510 (k) Summary for K963764

SUBMITTER:

JAN 30 1997

Submitted on behalf of:

Company Name:	Specialty UltraVision, Inc.
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DATE SUMMARY PREPARED: **December 13, 1996**

TRADE NAME: Specialty T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear

COMMON NAME: contact lens

SUBSTANTIALLY EQUIVALENT TO:

Specialty T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear is equivalent to Hydron Ultra T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear.

Specialty T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear is substantially equivalent to the indication for use of the Hydron Ultra T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear marketed for use in the US. This lens is in Group 3 ionic, low 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 T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear are equivalent to those of the Hydron Ultra T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear. The subject device utilizes the same formulation, manufacturing and sterilization processes, packaging, Quality Control/Quality Assurance Procedures and established shelf life as the predicate device, the Ocular Sciences/American Hydron Ultra T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear. A side by side comparison of the physical, optical and mechanical properties clearly establish the equivalency of these two contact lens products.

Comparison of physical/optical/mechanical properties of Ultra T lenses Vs. Specialty T Lenses

PARAMETER	Ocular Sciences/Am. Hydron Ultra T (ocufilcon A) Toric				Specialty T (ocufilcon A) Toric			
	units	mean	st. dev.	n	units	mean	st. dev.	n
refractive index		1.427	0.002	30		1.427	0.001	30
specific gravity		1.16*				1.16*		
water content	%	43.7	0.45	29	%	44.1	0.37	30
oxygen permeability								
Dk (@35 ° C)	Dk**	10.2	1.41	20	Dk**	11.3	1.43	20
light transmittance								
(@590 Nm)	%	98.31	1.27	10	%	98.51	0.82	10
Mechanical Properties								
modulus	N/mm^2	0.37	0.048	21	N/mm^2	0.36	0.051	18
tensile strength	N/mm^2	0.37	0.048	21	N/mm^2	0.34	0.136	18
Elongation @ break	%	148	53	21	%	165	69	18

Notes:

All products are produced by a spin casting process, consequently, only hydrated lenses are available for testing.

* Measured using 10 lenses for a single measurement. The range was 1.15 to 1.17

** $(cm^2 \times ml\ O_2) / (sec \times ml \times mmHg) \times 10^{-11}$

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 7mm. 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. The lens is manufactured by spin casting and has a front toric surface which is determined by the shape of the mold to provide consistent optics. Orientation marks are molded into the front surface as part ofd the spin casting process. The lens is a prism ballasted, non-truncated toric, with an inferior slab off to help maintain patient comfort. Axis stabilization is achieved by the action of the lids on the differential thickness profile (prism) of the lens squeezing the thicker portion of the lens to the bottom.

INDICATIONS FOR USE:

Device Name: ***Specialty T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear***

The **Specialty T (ocufilcon A) Soft (hydrophilic) Toric Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.50 diopters.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning, disinfection and replacement. The lens may be disinfected using either a heat, chemical or hydrogen peroxide disinfection system.

PARAMETERS AVAILABLE:

Specialty T(ocufilcon A)

Powers:	plano to -6.00 diopters (in 0.25 diopter steps)
Cylinder Powers:	-1.00, -1.50, -2.00 diopters
Axis	10° to 180° in 10° steps
Center Thickness:	0.15 mm
Diameter:	14.5 mm
Base Curve:	Varies with power