

NOV 20 1996

**510 (k) Summary**

K 963488

**SUBMITTER:****Submitted on behalf of:**

**Company Name:** Specialty UltraVision, Inc.  
**Address:** 307 Orchard City Drive  
Campbell, CA 95008  
**Phone:** (408) 341-0700  
**Fax:** (408) 341-0717

**CONTACT PERSON:** Dr. Garold Edwards

**DATE SUMMARY PREPARED:** October 8, 1996

**TRADE NAME:** Specialty Progressive (methafilcon A) Soft (Hydrophilic) Multifocal Contact Lenses for Daily Wear (clear and tinted) and Specialty Choice<sup>AB</sup> (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lenses for Daily Wear (clear and tinted)

**COMMON NAME:** contact lens

**SUBSTANTIALLY EQUIVALENT TO:**

The Specialty Progressive (methafilcon A) Soft (Hydrophilic) Multifocal Contact Lenses for Daily Wear (clear and tinted) and Specialty Choice<sup>AB</sup> (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lenses for Daily Wear (clear and tinted) are equivalent to The LifeStyle FREQUENCY PROGRESSIVE (methafilcon A) Multifocal Soft (Hydrophilic) Contact Lens for Daily Wear (clear and tinted) currently marketed in the U.S and the LifeStyle 55 (methafilcon A) Single Vision Soft (Hydrophilic) Contact Lens for Daily Wear (clear and tinted) .

The Specialty Progressive (methafilcon A) Soft (Hydrophilic) Multifocal Contact Lenses for Daily Wear (clear and tinted) and Specialty Choice<sup>AB</sup> (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lenses for Daily Wear (clear and tinted) are substantially equivalent to the indication for use of the LifeStyle FREQUENCY PROGRESSIVE (methafilcon A) Multifocal Soft Contact Lens for Daily Wear (clear and tinted) marketed for use in the U.S. and the LifeStyle 55 (methafilcon A) Single Vision Soft Contact Lens for Daily Wear (clear and tinted). Specialty UltraVision, Inc. has received from the manufacturer of the predicate device all manufacturing information including; but not limited to, formulation, manufacturing processes (including polymerization conditions, tinting process, lens parameter tolerances, sterilization and packaging, quality control/quality assurance, established shelf life data, shelf life

protocol), and labeling; necessary to manufacture the devices, which are the subject of K963488. In addition, Specialty UltraVision, Inc. will manufacture these devices at the same manufacturing location as the predicate devices.

This lens is in Group 4 ionic, high water content polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the Specialty Progressive (methafilcon A) Soft (Hydrophilic) Multifocal Contact Lenses for Daily Wear (clear and tinted) and the Specialty Choice<sup>AB</sup> (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lenses for Daily Wear (clear and tinted) are equivalent to those of the LifeStyle FREQUENCY PROGRESSIVE (methafilcon A) Multifocal Soft Contact Lens for Daily Wear (clear and tinted) and the Lifestyle 55 (methafilcon a) Single Vision Soft Contact Lens for Daily Wear (clear and tinted).

#### **DESCRIPTION of the DEVICE:**

Soft contact lenses are hemispherical shells manufactured of polymerized material of HEMA and other monomeric ingredients crosslinked with EGDMA and other components which yield the appearance of lenses which are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves which conform to the shape of the radius of the cornea and center over the apex of the cornea to provide corrective refraction for functional conditions of the eye including myopia (nearsightedness), hyperopia (farsightedness) and astigmatism (multiple foci). Each lens provides corrective power which is to correspond to the refractive power of the eye to which it is being treated. Each lens is designed with a base curve on the internal side of the lens and an optical zone in the center of the lens which is generally of a diameter greater than 6mm. Secondary and tertiary curves as well as beveled edge configurations are built into the lens for the purpose of aiding in lens centration and comfort.

#### **INDICATIONS FOR USE:**

**Device Name: Specialty Progressive (methafilcon A) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear (clear and tinted)**

The Specialty Progressive (methafilcon A) Soft (Hydrophilic) Multifocal Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

Eyecare practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

**Device Name: Specialty Choice<sup>AB</sup> (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lenses for Daily Wear (clear and tinted)**

**The Specialty Choice<sup>AB</sup> (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.**

**Eyecare practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.**

**PARAMETERS AVAILABLE:**

**Specialty Progressive (methafilcon A)**

**Powers: +4.00 to -5.00D**  
**Center Thickness: .17 mm**  
**Diameter: 14.5 mm**  
**Base Curve: 8.4 mm (Minus lenses)**  
**8.6 mm (Plus Lenses)**

**Specialty Choice<sup>AB</sup> (methafilcon A)**

**Powers: +20.00 to -20.00D**  
**Center Thickness: .07 mm**  
**Diameter: 14.3 mm**  
**Base Curve: 8.60 mm**