

JUL -7 1999

K984090

SPECIALTY

ULTRAVISION
INC.

510(k) Summary

Submitter Information:

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: May 24, 1999

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Names: Specialty 55 Multifocal (methafilcon A) Soft
(Hydrophilic) Contact Lens for Daily Wear

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)

Description of Devices:

The Specialty 55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear and the Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera. The Specialty 55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens is available as an aspherical multifocal lens and the Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens 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 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear and the Specialty 55 (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens for Daily Wear are tinted using Vat Blue #6 in an entrapment tinting process during polymerization of the lens.

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Predicate Devices:

The Specialty Progressive (methafilcon A) Soft (Hydrophilic) Multifocal Contact Lens and the Specialty Choice AB (methafilcon A) Soft Single Vision Contact Lens, and the IGEL 56 (hefilcon C) Soft (hydrophilic) Contact Lens were selected as the predicate devices.

The Specialty Choice AB and Specialty Progressive lenses were cleared under 510(k) K963488, and are manufactured by a molding process that uses the methafilcon A polymer and the same lens designs as the Specialty 55 lenses. The dye tinting process is different, the lenses are tinted with Reactive Blue #4 after lens hydration using a wet lens tinting process, where the Specialty 55 lenses are in-monomer tinted.

The IGEL 56 lenses were cleared under 510(k) K974837, and were selected as predicate devices because, although they are molded from a different polymer, and tinted with a different dye, they are produced in the same facility, under the same quality system, using the same molding, in-monomer tinting, packaging and sterilization processes as the Specialty 55 lenses.

Comparison to Predicate Device

PARAMETER	<i>Specialty 55 Multifocal and Specialty 55 Soft (Hydrophilic) Contact Lenses for Daily Wear</i>	<i>Progressive Multifocal and Choice AB Soft (Hydrophilic) Contact Lenses for Daily Wear</i>	<i>IGEL 56 Soft (hydrophilic) Contact Lenses for Daily Wear</i>
material	methafilcon A	methafilcon A	hefilcon C
material classification	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4	Hydrophilic Lens Group 2
indication for use	myopia, hyperopia, and presbyopia	myopia, hyperopia, and presbyopia	myopia, hyperopia and astigmatism
water content	55%	55%	56%
light transmittance	98%	90 to 97%, dependent upon tint	90 to 94%
Dk (35° C)	18.8×10^{-11}	19.7×10^{-11}	21×10^{-11}
powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters	+6.00 to -12.00 Diopters
color	blue visibility	blue visibility	clear or blue visibility
refractive index	1.42	1.41	1.41
specific gravity	1.06	1.09	1.16
Method of manufacture	Molded	Molded	Molded
Tint	Vat Blue #6	Reactive Blue #4	D&C Green #6
Tint process	Entrapment process during polymerization	Wet lens tinting process	Entrapment process during polymerization

Indications for Use:

The **Specialty 55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia 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 **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:

A series of preclinical tests were performed to demonstrate the safety and effectiveness of the Specialty 55 Multifocal and Specialty 55 (methafilcon A) Single Vision Contact Lenses for Daily Wear, and to establish substantial equivalence to the predicate devices.

Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. A Solution Compatibility test, using chemical and hydrogen peroxide regimens showed Specialty 55 lenses to be compatible with both regimens. Specialty 55 lenses were extracted and evaluated for presence of the Vat Blue #6 dye. Results show no detectable leachability of the dye. Physicochemical testing of the Specialty 55 lenses determined equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that the Specialty 55 Multifocal and Specialty 55 Single Vision Contact Lenses (methafilcon A) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Therefore, the devices are substantially equivalent to the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K984090

Trade Name: Specialty 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (blue visibility tinted); Specialty 55 (methafilcon A) Soft (hydrophilic) Single Vision Contact Lens for Daily Wear (blue visibility tinted)

Regulatory Class: II

Product Code: 86 LPL

Dated: May 25, 1999

Received: May 27, 1999

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 Names:

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

Indications for Use:

The **Specialty 55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia 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 **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.

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Mya Smith
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K984090



(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 _____