to demonstrate substantial equivalence to the predicate device, and to establish the safety and effectiveness of **the Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lenses for Daily Wear**. All testing was conducted in accordance to the *Premarket Notification 510(k) Guidance Document for Class II Contact Lenses* issued by FDA in May, 1994. Results of cytotoxicity testing show the lens material to be non-cytotoxic, the physicochemical properties of the lens to be comparable to the predicate device, and the leachability testing demonstrates no detectable level of tint in the test extracts.

Conclusion:
Information submitted in the 510(k) establishes that the **Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear** has comparable physicochemical properties to the predicate device and does not raise questions of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2000

Garold L. Edwards, O.D.
Vice President, Technical Affairs
Specialty Ultravision, Inc.
307 Orchard City Drive
Suite 100
Campbell, CA 95008

Re: K993580
Trade Name: Specialty 55 (methafilcon A) Soft (hydrophilic) Single Vision Lens For Daily Wear (cast-molded, visitint with D & C Green #6)
Regulatory Class: II
Product Code: 86 LPL
Dated: January 14, 2000
Received: January 18, 2000

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 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:

Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear

Indications for Use:

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(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 _____

E. S. Co, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993580