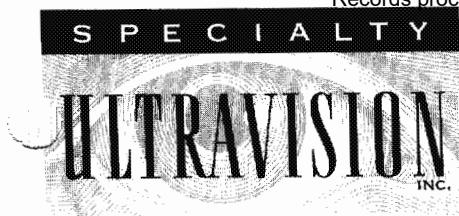


SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530. Released by CDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

V. 510(k) Summary

In response to the requirements of the Safe Medical Devices Act of 1990, a summary of the safety and effectiveness information upon which the substantial equivalence determination is based is included in this submission.

CONFIDENTIAL - This document contains Specialty UltraVision, Inc. proprietary information and shall not be duplicated, disclosed to others, or used for purposes other than to carry out the intent for which this material is delivered unless written consent is first obtained from Specialty UltraVision, Inc.



510(k) Summary

Submitter Information:

Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, CA 95008

Contact Person: Debbie McIntire
Manager, Clinical and Regulatory Affairs

Telephone: (408) 341-0700
Fax: (408) 341-0717

Date Prepared: December 5, 2000

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens
Trade/Proprietary Names: Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens
for Daily Wear
Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact
Lens for Daily Wear
Classification Name: Soft (Hydrophilic) Contact Lens
Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The IGEL 56 UV (hefilcon C) Soft (hydrophilic) Contact Lens was selected as the predicate device.

The Specialty 56 UV devices and IGEL 56 UV devices are manufactured in the same facility, under the same quality system, using the same formulation, molding, tinting, packaging and sterilization processes. The Specialty 56 UV lenses contain the same UV blocking agent as the IGEL 56 UV lenses, and the manufacturing process for adding the UV blocking agent is the same.

Description of Devices:

The Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens is a single vision lens. The Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens is a lens for the correction of astigmatism associated with either near-sightedness (myopia) or far-sightedness (hyperopia) or a combination of both. The lens is able to correct astigmatism up to 7.00 diopters. The Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses are flexible, hemispherical, transparent shells of the following dimensions:

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SUITE 100
CAMPBELL, CA 95008
TEL: 888-29-ULTRA
408-341-0700
FAX: 408-341-0717

3300, 2^EME RUE
ST-HUBERT, QUÉBEC
CANADA J3Y 8Y7
TEL: 800-668-9251
450-445-8082
FAX: 450-445-1893

Single Vision Lens:

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Powers: -20.00 to +20.00

Toric Lens

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Sphere: -20.00 to +20.00
- Cylinder: Up to 7.00 D
- Axis: 1 to 180°
- Stabilizing Mechanism: Dynamic Stabilizing Sectors

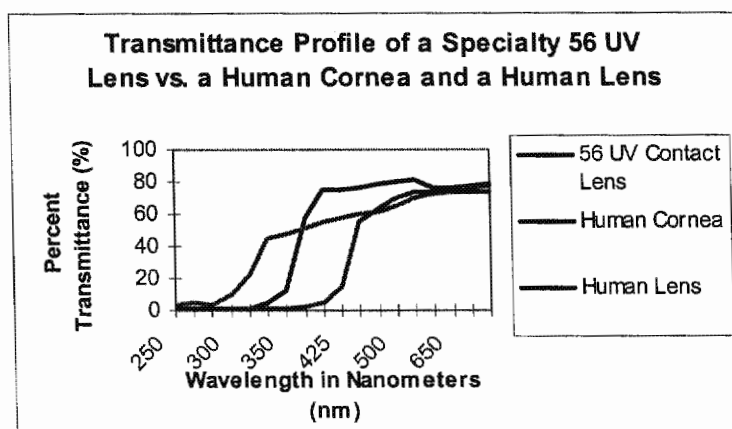
The lens material (hefilcon C) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-Vinyl pyrrolidinone and contains the UV absorbing compound 2-hydroxy-4-acrylethoxy benzophenone. The lens is swollen to equilibrium state in a sterile saline solution, and contains 44% hefilcon C with 56% water by weight when fully hydrated. The blue tinted lens contains D&C Green 6. The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of the lenses.

The physical properties of the lens are:

- Specific gravity: 1.16
- Refractive Index: 1.41, fully hydrated
- Light Transmittance : 94.5% clear (untinted)
90.3% (blue handling tint)
- UV Transmittance: < 10%
- Surface Character: hydrophilic
- Water Content: 56% by weight in normal saline
- Oxygen Permeability (Dk)* : 21×10^{-11} (cm²/sec) (ml O₂ /ml x mm Hg) at 35°C

*[Fatt Method for determination of oxygen permeability]

The following graph compares the UV transmittance curve of the **Specialty 56 UV** (hefilcon C) Soft (Hydrophilic) Contact Lens (-7.00 D) to that of the human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig 5.



Comparison to Predicate Device

PARAMETER	<i>Specialty 56 UV, and Specialty 56 UV Toric Hydrophilic Contact Lenses for Daily Wear</i>	<i>IGEL 56 UV Soft (hydrophilic) Contact Lens for Daily Wear</i>
Submission number		K984523
Material	hefilcon C	hefilcon C
Material classification	Hydrophilic Lens Group 2	Hydrophilic Lens Group 2
indication for use	myopia, hyperopia, and astigmatism	myopia, hyperopia, and astigmatism
water content	56%	56%
Visible light transmittance	90.3%	90.3%
UV transmittance	< 10%	< 10%
Dk (35° C)	21×10^{-11}	21×10^{-11}
Powers	+20.00 to -20.00 Diopters	+6.00 to -12.00 Diopters
Color	blue visibility D&C Green No. 6	blue visibility, D&C Green No. 6
refractive index	1.41	1.41
specific gravity	1.16	1.16
Method of manufacture	Molded	Molded

Indications for Use:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the single vision lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfection systems only.

Description of Safety and Substantial Equivalence:

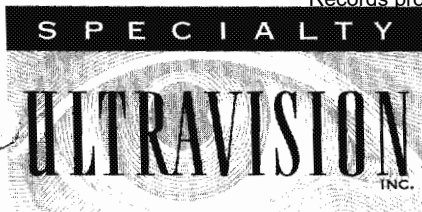
A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Specialty 56 UV and the Specialty 56 UV Toric (hefilcon C) Contact Lenses for Daily Wear. Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. Extraction and analysis of the lenses showed no detectable extractables. The Specialty 56 UV lenses passed the requirements of sterility and stability testing.

A 4-week clinical trial on 37 subjects wearing lenses on a daily wear basis showed that the product is substantially equivalent to other lenses available on the market. No adverse events, significant slit lamp findings, or significant decreases in visual acuity were reported in the study. There was a low incidence of symptoms, problems and complaints, and study discontinuations. Lens wear time was essentially unchanged over the study period, and the lenses remained clinically clean during the study.

Conclusion:

Information submitted in the 510(k) establishes that the Specialty 56 UV and the Specialty 56 UV Toric (hefilcon C) Contact Lenses are comparable to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.

K 003789



December 5, 2000

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

SUBJECT:

Premarket 510(k) Notification:

Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear
and Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for
Daily Wear

Dear Sir or Madam:

Pursuant to the May 12, 1994 Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, Specialty UltraVision, Inc. is hereby submitting the required copies of a premarket notification 510(k) for the Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear and the Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear.

These lenses are substantially equivalent to the IGEL 56 UV (hefilcon C) Soft (hydrophilic) Contact Lens for Daily Wear which was cleared on February 16, 1999 under K984523. The Specialty 56 UV lenses will be manufactured and sterilized at the same manufacturing site, using the identical formulation, molding, sterilization, and packaging processes as the predicate device. The only difference between the IGEL 56 UV lenses and the Specialty 56 UV lenses is the lens name.

The purpose of this premarket notification is to obtain clearance for Specialty UltraVision, Inc. to market the Specialty 56 UV lenses in the United States. This submission contains a Letter of Reference from IGEL Vision Care Pte., Ltd., granting permission for FDA to reference all manufacturing, biocompatibility, clinical and microbiology information contained in K984523 for the purpose of determining substantial equivalence. In addition, a letter confirming that IGEL Vision Care Pte Ltd. has provided all manufacturing and labeling information to Specialty UltraVision, Inc. can also be found in this submission. This submission also contains labeling for the Specialty 56 UV lenses which was developed to duplicate the approved labeling for the predicate devices, and was designed to meet the guidelines as set forth in the May, 1994 Premarket Notification 510(k) Guidance Document for Class II Contact Lenses.

In response to the requirements of the Safe Medical Devices Act of 1990, a summary of the safety and effectiveness information upon which the substantial equivalence determination is based is included in this submission. This 510(k) notification is being submitted by Specialty UltraVision, Inc., 307 Orchard City Drive, Suite 100, Campbell, CA 95008. If you should have any questions regarding this document, please contact me at (408) 341-0700, or by fax at 408-341-0717.

Sincerely,

(b)(6)

Debbie McIntire
Manager, Clinical and Regulatory Affairs

307 ORCHARD CITY DRIVE
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CANADA J3Y 8Y7
TEL: 800-668-9251
450-445-9082
FAX: 450-445-1893

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PROFESSIONAL FITTING AND INFORMATION GUIDE

**Specialty 56 UV (hefilcon C) Soft (Hydrophilic)
Contact Lens for Daily Wear**

**Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic)
Contact Lens for Daily Wear**

CAUTION: Federal Law Prohibits Dispensing Without a Prescription

PRODUCT DESCRIPTION:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** is a single vision lens. The **Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens** is a lens for the correction of astigmatism associated with either near-sightedness (myopia) or far-sightedness (hyperopia) or a combination of both. The lens is able to correct astigmatism up to 7.00 diopters. The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are flexible, hemispherical, transparent shells of the following dimensions:

Single Vision Lens:

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Powers: -20.00 to +20.00

Toric Lens:

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Sphere: -20.00 to +20.00
- Cylinder: Up to 7.00 D
- Axis: 1 to 180°
- Stabilizing Mechanism: Dynamic Stabilizing Sectors

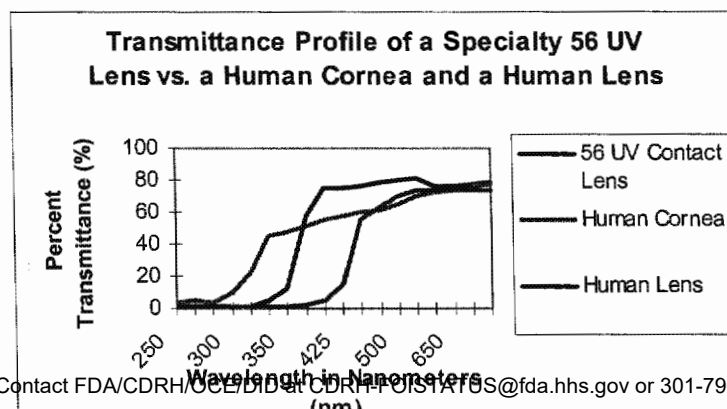
The lens material (hefilcon C) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-Vinyl pyrrolidinone and contains the UV absorbing compound 2-hydroxy-4-acrylethoxy benzophenone. The lens is swollen to equilibrium state in a sterile buffered saline solution, and contains 44% hefilcon C with 56% water by weight when fully hydrated. The blue tinted lens contains D&C Green No. 6. The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of the lenses.

The physical properties of the lens are:

- Specific gravity: 1.16
- Refractive Index: 1.41, fully hydrated
- Light Transmittance : 94.5% clear (untinted)
90.3% (blue handling tint)
- UV Transmittance: < 10%
- Surface Character: hydrophilic
- Water Content: 56% by weight in normal saline
- Oxygen Permeability (Dk)* : 21×10^{-11} (cm²/sec) (ml O₂ /ml x mm Hg) at 35°C

*[Fatt Method for determination of oxygen permeability]

The following graph compares the UV transmittance curve of the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** (-7.00 D) to that of the human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig 5.



LENS PARAMETERS AVAILABLE:

Single Vision Lens

- Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Powers: -20.00 to +20.00

Toric Lens

- Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.15mm
- Optic zone: 8.45mm
- Base Curve: 8.00mm – 9.00mm
- Powers: -20.00 to +20.00
- Cylinder: up to 7.00 D
- Axis: 1 to 180°

ACTIONS:

When placed on the human cornea, the hydrated lens acts as a corrective refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays onto the retina.

INDICATIONS (USES):

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism, for the single vision lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfection systems only.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS:

See the Package Insert (attached) for Contraindications, Warnings, Precautions and Adverse Reactions.

SELECTION OF PATIENTS:

Patients selected to wear the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** or the **Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens** should be chosen for their motivation to wear contact lenses, general health and cooperation. The eyecare practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to wearing success.

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** may mask up to 1.50 D of corneal astigmatism. The **Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens** should be used for patients with more than 0.50 D of corneal astigmatism.

FITTING GUIDELINES

1. Prefitting Examination:

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear contact lenses (considering patient hygiene and mental and physical state).
- Consider the needs and motivations of the patient for contact lens wear.
- Make ocular measurements for initial contact lens parameter selection.
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

1. Initial Lens Power Selection

Initial power should be selected according to the measured refraction.

2. Initial Lens Diameter Selection

Initial diameter should be selected according to lens movement and availability of diameter(s).

3. Initial Lens Base Curve Selection

Initial base curve should be selected according to lens movement and availability of base curves(s).

4. Initial Lens Evaluation

The unique "tangential" back surface edge lift design allows the lens to have a very thin cosmetically acceptable edge and a greater latitude of fit.

The **Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens** has a diamond-cut orientation mark at the 6 o'clock position (270 degrees) to allow accurate axis evaluation.

ASSESSMENT OF FIT:

Apply the lenses onto the eyes and allow at least 20 minutes to elapse for the lenses to stabilize before the final fitting assessment.

OPTIMAL FIT CRITERIA

Comfort	No discomfort in the direction of gaze.
Centration	Good limbal coverage. No decentration in primary position except for slight lag.
Movement	Approximately 1.0 to 1.5 mm on upward gaze. No excursion with normal eye movement.
Visual Acuity	Good, stable vision.
Push-up test	Small lens movement of the push-up test is the most important indicator of the lens mobility.
Scleral Indentation	No conjunctival blanching or scleral indentation detected.
Toric Lens:	
Lens Orientation	Diamond-cut marking at 6 o'clock position (270°)

FINAL LENS SELECTION:

If an over-refraction is required to determine the final prescription of the required lens, it should be ensured that this over-refraction is performed over a correctly fitting lens. If the power of this over-refraction is above ± 3.75 D an allowance must be made for this in the prescription.

FOLLOW-UP CARE:

- a. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 1 hour continuously worn to the examining practitioner's office, and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- c. With the lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- d. After lens removal, conduct a thorough biomicroscopic examination.
 1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
 3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

IN OFFICE CARE OF TRIAL LENSES:

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

Each contact lens is shipped sterile in a blister pack with buffered saline solution. Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected. Any chemical disinfecting solution recommended for use with soft hydrophilic contact lenses may be used, according to the solution manufacturer's instructions.

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to follow carefully the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

DAILY WEAR MAXIMUM WEARING TIME

Day	Continuous Hours
1	4
2	6
3	8
4	10
5	12
6	14
7	All waking hours

Studies have not been completed to show that the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** is safe to wear during sleep. Do not wear the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** while sleeping.

***WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.**

Adherence to a gradual increase in wearing time is very important. Some wearing flexibility as necessitated by the patient's daily routine is permissible after the first seven days of lens wear. The suggested wearing time may be broken into two periods, separated by a one or two hour rest period of no lens wear.

CLINICAL ASSESSMENT:

All six fitting points should be checked when lens is well settled.

Criteria for a Well Fitted Lens**Comfort**

No discomfort in any direction of gaze.

Centration

Limbus to limbus coverage. No decentration in primary position of gaze except perhaps for slight lag.

Movement

Post blink movement from 1.50 to 2.00 mm

Characteristics of a Tight (Steep) Fitting Lens**Comfort**

Tight sensation but no apparent discomfort

Centration

Centered and no movement

Movement

Very little movement even with violent eye motion. A slightly steep-fitting lens will cause blanching of the conjunctival blood vessels under the periphery of the lens.

Characteristics of a Loose (Flat) Fitting Lens**Comfort**

Excessive lacrimation and some conjunctival injection.

Centration

Liable to lag in primary position of gaze.

Movement

Unacceptable post blink movement; lag on upward gaze or lag on lateral excursions. Lens liable to displace off cornea particularly into upper fornix or nasal region. Small air bubbles under edge.

Retinoscopic reflex

Crisp before and after blink.

Retinoscopic reflex

Central and peripheral distortion fluctuating between blinks. Steep-fitting lens may cause a central air bubble.

Retinoscopic reflex

Crisp in center with a peripheral distortion before next blink.

Visual Acuity and Over**Refraction**

Good, non-fluctuating. Clear and easily defined.

Visual Acuity and Over**Refraction**

Very difficult. Variable and inconsistent.

Visual Acuity and Over**Refraction**

Difficult due to fluctuation in lens shape and position.

Keratometry – with a lens in place

Should produce little or no distortion at any stage of a blink.

Keratometry – with a lens in place

Considerable distortion on blinking even in the lid position. Mires are blurred or doubled.

Keratometry – with a lens in place

Fluctuation with the blink. Mires are clear but swim.

MONOVISION FITTING GUIDELINES**1. Patient Selection****A. Monovision Needs Assessment**

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one diopter) in one eye may not be a good candidate for monovision with the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens**.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for activities such as:

- (1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- (2) driving automobiles (e.g. driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised not to drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example: A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left corrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in this guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last a brief

minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the instructions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions.

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
- **The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Patient's Instructions for the Specialty 56 UV (hefilcon C) Contact Lens.**

HANDLING OF SPECIALTY 56 UV (HEFILCON C) SOFT (HYDROPHILIC) CONTACT LENSES:

These lenses may be handled as any soft (hydrophilic) contact lenses.

PATIENT LENS CARE DIRECTIONS

See PACKAGE INSERT for PATIENT LENS CARE DIRECTIONS.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:

See PACKAGE INSERT for LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE.

LENS CASE CLEANING AND MAINTENANCE:

See PACKAGE INSERT for LENS CASE CLEANING AND MAINTENANCE.

CARE FOR A STICKING (NON-MOVING) LENS:

See PACKAGE INSERT for CARE FOR A STICKING (NON MOVING) LENS.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** should be reported to:

Specialty UltraVision, Inc.
307 Orchard City Drive Suite 100
Campbell, CA 95008
1-888-29ULTRA

HOW SUPPLIED:

Each lens is supplied sterile in blister packs containing buffered saline solution. The blister pack is marked with the base curve, dioptric power, diameter, color, manufacturing lot number, and expiration date of the lens. The toric lens blister pack also contains the cylinder and axis.

PACKAGE INSERT ATTACHED

Issued November, 2000



FEB 21 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Debbie McIntire
Manager, Clinical and Regulatory Affairs
Specialty Ultravision, Inc.
307 Orchard City Drive
Suite 100
Campbell, CA 95008

Re: K003789

Trade Name: Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily
Wear and Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact
Lens for Daily Wear.

Regulatory Class: II

Product Code: 86 LPL

Dated: December 5, 2000

Received: December 8, 2000

Dear Ms. McIntire:

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.

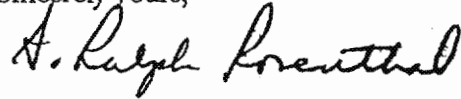
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Debbie McIntire

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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS STATEMENT

Device Names:

Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Indications for Use:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfecting systems only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use

Daniel W. C. Brown, Ph.D. *4/5/18*

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K003789

Memorandum

From: Reviewer(s) - Name(s) Daniel W. C. Brown, Ph.D. *DWCB*Subject: 510(k) Number *1K 003789*

To: The Record - It is my recommendation that the subject 510(k) Notification:

☐ Refused to accept.☐ Requires additional information (other than refuse to accept).☒ Is substantially equivalent to marketed devices.☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

☐ YES☒ NO☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.) n/a

Is this device subject to Postmarket Surveillance?

☐ YES☒ NO

Is this device subject to the Tracking Regulation?

☐ YES☒ NO

Was clinical data necessary to support the review of this 510(k)?

☐ YES☒ NO

Is this a prescription device?

☒ YES☐ NO

Was this 510(k) reviewed by a Third Party?

☐ YES☒ NO

Special 510(k)?

☐ YES☒ NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers

☐ YES☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)☒ A 510(k) summary OR ☐ A 510(k) statement☐ The required certification and summary for class III devices n/a☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin

☐ YES☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

*EPL 5985**II**886.5925**86*

Review:

(Branch Chief)

Lariva

(Branch Code)

USDB

(Date)

1/31/01 2/16/01

Final Review:

(Division Director)

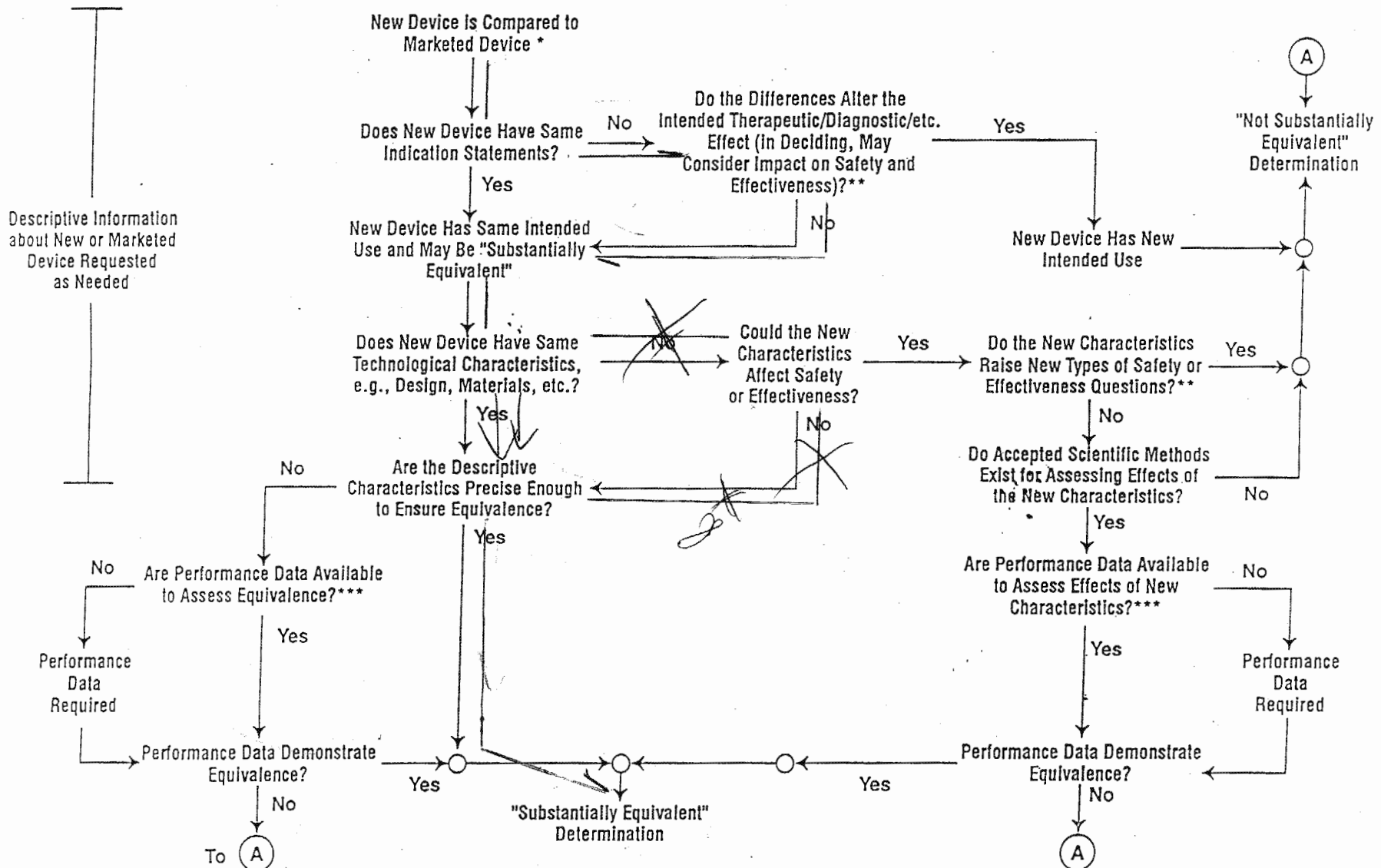
David M. Myrle for DOED

(Date)

2/21/01

Revised: 8/17/99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and Proposed (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But

*** Data In the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K)
BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH
EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 003789

Reviewer: Daniel W.C. Brown, Ph.D.

Division/Branch: DOED/VEDB, Vitreoretinal and Extraocular Devices Branch

Device Name: Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens and
Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact
Lens for Daily Wear

Product To Which Compared (510(K) Number If Known): K984523 IGEL 56 UV Soft
(hefilcon C) Contact Lens for Daily Wear

	YES	NO	
1. Is Product A Device	x		If NO = Stop
2. Is Device Subject To 510(k)?	x		If NO = Stop
3. Same Indication Statement?		x	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		x	If YES = Stop NE
5. Same Technological Characteristics?	x		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	x		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

(b)(5)

(b)(5)

**IGEL® 56 UV (hefilcon C) SOFT (hydrophilic) CONTACT LENS
 FOR DAILY WEAR**

NOTE: This summary is identical to that provided for K974837, except for the name change, the inclusion of the UV absorbing compound in the material description, and the inclusion of the UV transmittance in the physical properties. Labeling changes include the name change and the inclusion of the appropriate UV transmittance graphs and warnings.

1. Submitted by: Igel Vision Care PTE, Ltd
 139 Joo Seng Road, #06-01
 ATD Centre
 Singapore 368362

 Contact: John M. Szabocsik, Ph.D.
 Official agent Szabocsik and Associates
 203 N. Wabash, Ste 1200
 Chicago, IL 60601
 (312) 553-0828
2. Date prepared: February 9, 1999
3. Device:
 Common Name Igel® 56 UV (hefilcon C) Soft (hydrophilic)
 Contact Lens
 Trade Name Igel® 56 UV (hefilcon C) Soft (hydrophilic)
 Contact Lens
4. Classification Class II (Performance Standards)
 21 CFR 886.5925
 Soft (hydrophilic) contact lens
5. Substantial
 equivalence This product is substantially
 equivalent to other currently marketed
 hefilcon lenses, such as Gold Medalist Toric
 lenses
6. Device
 description The Igel® 56 UV (hefilcon C) soft
 (hydrophilic) contact lens is a
 hemispherical, flexible transparent shell of
 the following dimensions:
 Chord diameter: 14.2mm
 Center thickness: 0.09mm (at -3.00 D)
 Optic Zone: variable optic zone with
 power
 Base Curve: 8.60mm
 Power: -0.50D to -8.00D (in
 0.25D steps); -8.50D to
 -12.00D (in 0.50D steps);
 +0.50D to +6.00D (in
 0.25D steps)

K984523, FOI Summary, Pg 1

The lens material (hefilcon C) is a copolymer of 2 hydroxyethylmethacrylate and N-Vinyl pyrrolidone, and contains a UV absorbing compound. The blue tinted lens also contains D&C Green #6. When fully hydrated, the lens is 56% water by weight.

7. Intended use

The Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lens for Daily Wear is available as a spherical lens for the correction of near-sightedness (myopia) and farsightedness (hyperopia). A toric version of the same lens is able to correct for astigmatism from 0.50D to 7.00D.

8. Comparison to predicate devices: see following table

SUBSTANTIAL EQUIVALENCE

Material	Igel® 56 UV hefilcon C	Gold Medalist™ Toric hefilcon C
Description	random copolymer of 2-hydroxyethyl methacrylate and N- vinyl-2-pyrrolidone	random copolymer of 2-hydroxyethyl methacrylate and N- vinyl-pyrrolidone
Water Content	56% in buffered saline	57% in normal saline
Specific Gravity	1.16	1.1
Refractive Index	1.41 (hydrated)	1.41
Light Transmittance (visible)	94.5% (clear) 90.3% (blue handling tint)	at least 90%
UV Transmittance	<10% (-7.00D, thinnest lens)	not applicable
Oxygen permeability	21×10^{-11} (cm/sec) (ml O ₂ /mlxmm Hg) Measured at 35°C (revised Fatt method).	17×10^{-11} (cm/sec) (ml O ₂ /mlxmm Hg) Measured at 35°C (revised Fatt method).

Material	Igel® 56 UV hefilcon C	Gold Medalist™ Toric hefilcon C
Actions	When placed on the human cornea, the hydrated Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lens acts as a corrective refracting medium to focus light rays on the retina.	In its hydrated state, the Bausch & Lomb Gold Medalist™ Toric (hefilcon C) Visibility Tinted Contact Lens when placed on the cornea acts as a corrective refracting medium to focus light rays on the retina.
Chord Diameter*	14.2mm	12.0 to 18.0mm
Center thickness*	0.09mm (at -3.00D)	0.02mm to 1.0mm
Base Curve*	8.6mm	8.3mm to 9.2mm
Powers (Spherical) (Cylinder)	-12.00 to +6.00D up to 7.00D	+20.00 to -20.00D up to 5.00D
Optical Zone	vary with power	

* Igel® 56 UV parameters for spheres only provided in this table

Introduction

The Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lens is a spherical lens for the correction of near-sightedness (myopia) and farsightedness (hyperopia). A toric version of the same lens is able to correct for astigmatism from 0.50D to 7.00D.

Contained in the submission are comparisons of the product to the predicate device, information on the chemistry and manufacturing, results of toxicological and microbiological tests, and the report of a clinical trial of 37 subjects, who have used the product over a period of four weeks.

I. Chemistry and Manufacturing

The lens material (hefilcon C) is a copolymer of 2 hydroxethylmethacrylate and N-Vinyl pyrrolidinone and contains a UV absorbing compound. The blue tinted lens also contains D&C Green #6. When fully hydrated, the lens is 56% water by weight.

Records processed under FOIA Request 2024-0580, Release by CDRH, 105-163021
The Igel® 56 UV (hefilcon C) Soft (hydrophilic)

Spherical Contact Lens is a hemispherical, flexible transparent shell of the following dimensions:

Chord diameter:	14.2mm
Center thickness:	0.09mm (at -3.00 D)
Optic Zone:	variable optic zone with power
Base Curve:	8.60mm
Power:	-0.50D to -8.00D (in 0.25D steps) -8.50D to -12.00D (in 0.50D steps) +0.50D to +6.00D (in 0.25D steps)

The Igel® 56 UV (hefilcon C) Soft (hydrophilic) Toric Contact Lens has the following characteristics:

Chord diameter:	14.6mm
Center thickness:	0.15mm
Optic Zone:	8.45mm
Base Curve:	8.70mm
Sphere:	Plano to -8.00 D (in 0.25 D steps) Plano to +6.00 D (in 0.25 D steps)
Cylinder:	up to 7.00 D
Axis:	80, 90, 100, 160, 170, 180, 10 & 20
Stabilizing Mechanism:	Dynamic Stabilizing Sectors

The physical properties of the lens (sphere or toric) are as follows:

Specific Gravity:	1.16
Refractive index:	1.41 (hydrated)
Light transmission:	94.5% (clear) 90.3% (blue handling tint)
UV transmittance	<10% (-7.00D, thinnest lens)
Surface character:	hydrophilic
Water content:	56% weight in normal buffered saline
Tensile strength:	2.85 kg/cm ²
Elongation:	72%
Modulus of Elasticity:	5.20 kg/cm ²
Oxygen permeability:	D _k : 21x10 ⁻¹¹ (cm/sec)(ml O ₂ /mlxmm Hg) Measured at 35°C (revised Fatt method).

A. Extractables

Samples of lenses were extracted in saline, and the extracts analyzed by high performance liquid chromatography to determine if any monomers were extracted from the material. There were no extractables detected.

B. Process Validation

The manufacturing process for this cast-moulded lens was shown to be valid both for lens quality and sterility.

II. Toxicology

The toxicological testing is summarized below. The lens material was shown to be non-toxic in all tests.

A. Agar Overlay Cytotoxicity:

Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lenses were tested in a direct contact cytotoxicity assay. The lenses were noncytotoxic.

B. Systemic toxicity:

Saline and cottonseed oil extracts of Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lenses were evaluated for systemic toxicity by intravenous (iv, saline) and intraperitoneal (ip, cottonseed oil) injection in healthy mice, both at 50ml/kg body weight. The animals were observed over a 72 hour period, and showed no difference from control animals. The lenses passed the test requirements, that there be no difference between the response of test and control animals.

C. Acute Ocular irritation:

Saline and cottonseed oil extracts of Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lenses were evaluated for ocular irritation by instillation into the inferior ocular cul-de-sac of rabbits. The eyes were examined over a 72 hour period and showed no irritation.

III. Microbiology**A. Sterility**

The Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lenses passed the requirements of sterility testing.

B. Stability

Stability data, including package integrity, lens parameters (diameter, base curve, power, optics, appearance), stability of tint and UV transmittance, and sterility will be collected according to protocol. Product will not be marketed until data supporting the expiration dating are available.

K984523, FOI Summary, Pg 5

IV. Clinical Studies Records processed under FOIA Request 2024-2530; Released by CDRH on 05-16-2024

A clinical trial of 4 weeks usage of the Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lenses by 37 subjects, wearing lenses on a daily wear schedule, showed that the product is substantially equivalent to other lenses available on the market. The clinical summary follows.

The study was conducted over 1 month of wear, subjects being seen initially, and after 1, 2 and 4 weeks. The study was initiated July 11, 1997 and completed August 19, 1997.

Two (2) investigators enrolled a total of 37 test subjects. The age range of the test population was from 17 to 61, with 26 (70.3%) females and 11 (29.7%) males.

Of the 37 subjects, 35 (94.6%) completed 1 month of wear, and 2 (5.4%) discontinued.

FINDINGS

a. SAFETY:

(1) Adverse Reactions

The FDA regulations for medical devices (21 CFR 812.3) define an unanticipated adverse device effect as:

"any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that related to the rights, safety or welfare of the subject"

There were no adverse events during this study.

(2) Slit Lamp Findings:

A positive slit lamp finding is a routinely occurring complication that can be expected with or without the presence of contact lenses. The degree of severity may range from very slight, representing no medical concern, to serious, requiring medical treatment.

Table B shows the incidence of slit lamp findings in the investigational group at the initial and final visits.

The slit lamp finding listed as "Other" at the initial visit was an old healed neovascularization.

Records processed under FOIA Request 2024-2537, TABLE B, by CDRH on 05-16-2024

FINDINGS**INCIDENCE OF SLIT LAMP FINDINGS**

PINDING	INITIAL	FINAL
NO FINDINGS^a	51.4	58.6
EDEMA^b	0.0	0.0
NEOVASCULAR	18.9	11.4
STAINING	5.4	1.4
INJECTION	0.0	0.0
TARSAL	48.6	40.0
OTHER	1.4	0.0

^a Percent of eyes examined with no findings, regularly scheduled visits only

^b Percent of eyes with finding, regularly scheduled visits only

The Trend Analysis Profile showed no reports of positive slit lamp findings greater than Grade 2.

(3) Symptoms, Problems and Complaints:

Symptoms, problems and complaints were reported by the investigators at each visit. Lens awareness, handling problems and reading problems were the most frequently reported symptoms among all subjects. Table C shows the overall incidence of these selected symptoms.

The "other" symptoms were dryness (reported by 2 subjects); torn lenses reported by 1 subject.

TABLE C**SELECTED SYMPTOMS, PROBLEMS AND COMPLAINTS**

SYMPTOM	Incidence
NONE^a	62.6%
LENS AWARENESS^b	14.5%
HANDLING PROBLEMS	8.4%
READING PROBLEMS	7.9%

^a Percent of eyes examined with no findings, regularly scheduled visits only

^b Percent of eyes with finding, regularly scheduled visits only

(4) Discontinuations:

Throughout the study, 2 subjects (5.4%) were discontinued.

B. EFFICACY:**(1) Visual Acuity:**

All but 2 eyes had a final visual acuity within 1 line of the initial best corrected acuity. The appropriate acuity was achieved by all eyes, since those two eyes were in subjects fit for monovision.

(2) Wear Time:

Wear time remained essentially unchanged over the one month of the study, indicating continuing comfort and cleanliness with the investigational solution.

(3) Lens Cleanliness:

Lenses were evaluated at each visit, according to a modified Rudko classification. Overall, the reports of the Rudko evaluation showed that 91% of test lenses were clinically clean during the study. (Rudko grades I and II are considered clinically clean.)

These results confirm that the Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lenses are effective in the correction of myopia and hyperopia.

Gender Comparisons:

The overall test population was 70.3% female, 29.7% male, and the visit distribution over the study was 69% female, 31% male. Overall, there were no slit lamp findings at 58% of the visits; among females, at 63%, among males at 47% of the visits. There were no symptoms reported at 61% of the visits; among females, no symptoms were reported at 64%, among males, at 56%. There is no significant difference in the findings, and no further analysis was warranted. Because of the small sample size, the gender analysis may be statistically irrelevant.

OVERALL CONCLUSION OF THE CLINICAL STUDY:

The data of the clinical trial confirm that the Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lenses are substantially equivalent to currently marketed lenses in safety and efficacy.

LABELING

The name of the lens has been changed from the Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lens to the Igel® 56 UV (hefilcon C) Soft (hydrophilic) Contact Lens. The appropriate UV transmittance graphs, warnings, and note have been included in the labeling.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 1999

Igel Vision Care PTE, Ltd.
c/o John M. Szabocsik, Ph.D.
Szabocsik and Associates
203 N. Wabash Avenue, Suite 1200
Chicago, IL 60601

Re: K984523

Trade Name: IGEL ® 56 UV (hefilcon C) soft (hydrophilic) Contact Lens for Daily Wear (clear or visitint, Spherical and Toric, cast molded)

Regulatory Class: II

Product Code: 86 LPL

Dated: December 14, 1998

Received: December 21, 1998

Dear Dr. Szabocsik:

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.

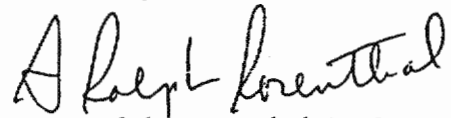
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Dr. John M. Szabocsik, Ph.D.

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

510(k) NUMBER (IF KNOWN) _____

DEVICE NAME Igel®56 UV (hefilcon C) Soft
(hydrophilic) Contact Lens

INDICATIONS FOR USE

The Igel®56 UV (hefilcon C) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism, for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfecting systems only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per

OR Over-The-Counter-Use _____

21 CFR 801.109)

(Optional Format 1-2-96)

5 1 0
(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K984523

Igel-7

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name: Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens and Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for						K) 003789														
Submitter (Company): Daily Wear SPECIALTY OULTRAVISION, INC.																				
Items which should be included (circle missing & needed information)	SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING													
	YES	NO	YES	NO	YES	NO														
1. Cover Letter clearly identifies Submission as:																				
a) "Special 510(k): Device Modification"																				
b) "Abbreviated 510(k)"																				
c) Traditional 510(k)																				
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS																				
✓ IF ITEM IS NEEDED																				
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)																				
<table border="1"> <tr> <td colspan="2">SPECIALS</td> <td colspan="2">ABBREVIATED</td> <td colspan="2">TRADITIONAL</td> <td rowspan="2">AND IS MISSING</td> </tr> <tr> <td>YES</td> <td>NO</td> <td>YES</td> <td>NO</td> <td>YES</td> <td>NO</td> </tr> </table>								SPECIALS		ABBREVIATED		TRADITIONAL		AND IS MISSING	YES	NO	YES	NO	YES	NO
SPECIALS		ABBREVIATED		TRADITIONAL		AND IS MISSING														
YES	NO	YES	NO	YES	NO															
a) trade name, classification name, establishment registration number, device class					x															
b) OR a statement that the device is not yet classified	FDA may be a classification request; see coordinator																			
c) identification of legally marketed equivalent device	NA				x															
d) compliance with Section 514 - performance standards	NA				n/a															
e) address of manufacturer					x															
f) Truthful and Accurate Statement					x															
g) Indications for Use enclosure					x															
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					x															
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)					n/a															
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					x															
k) Proposed Labeling:					x															
i) package labeling (user info)					x															
ii) statement of intended use					x															
iii) advertisements or promotional materials					n/a															
i) MRI compatibility (if claimed)					"															
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					x															
i) Labeling					x															
ii) intended use					x															
iii) physical characteristics					x															
iv) anatomical sites of use					x															
v) performance (bench, animal, clinical) testing	NA				x															
vi) safety characteristics	NA				x															
m) If kit, kit certification					n/a															
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE																				
a) Name & 510(k) number of legally marketed (unmodified) predicate device																				
b) STATEMENT - INTENDED USE AND INDICATIONS					* If no - STOP not a special															

FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*		Released by CDRH on 05-16-2024	
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special
d) Design Control Activities Summary			
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis			
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied			
iii) A declaration of conformity with design controls. The declaration of conformity should include:			
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met			
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable							

requirements, deviations, or other information	2024-2530; Released by CDRH on 05-16-2024
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed	
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device	
v) A specification of any deviations from each applicable standard that were applied	
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference	
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations	
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards	

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							x
i) component & material							x
ii) identify patient-contacting materials							x
iii) biocompatibility of final sterilized product							x
b) Sterilization and expiration dating information:							x
i) sterilization method							x
ii) SAL							x
iii) packaging							x
iv) specify pyrogen free							n/a
v) ETO residues							"
vi) radiation dose							"
c) Software validation & verification:							"
i) hazard analysis							"
ii) level of concern							"
iii) development documentation							"
iv) certification							"

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening X Yes No
 Date: 15 Dec 2000

Reviewer: Daniel W. C. Brown, Ph.D.
 Concurrence by Review Branch: [Signature]

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP _{n/a} purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 08, 2000

SPECIALTY ULTRAVISION, INC.
307 ORCHARD CITY DRIVE
SUITE 100
CAMPBELL, CA 95008
ATTN: DEBBIE MCINTIRE

510(k) Number: K003789
Received: 08-DEC-2000
Product: SPECIALITY 56 UV
(HEFILCON C) SOFT
(HYDROPHILLIC)
CONTACT LENS FOR

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

24

SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530. Released by CDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

IV. Labeling

Labeling is provided in this section for the Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear, and the Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens. The labeling was developed to duplicate the approved labeling for the predicate devices, and was designed to meet the guidelines as set forth in the May, 1994 Premarket Notification 510(k) Guidance Document for Class II Contact Lenses.

Lens blister labels for the Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear, and the Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens are provided in **Appendix IV-A**. The package insert for the Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear, and the Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens is provided in **Appendix IV-B**.

The Patient Instruction booklet for the Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear, and the Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens is provided in **Appendix IV-C**. The Professional Fitting and Information Guide for the Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear, and the Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens is provided in **Appendix IV-D**.

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K _____ Date DMC Received _____

Device Trade Name: Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses for Daily Wear, and Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lenses for Daily Wear

Reason for 510 (k): New 510(k)

Division/Branch: Ophthalmic Devices

Administrative Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

		Comments/ Reference Page in 510(k)
I.	Critical Elements:	
A.	Is the Product a device?	Yes
B.	Is the Device exempt from 510(k) by regulation or policy?	No
C.	Is the Device subject to review by CDRH?	Yes
D. i.	Are you aware that this device has been the subject of a previous NSE decision?	No
ii.	If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	N/A
E. i.	Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.	No
ii.	Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N-0332, September 10, 1991)	N/A
F.	Does the submission contain the information required under Sections 510(k), 513(f), and 513(l) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?	Yes
i.	Device trade or proprietary name	Page 009
ii.	Device common or usual name or classification name	Page 009
iii.	Establishment registration number (only applies if establishment is registered)	Page 009
iv.	Class into which the device is classified under (21 CFR Parts 862 to 892)	Page 009
v.	Classification Panel	Page 009
vi.	Action taken to comply with Section 514 of the Act	Page 009
vii.	Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	Page 023
viii.	Write a 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request.	Page 016
ix.	For Class III devices only, a Class III certification and a Class III Summary	N/A
x.	Photographs of the device	N/A
xi.	Engineering drawings for the device with dimensions and tolerances	Reference letter
xii.	The marketed device(s) to which equivalence is claimed including labeling and description of the device(s)	Page 013

xiii.	Statement of similarities and/or differences with marketed device(s)	Page 013
xiv.	Data to show consequences and affects of a modified device	N/A
II.	Additional Information that <u>is</u> necessary under 21 CFR 807.87(h):	
A.	Submitter's name and address	Page 004
B.	Contact person, telephone number and fax number	Page 004
C.	Representative/Consultant, if applicable	N/A
D.	Table of Contents with pagination	Yes
E.	Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	Page 009
III.	Additional Information that <u>may be</u> necessary under 21 CFR 807.87(h):	
A.	Comparison table of the new device to the marketed device(s)	Page 013
B.	Action to be taken to comply with voluntary standards	Page 009
C.	Performance data	
i.	Marketed Device:	N/A
	a. Bench testing	N/A
	b. Animal testing	N/A
	c. Clinical data	N/A
ii.	New Device:	
	a. Bench testing	Reference letter
	b. Animal testing	Reference letter
	c. Clinical data	N/A
D.	Sterilization information	Reference letter
E.	Software information	N/A
F.	Hardware information	N/A
G.	If this 510(k) is for a kit, has the kit certification statement been provided?	N/A
H. i.	Is this device subject to issues that have been addressed in specific guidance documents?	Yes
ii.	If yes, continue review with checklist from any appropriate guidance documents	Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, May, 1994.
iii.	If no, is 510(k) sufficiently complete to allow substantive review?	
I.	Other (specify)	

SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530. Released by GDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

III. Device Testing and Manufacturing Information

The Specialty 56 UV lenses that are the subject of this 510(k) submission are identical to the IGEL 56 UV lenses that were previously submitted and cleared under K984523. All biocompatibility, leachability, physical/chemical, compatibility, preservative uptake and release and shelf life testing is contained in that submission, as well as information on the 4 week clinical study that was conducted. Complete information on manufacturing processes, formulation, packaging and sterilization testing was also submitted. **Appendix III-A** contains a Letter of Reference from IGEL Vision Care Pte, Ltd., allowing FDA to reference all pertinent information contained in K984523 for the purpose of this 510(k) submission. **Appendix III-B** contains a letter confirming that IGEL Vision Care Pte, Ltd. has provided all necessary manufacturing and labeling information to Specialty UltraVision, Inc.

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SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530 - Released by CDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

I. Device Identification and Classification

A. Device Name:

Proprietary Names: **Specialty 56 UV** (hefilcon C) Soft (Hydrophilic)
Contact Lens for Daily Wear

Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact
Lens for Daily Wear

Polymer Name: hefilcon C

Common Name: Soft (hydrophilic) Contact Lens

B. Establishment/Registration Number

Specialty UltraVision, Inc.	Manufactured at:
307 Orchard City Drive, Suite 100	IGEL C M Laboratory Pte. Ltd.
Campbell, CA 95008	139 Joo Seng Road #06-01
Telephone:(408) 341-0700	ATD Centre
Registration Number: 2952578	Singapore 368362
	Registration Number: 9614154

C. Classification

Daily wear, hydrophilic contact lenses have been placed in **Class II**, under 21 CFR, Part 886.5925.

Product Code/Classification Panel: **86 LPL** (Ophthalmic)

Hefilcon C is a hydrophilic lens polymer falling into **Group 2** of the Hydrophilic Contact Lens Groupings (containing > 50% water, non-ionic), as established in the Premarket Notification (510K) Guidance Document for Daily Wear Contact Lenses, May, 1994.

D. Performance Standards

Performance standards have not been established for hydrophilic contact lenses under section 514.

SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530; Released by CDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

E. Device Description

The Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens is a single vision lens. The Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens is a lens for the correction of astigmatism associated with either near-sightedness (myopia) or far-sightedness (hyperopia) or a combination of both. The lens is able to correct astigmatism up to 7.00 diopters. The Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses are flexible, hemispherical, transparent shells of the following dimensions:

Single Vision Lens

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Powers: -20.00 to +20.00

Toric Lens

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Sphere: -20.00 to +20.00
- Cylinder: Up to 7.00 D
- Axis: 1 to 180°
- Stabilizing Mechanism: Dynamic Stabilizing Sectors

The lens material (hefilcon C) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-Vinyl pyrrolidinone and contains the UV absorbing compound 2-hydroxy-4-acrylethoxy benzophenone. The lens is swollen to equilibrium state in a sterile saline solution, and contains 44% hefilcon C with 56% water by weight when fully hydrated. The blue tinted lens contains D&C Green 6. The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of the lenses.

The physical properties of the lens are:

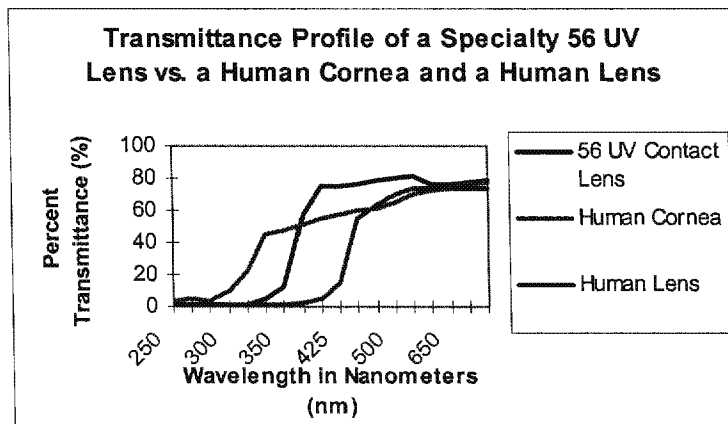
- Specific gravity: 1.16
- Refractive Index: 1.41, fully hydrated
- Light Transmittance : 94.5% clear (untinted)
90.3% (blue handling tint)
- UV Transmittance: < 10%
- Surface Character: hydrophilic
- Water Content: 56% by weight in normal saline
- Oxygen Permeability (Dk)* : 21×10^{-11} (cm²/sec) (ml O₂ /ml x mm Hg) at 35°C

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SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530. Released by CDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

*[Fatt Method for determination of oxygen permeability]

The following graph compares the UV transmittance curve of the **Specialty 56 UV** (hefilcon C) Soft (Hydrophilic) Contact Lens (-7.00 D) to that of the human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year



old, as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig 5.

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SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530; Released by CDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

F. Intended Use

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the single vision lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfecting systems only.

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05/10 '00 19:02 FAX 65 2848534

IGEL VISION CARE

→ ULTRAVISION USA

003

Records processed under FOIA Request 2024-2530; Released by CDRH on 05-16-2024

IGEL VISIONCARE PTE LTD

September 18, 2000

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Reference: Specialty UltraVision Premarket (510(k)) Notification

To Whom It May Concern:

This is to inform the FDA that Igel Vision Care Pte Ltd. has provided Specialty UltraVision, Inc. with 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 their 510(k) application for hefilcon C (K984523).

Should there be additional information needed with respect to this letter, please contact the undersigned at the address on this letterhead.

Sincerely,

(b)(6)

Wong Hoe Leong
President

FEB 21 2001



K003789

510(k) Summary

Submitter Information:

Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, CA 95008

Contact Person: Debbie McIntire
Manager, Clinical and Regulatory Affairs

Telephone: (408) 341-0700
Fax: (408) 341-0717

Date Prepared: December 5, 2000

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Names: Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens
for Daily Wear

Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact
Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The IGEL 56 UV (hefilcon C) Soft (hydrophilic) Contact Lens was selected as the predicate device.

The Specialty 56 UV devices and IGEL 56 UV devices are manufactured in the same facility, under the same quality system, using the same formulation, molding, tinting, packaging and sterilization processes. The Specialty 56 UV lenses contain the same UV blocking agent as the IGEL 56 UV lenses, and the manufacturing process for adding the UV blocking agent is the same.

Description of Devices:

The Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens is a single vision lens. The Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens is a lens for the correction of astigmatism associated with either near-sightedness (myopia) or far-sightedness (hyperopia) or a combination of both. The lens is able to correct astigmatism up to 7.00 diopters. The Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses are flexible, hemispherical, transparent shells of the following dimensions:

307 ORCHARD CITY DRIVE
SUITE 100
CAMPBELL, CA 95008
TEL: 888-29-ULTRA
408-341-0700
FAX: 408-341-0717

3300, 2^EME RUE
ST-HUBERT, QUÉBEC
CANADA J3Y 8Y7
TEL: 800-668-9251
FAX: 450-445-1893

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

Single Vision Lens:

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Powers: -20.00 to +20.00

Toric Lens

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Sphere: -20.00 to +20.00
- Cylinder: Up to 7.00 D
- Axis: 1 to 180°
- Stabilizing Mechanism: Dynamic Stabilizing Sectors

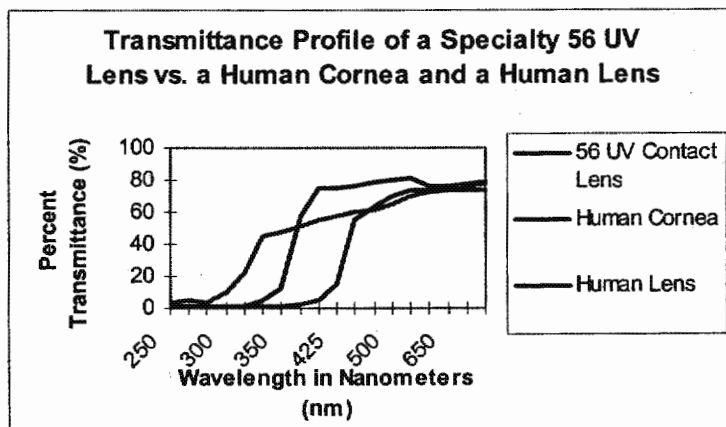
The lens material (hefilcon C) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-Vinyl pyrrolidinone and contains the UV absorbing compound 2-hydroxy-4-acrylethoxy benzophenone. The lens is swollen to equilibrium state in a sterile saline solution, and contains 44% hefilcon C with 56% water by weight when fully hydrated. The blue tinted lens contains D&C Green 6. The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of the lenses.

The physical properties of the lens are:

- Specific gravity: 1.16
- Refractive Index: 1.41, fully hydrated
- Light Transmittance : 94.5% clear (untinted)
90.3% (blue handling tint)
- UV Transmittance: < 10%
- Surface Character: hydrophilic
- Water Content: 56% by weight in normal saline
- Oxygen Permeability (Dk)* : 21×10^{-11} (cm²/sec) (ml O₂ /ml x mm Hg) at 35°C

*[Fatt Method for determination of oxygen permeability]

The following graph compares the UV transmittance curve of the **Specialty 56 UV** (hefilcon C) Soft (Hydrophilic) Contact Lens (-7.00 D) to that of the human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig 5.



Comparison to Predicate Device

PARAMETER	<i>Specialty 56 UV, and Specialty 56 UV Toric Hydrophilic Contact Lenses for Daily Wear</i>	<i>IGEL 56 UV Soft (hydrophilic) Contact Lens for Daily Wear</i>
Submission number		K984523
Material	hefilcon C	hefilcon C
Material classification	Hydrophilic Lens Group 2	Hydrophilic Lens Group 2
Indication for use	myopia, hyperopia, and astigmatism	myopia, hyperopia, and astigmatism
water content	56%	56%
Visible light transmittance	90.3%	90.3%
UV transmittance	< 10%	< 10%
Dk (35° C)	21×10^{-11}	21×10^{-11}
Powers	+20.00 to -20.00 Diopters	+6.00 to -12.00 Diopters
Color	blue visibility D&C Green No. 6	blue visibility, D&C Green No. 6
refractive index	1.41	1.41
specific gravity	1.16	1.16
Method of manufacture	Molded	Molded

Indications for Use:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the single vision lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfection systems only.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Specialty 56 UV and the Specialty 56 UV Toric (hefilcon C) Contact Lenses for Daily Wear. Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. Extraction and analysis of the lenses showed no detectable extractables. The Specialty 56 UV lenses passed the requirements of sterility and stability testing.

A 4-week clinical trial on 37 subjects wearing lenses on a daily wear basis showed that the product is substantially equivalent to other lenses available on the market. No adverse events, significant slit lamp findings, or significant decreases in visual acuity were reported in the study. There was a low incidence of symptoms, problems and complaints, and study discontinuations. Lens wear time was essentially unchanged over the study period, and the lenses remained clinically clean during the study.

Conclusion:

Information submitted in the 510(k) establishes that the Specialty 56 UV and the Specialty 56 UV Toric (hefilcon C) Contact Lenses are comparable to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 21 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Debbie McIntire
Manager, Clinical and Regulatory Affairs
Specialty Ultravision, Inc.
307 Orchard City Drive
Suite 100
Campbell, CA 95008

Re: K003789

Trade Name: Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear and Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear.

Regulatory Class: II

Product Code: 86 LPL

Dated: December 5, 2000

Received: December 8, 2000

Dear Ms. McIntire:

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.

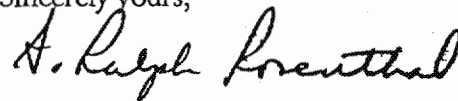
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Debbie McIntire

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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS STATEMENT

Device Names:

Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Indications for Use:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfecting systems only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use

Daniel W. C. Brown, Ph.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003789

JS

BLISTER LABELS

Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

CONTAINS: One sterile, blue visibility tinted contact lens (44% hefilcon C and 56% water) immersed in buffered saline solution.

Base Curve: Diameter:
Power:
Lot Number: Expiration Date:

CAUTION: Federal law prohibits dispensing without a prescription

Manufactured for: Specialty UltraVision, Inc. Campbell, CA 95008

Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

CONTAINS: One sterile, blue visibility tinted contact lens (44% hefilcon C and 56% water) immersed in buffered saline solution.

Base Curve: Diameter:
Power: Cylinder Power: Axis:
Lot Number: Expiration Date:

CAUTION: Federal law prohibits dispensing without a prescription

Manufactured for: Specialty UltraVision, Inc. Campbell, CA 95008

SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530. Released by CDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

II. Substantial Equivalence Discussion

The purpose of this submission is to receive clearance for Specialty UltraVision, Inc. to market hefilcon C (56% water) contact lenses that have an UV blocking agent incorporated into the polymer. Specialty UltraVision, Inc. believes the lenses are substantially equivalent to the predicate devices. The lenses will be made of the same polymer, hefilcon C (56% water) and manufactured and sterilized at the same manufacturing site, using identical formulation, moulding and sterilization processes. Lenses will be blister-packaged at the manufacturing site using packaging materials that are biocompatible and equivalent with respect to shelf life stability and sterility tests. The physical and optical characteristics of the lenses are equivalent. A side-by-side comparison of the lenses with the predicate devices is provided in **Table II - 1** below.

TABLE II - 1
Side-by-Side Substantial Equivalence Comparison
of Specialty 56 UV Contact Lenses with IGEL 56 UV Contact Lenses

PARAMETER	Specialty 56 UV, and Specialty 56 UV Toric Hydrophilic Contact Lenses for Daily Wear	IGEL 56 UV Soft (hydrophilic) Contact Lens for Daily Wear
Submission number		K984523
Material	hefilcon C	hefilcon C
Material classification	Hydrophilic Lens Group 2	Hydrophilic Lens Group 2
indication for use	myopia, hyperopia, and astigmatism	myopia, hyperopia, and astigmatism
water content	56%	56%
Visible light transmittance	90.3%	90.3%
UV transmittance	< 10%	< 10%
Dk (35° C)	21×10^{-11}	21×10^{-11}
Powers	+20.00 to -12.00 Diopters	+6.00 to -12.00 Diopters
Color	blue visibility D&C Green No. 6	blue visibility, D&C Green No. 6
refractive index	1.41	1.41
specific gravity	1.16	1.16
Method of manufacture	Molded	Molded

CONFIDENTIAL - This document contains Specialty UltraVision, Inc. proprietary information and shall not be duplicated, disclosed to others, or used for purposes other than to carry out the intent for which this material is delivered unless written consent is first obtained from Specialty UltraVision, Inc.

SPECIALTY ULTRAVISION, Inc.	Records processed under FOIA Request 2024-2530. Released by CDRH on 05-16-2024 Specialty 56 UV and Specialty 56 UV Toric (hefilcon C, 56% water) Hydrophilic Contact Lenses
Campbell, CA	Premarket Notification 510(k)

TABLE OF CONTENTS

	Page
Premarket Cover Sheet.....	001
Checklist for Acceptance Decision - completed by Submitter	005
Truthful and Accurate Statement	007
Indications for Use.....	008
510(k) Submission	009
I. Device Identification and Classification.....	009
A. Device Name.....	009
B. Establishment Registration Number.....	009
C. Classification.....	009
D. Performance Standards	009
E. Device Description.....	010
F. Intended Use	012
II. Substantial Equivalence Discussion	013
III. Device Testing and Manufacturing Information.....	014
IV. Labeling.....	015
V. 510(k) Summary.....	016
 APPENDICES:	
Appendix III-A: Permission to Reference Letter from IGEL Vision Care	021
Appendix III-B: Transfer of Information Letter	022
Appendix IV-A: Blister Labels	023
Appendix IV-B: Package Insert.....	024
Appendix IV-C: Patient Instructions.....	030
Appendix IV-D: Professional Fitting Guide	039

INDICATIONS STATEMENT

Device Names:

Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Indications for Use:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfecting systems only.

(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 ☐

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number 6003784

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR § 807.87(j))

I certify that, in my capacity as Vice President, Technical Affairs at Specialty UltraVision, Inc., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Garold L. Edwards, O.D., F.A.A.O.
Specialty UltraVision, Inc.

SDU 2000
Date

Premarket Notification [510(k)] Number

Premarket Submission Cover Sheet

Date of Submission **December 5, 2000**

FDA Document Number:

Section A

Type of Submission

- | | | | |
|---|---|--|---|
| ☒ 510(k) | ☐ IDE | ☐ PMA | ☐ PMA Supplement - Regular |
| ☐ 510(k) Add'l information | ☐ IDE Amendment | ☐ PMA Amendment | ☐ PMA Supplement - Special |
| | ☐ IDE Supplement | ☐ PMA Report | ☐ PMA Supplement - 30 day |
| | ☐ IDE Report | | ☐ PMA Supplement - Panel Track |

Section B1

Reason for Submission - 510(k)s Only

- | | | |
|--|---|--|
| ☒ New device | ☐ Additional or expanded indications | ☐ Change in technology, design, materials, or manufacturing process |
| ☐ Other reason (specify): | | |

Section B2

Reason for Submission - PMAs Only

- | | | |
|---|---|--|
| ☐ New device | ☐ Change in design, component, or specification: | ☐ Location change: |
| ☐ Withdrawal | ☐ Software | ☐ Manufacturer |
| ☐ Additional or expanded indications | ☐ Color Additive | ☐ Sterilizer |
| ☐ Licensing agreement | ☐ Other (specify below) | ☐ Packager |
| | | ☐ Distributor |
| ☐ Labeling change: | | |
| ☐ Indications | ☐ Process Change: | ☐ Report submission: |
| ☐ Instructions | ☐ Manufacturer | ☐ Annual or periodic |
| ☐ Performance Characteristics | ☐ Sterilizer | ☐ Post-approval study |
| ☐ Shelf life | ☐ Packager | ☐ Adverse reaction |
| ☐ Trade name | | ☐ Device defect |
| ☐ Other (specify below) | | ☐ Amendment |
| ☐ Change in ownership | ☐ Response to FDA correspondence (specify below) | |
| ☐ Change in correspondent | ☐ Request for applicant hold | |
| ☐ Other reason (specify): | ☐ Request for removal of applicant hold | |
| | ☐ Request for extension | |
| | ☐ Request to remove or add manufacturing site | |

Section B3

Reason for Submission - IDEs Only

- | | | |
|--|--|--|
| ☐ New device | ☐ Change in: | ☐ Response to FDA letter concerning: |
| ☐ Addition of institution | ☐ Correspondent | ☐ Conditional approval |
| ☐ Expansion/extension of study | ☐ Design | ☐ Deemed approval |
| ☐ IRB certification | ☐ Informed Consent | ☐ Deficient final report |
| ☐ Request hearing | ☐ Manufacturer | ☐ Deficient progress report |
| ☐ Request waiver | ☐ Manufacturing | ☐ Deficient progress report |
| ☐ Termination of study | ☐ Protocol - feasibility | ☐ Deficient investigator report |
| ☐ Withdrawal of application | ☐ Protocol - other | ☐ Disapproval |
| ☐ Unanticipated adverse effect | ☐ Sponsor | ☐ Request extension of time to respond to FDA |
| | | ☐ Request meeting |
| ☐ Emergency use: | ☐ Report submission: | ☐ IOL submissions only: |
| ☐ Notification of emergency use | ☐ Current investigator | ☐ Change in IOL style |
| ☐ Additional information: | ☐ Annual progress | ☐ Request for protocol waiver |
| | ☐ Site waiver limit reached | |
| | ☐ Final | |
| ☐ Other reason (specify): | | |

Section C Product Classification

Product Code: 86 LPL	C.F.R. Section: 21 CFR § 886.5925	Device class: ☐ Class I ☐ Class III ☒ Class II ☐ Unclassified
Classification panel: Ophthalmic		

Section D Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: ☒ 510(k) summary attached ☐ 510(k) statement
1 86 LPL	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K984523	1 IGEL 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear	1 IGEL Visioncare Pte. Ltd..
2	2	2
3	3	3
4	4	4
5	5	5

Section E Product Information - Applicable to All Applications

Common or usual name or classification name:

Hydrophilic Contact Lenses

Trade or proprietary or model name	Model Number
1 Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear	1 N/A
2 Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear	2. N/A
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling): The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens and Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfection systems only.

Section F Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete		FDA establishment registration number: 9614154		☒ Manufacturer ☐ Contract manufacturer		☐ Contract sterilizer ☐ Repackager/relabeler	
Company / Institution name: IGEL CM Laboratory Pte. Ltd.							
Division name (if applicable): N/A					Phone number (include area code): 011-65-7491090		
Street address: 139 Joo Seng Road #06-01 ATD Centre					FAX number (include area code): 011-65-2848534		
City: --		State / Province: --		Country: Singapore		ZIP / Postal Code: 368362	
Contact name: Steve Newman							
Contact title: General/Operations Manager							
☐ Original ☐ Add ☐ Delete		FDA establishment registration number:		☐ Manufacturer ☐ Contract manufacturer		☐ Contract sterilizer ☐ Repackager/relabeler	
Company / Institution name:							
Division name (if applicable):					Phone number (include area code):		
Street address:					FAX number (include area code):		
City:		State / Province:		Country:		ZIP / Postal Code:	
Contact name:							
Contact title:							
☐ Original ☐ Add ☐ Delete		FDA establishment registration number:		☐ Manufacturer ☐ Contract manufacturer		☐ Contract sterilizer ☐ Repackager/relabeler	
Company / Institution name:							
Division name (if applicable):					Phone number (include area code): ()		
Street address:					FAX number (include area code): ()		
City:		State / Province:		Country:		ZIP / Postal Code:	
Contact name:							
Contact title:							

		FDA Document Number:	
Section G Applicant or Sponsor			
Company / Institution name: Specialty UltraVision, Inc.		FDA establishment registration number: 2952578	
Division name (if applicable): N/A		Phone number (include area code): (408) 341-0700	
Street address: 307 Orchard City Drive, Suite 100		FAX number (include area code): (408) 341-0717	
City: Campbell	State / Province: CA	Country: U.S.	ZIP / Postal Code: 95008
Signature: (b)(6)			
Name: Garold L. Edwards, O.D., F.A.A.O.			
Title: Vice President, Technical Affairs			
Section H Submission correspondent (if different from above)			
Company / Institution name: Specialty UltraVision, Inc.		FDA establishment registration number: 2952578	
Division name (if applicable): N/A		Phone number (include area code): (408) 341-0700	
Street address: 307 Orchard City Drive, Suite 100		FAX number (include area code): (408) 341-0717	
City: Campbell	State / Province: CA	Country: U.S.	ZIP / Postal Code: 95008
Contact name: Debbie McIntire			
Contact title: Manager, Clinical and Regulatory Affairs			

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

PATIENT INSTRUCTIONS

For

**Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens
for Daily Wear**

**Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens
for Daily Wear**

CAUTION: Federal Law Prohibits Dispensing Without a Prescription

CONGRATULATIONS:

You have just received your new **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens(es)** or **Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Len(es)**. This booklet has been prepared to help you care for it(them). Please read it carefully and follow the instructions so that you receive full satisfaction from your lens(es).

IMPORTANT: In the event that you do experience any difficulty wearing your lens(es) or you do not understand the instructions given to you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.

INTRODUCTION:

With your decision to wear soft (hydrophilic) contact lenses, you have joined a growing number of people who are discovering new pleasures from this important advance in vision correction.

Your **Specialty 56 UV or Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens(es)** is(are) made of a stable, inert, highly purified, hydrophilic (water absorbing) polymer with properties different from conventional hard lenses. Molded to optical precision in the dry state, your lens(es) hold these qualities in the soft, moist state in which it(they) is(are) suited for your use. Kept moist by the tears in your eyes, the lens(es) is(are) soft and comfort can be immediate. You are cautioned, however, to follow the initial wearing time schedule prescribed by your practitioner and not to overwear the lens(es) simply because they remain comfortable.

Your eyecare practitioner will determine your appropriate wearing schedule.

Although soft and pliable, your lens(es) is(are) strong and durable. The life of your **Specialty 56 UV or Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens(es)** will depend to a large extent on how you handle and care for it(them). The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of your lens(es). As with all precision devices, proper use will assure you the benefits of convenience, comfort and confidence in your lens(es).

Read this Wearer's Guide carefully. It contains the information you need to know to wear, handle, and care for your **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens(es)**. If you are in doubt about any instructions, request clarification from your eyecare practitioner.

WEARING RESTRICTIONS AND INDICATIONS (USES):

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the single vision lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in not aphakic persons with non-diseased eyes. The lenses may be disinfected using chemical disinfecting systems only.

The **Specialty 56 UV and Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lenses** described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eyecare practitioner. **DO NOT WEAR YOUR SPECIALTY 56 UV (HEFILCON C) SOFT (HYDROPHILIC) CONTACT LENSES WHILE SLEEPING.**

CONTRAINDICATIONS (REASONS NOT TO USE):

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are contraindicated in the presence of any of the following conditions:

- Acute and subacute inflammation or infection of the anterior chamber of the eye (red eyes);
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids;
- Insufficiency of lacrimal secretion (dry eyes);
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic;

- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses;
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions;
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses**;
- Any active corneal infection (bacterial, fungal, or viral);
- If eyes become red or irritated;
- You are unable to follow lens care regimen or unable to obtain assistance to do so;
- Incomplete healing following eye surgery.

WARNINGS:

You are advised of the following warnings pertaining to contact lens wear:

- **PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. IT IS ESSENTIAL THAT YOU FOLLOW YOUR EYECARE PRACTITIONER'S DIRECTION AND ALL LABELING INSTRUCTIONS FOR PROPER USE OF LENSES AND LENS CARE PRODUCTS, INCLUDING THE LENS CASE. EYE PROBLEMS, INCLUDING CORNEAL ULCERS CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.**
- **DAILY WEAR LENSES ARE NOT INDICATED FOR OVERNIGHT WEAR AND YOU SHOULD NOT WEAR LENSES WHILE SLEEPING. CLINICAL STUDIES HAVE SHOWN THAT THE RISK OF SERIOUS ADVERSE REACTIONS IS INCREASED WHEN THESE LENSES ARE WORN OVERNIGHT.**

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

NOTE: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV-light has not been established at this time.

- **STUDIES HAVE SHOWN THAT CONTACT LENS WEARERS WHO ARE SMOKERS HAVE A HIGHER INCIDENCE OF ADVERSE REACTIONS THAN NON-SMOKERS.**
- **IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, YOU SHOULD IMMEDIATELY REMOVE THE LENSES AND CONTACT YOUR EYECARE PRACTITIONER.**

PRECAUTIONS:

- Before leaving your eyecare practitioner's office, you should be able to promptly remove lens(es) or should have someone else available who can remove the lenses.
- You should remove your lens(es) immediately if your eye becomes red or irritated.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional **hard** contact lenses only.
- Chemical disinfecting solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfecting.
- Always use fresh, unexpired lens care solutions. NEVER reuse solution.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage your **Specialty 56 UV or Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens(es)**.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- **Do not** use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

- Always keep your lenses completely immersed in the recommended storage solution when your lenses are not being worn (stored). Prolonged periods of drying will damage lenses (reduce the ability of the lens surface to return to a wettable state). Follow the lens care directions for CARE FOR A DRIED OUT (DEHYDRATED) LENS if lens surface does become dried out.
- If your lens sticks (stops moving) on the eye, follow the recommended directions on CARE FOR A STICKING LENS. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch your contact lenses with the fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this pamphlet and those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during water activities and other sports.
- Inform your health care practitioner about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand when removing from case.
- Do not touch your lens with your fingernails.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Be sure to keep your follow-up appointments.
- Serious corneal damage may result from wearing a lens which has been soaking in a conventional hard contact lens solution containing preservatives and chemicals which should not be used with any soft (hydrophilic) contact lenses.
- Eye irritation may occur within a short time after putting on a hypertonic lens. Remove your lens to relieve the irritation.
- You should adhere to the recommended care procedures for your **Specialty 56 UV or Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens(es)**. Failure to follow these procedures may result in the development of serious ocular infections.
- You should remove your **Specialty 56 UV or Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens(es)** before sleeping. Your lens(es) should also be removed before swimming or in the presence of noxious and irritating vapors. You may experience irritation in areas of high environmental pollution.

ADVERSE EFFECTS (Problems and What to Do):

The following problems may occur:

- Eye pain;
- Eyes sting, burn, or itch (irritation);
- Comfort is less than when lens was first placed on eye;
- Abnormal feeling of something in the eye (foreign body, scratched area);
- Excessive watering (tearing) of the eyes;
- Unusual eye secretions;
- Redness of the eyes;
- Reduced sharpness of vision (poor visual acuity);
- Blurred vision, rainbows, or halos around objects;
- Sensitivity to light (photophobia);

- Dry eyes;
- If your lens becomes less comfortable than when you first placed it on the cornea, it may indicate the presence of a foreign body. Remove your lens immediately and have your eye examined; if any eye abrasion, ulceration, irritation, or infection is present, a physician should be consulted immediately.
- When visual blurring occurs, your lens must be removed until the condition subsides. Clean, rinse and disinfect your lens before reinsertion.
- Rainbows or halos around objects, or blurring of your vision may occur if you wear your lenses continuously for too long a time. Removal of your lenses and a rest period of at least one hour generally relieves these symptoms.
- Excessive tearing, unusual eye secretions, and light sensitivity are not normal; if these symptoms occur, consult your eyecare practitioner to determine the cause.

PERSONAL CLEANLINESS FOR LENS HANDLING:

1. Preparing the Lens for Wearing:

It is essential that you learn and use good hygienic methods in the care and handling of your lens(es). Cleanliness is the first and most important aspect of contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lens(es). The procedures are:

- Always wash your hands thoroughly with a mild soap, and dry them with a lint-free towel before handling the lens(es).
- Avoid the use of soaps containing cold cream, lotion or oily cosmetics, before handling your lens(es), since these substances may come into contact with your lens(es) and interfere with successful wearing.
- Handle your lens(es) with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Handling the Lens:

- Always handle the same lens, the right or the left, first in order to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, and free of any nicks or tears.

3. Placing the Lens on Your Eye:

- Before inserting your lens, rinse it well with fresh rinsing solution. Then place your lens on the tip of the index finger of your dominant hand.
- While it is positioned on your index finger, check to ensure your lens is not turned inside out. To check this, look at the profile of the lens against a light background. If the edge profile appears convex and bowl shaped, then it is correct. If the lens is inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.
- Look straight ahead and raise the upper lid with your other index finger.
- While looking down and keeping both eyes open, place the lens on the upper white part of the eye.
- Slowly release upper lid and gently close your eye.
- The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.
- Repeat the above procedure for the second lens.
- If a lens appears to be stuck on your eye, apply one or two drops of a recommended lubricating solution to the eye and blink a few times. If your lens does not move freely on your eye, contact your eyecare practitioner for further instructions.
- There is no single "right way" of putting on lenses. If you find this method of lens placement difficult, your eyecare practitioner will suggest another method or provide additional instruction.

NOTE: If after placement of your lens, your vision is blurred, check for the following:

- Your lens is not centered on your eye (see "Centering the Lens," next in the booklet).

- If your lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
 - a. Cosmetics or oils on the lens; Clean, rinse, disinfect, and place on the eye again;
 - b. The lens is on the wrong eye;
 - c. The lens is inside-out (it would also not be as comfortable as usual).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eyecare practitioner.

4. Centering Your Lens:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow the procedure below, or one recommended by your eyecare practitioner:

- Apply one or two drops of a recommended lubricating solution to the eye and blink a few times;
- Move your lens on center by gentle fingertip pressure through the lids.

5. Removing Your Lenses

Preparation:

- a. Wash and rinse your hands thoroughly;
- b. Dry hands with a lint-free towel;
- c. Check that your lens is centered on your cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens is off-center. Recenter the lens before attempting to remove it.

Removal:

- a. To avoid the possibility of lens mixups, always begin with the same lens;
- b. Look up and keep both eyes open;
- c. Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye; Using the tip of the index finger of the same hand, touch the lens and slide it onto the white of the eye;
- d. Gently "pinch" the lens between the index finger and the thumb and remove;
- e. Repeat the procedure for the second eye;
- f. If your lens cannot be easily moved, apply a few drips of lubricating solution to the eye, blink a few times, and when the lens moves freely on the eye, remove in the manner described above. If the lens still cannot be easily moved, contact your eyecare practitioner for further instruction.
- g. Follow the required lens care procedures described under the heading "CARE FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING /LUBRICATING)."

IMPORTANT: Always avoid touching your lens(es) with your fingernails. Use only your fingertips.

NOTE: If this method of removing your lens(es) is difficult for you, your eyecare practitioner will provide you with an alternative method.

NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.

If your lens(es) is(are) chipped or torn, do not put the lens back on your eye. Return the lens to the storage case with fresh storage solution and contact your eyecare practitioner.

CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING:

1. Basic Instructions:

For continued safe and comfortable wear of your lens(es), it is important that you first clean and rinse, then disinfect your lenses after each removal, using the care regimen recommended by your eyecare practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films or deposits which may have accumulated during wear. The ideal time to clean your lens(es) is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure to put the lenses on and remove them while you are in your eyecare practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of this booklet.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse and dry your hands before handling contact lenses.
- Always use fresh unexpired lens care solution.
- Use the recommended system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution is no substitute for disinfecting.

NOTE: Heat (thermal) disinfecting is not recommended for use with your Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses.

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lens(es). Do not put lens(es) in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
 - a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - b. You might lose the lens down the drain.
- Your eyecare practitioner should recommend a care system that is appropriate for the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens**. Each lens care product contains specific directions for use and important safety information, which you should read and carefully follow.

2. Care for a Sticking (Non-Moving) Lens:

Very rarely, your lens may adhere to your eye as a result of your sleeping while wearing your lenses or wearing a hypotonic lens. If your lens adheres for any reason, apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, **immediately** consult your eyecare practitioner.

3. Lens Case Cleaning And Maintenance:

Your contact lens case can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with rinsing solution, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

4. Care for a Dried Out or Dehydrated Lens:

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline before handling.

To re-hydrate the lens:

- Handle the lens(es) carefully.
- Place the lens(es) in its storage case and soak the lens(es) in a recommended rinsing and storing solution for at least 1 hour or until it returns to a soft state.
- Clean lens first, then disinfect the re-hydrated lens using a recommended lens care system.
- If after soaking, the lens(es) does(do) not become soft, if the surface remains dry, **DO NOT USE UNLESS IT HAS BEEN EXAMINED BY YOUR EYECARE PRACTITIONER.**

5. Emergencies:

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENS(ES) PROMPTLY. CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

INSTRUCTIONS FOR THE MONOVISION WEARER:

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with these lenses if you pass your state drivers license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULE:

Prescribed Wearing Schedule

Day	Wearing Time (Hours)	Appointment Schedule
1	_____	Your appointments are on:
2	_____	Day Month Year Time
3	_____	
4	_____	
5	_____	_____
6	_____	_____
7	_____	_____
8	_____	_____
9	_____	_____
10	_____	_____
11	_____	
12	_____	
13	_____	
14	_____	

Studies have not been completed to show that the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** or **Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens** are safe to wear during sleep. Do not wear **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** while sleeping.

NAME AND ADDRESS OF MANUFACTURER:

Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, California 95008

408-341-0700
888-29 ULTRA

Issued November, 2000

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION : FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION

Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses for Daily Wear - Sphere and Toric

DESCRIPTION:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear** and **Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lenses for Daily Wear** are available as a single vision lens, and as an astigmatic (toric) lens. The lens material (hefilcon C) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and N-vinyl pyrrolidinone and contains the UV absorbing compound 2-hydroxy-4-acrylethoxy benzophenone. The lens is swollen to equilibrium state in a sterile buffered saline solution, and contains 44% hefilcon C with 56% water by weight when fully hydrated. The blue tinted lens contains D&C Green 6. The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of the lenses. The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are a flexible, hemispherical, transparent shell of the following dimensions:

Single Vision Lens

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Powers: -20.00 to +20.00

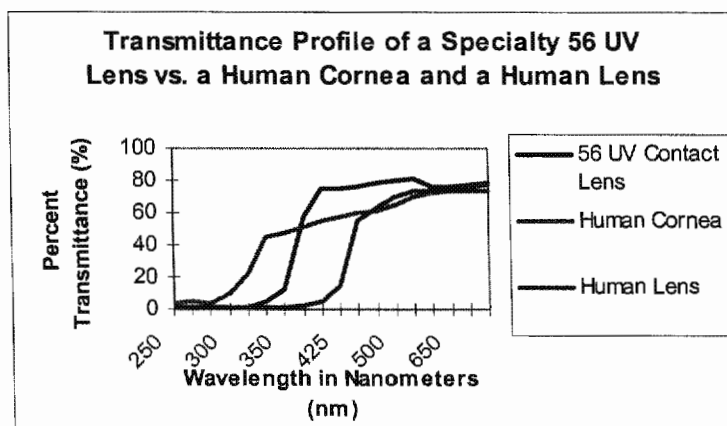
Toric Lens

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at -3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Sphere: -20.00 to +20.00
- Cylinder: Up to 7.00 D
- Axis: 1 to 180°
- Stabilizing Mechanism: Dynamic Stabilizing Sectors

The physical/optical properties of the lens are:

- Specific Gravity: 1.16
 - Refractive Index: 1.41, fully hydrated
 - Light Transmittance: 94.5% clear (untinted)
90.3% blue (handling tint)
 - UV Transmittance: < 10%
 - Surface Characteristics: hydrophilic
 - Water Content: 56% by weight in normal saline
 - Oxygen Permeability (Dk)* : 21×10^{-11} (cm²/sec) (ml O₂ /ml x mm Hg) at 35°C
- *[Fatt Method for determination of oxygen permeability]

The following graph compares the UV transmittance curve of the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens (-7.00 D)** to that of the human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig 5.



ACTIONS:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** when placed on the human cornea acts as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the highly uneven astigmatic cornea, and thus helps to focus light rays on the retina.

INDICATIONS (USES):

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the single vision lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfection systems only.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye;
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids;
- Insufficiency of lacrimal secretion (dry eyes);
- Corneal hypoesthesia (reduced corneal sensitivity);
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses;
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions;
- Allergy to any ingredient, such as mercury or Thimerosal in a solution which is to be used to care for the lens ;
- Any active corneal infection: Pus (purulent), bacterial, fungal, or viral infection;
- If the eyes become red or irritated;
- Patients unable to follow lens care regimen or unable to obtain assistance to do so;
- Incomplete healing following eye surgery.

WARNINGS:

Patients should be advised of the following warnings pertaining to contact lens wear:

- **PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. IT IS ESSENTIAL THAT PATIENTS FOLLOW THEIR EYECARE PRACTITIONER'S DIRECTION AND ALL LABELING INSTRUCTIONS FOR PROPER USE OF LENSES AND LENS CARE PRODUCTS, INCLUDING THE LENS CASE. EYE PROBLEMS, INCLUDING CORNEAL ULCERS CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.**
- **DAILY WEAR LENSES ARE NOT INDICATED FOR OVERNIGHT WEAR AND PATIENTS SHOULD BE INSTRUCTED NOT TO WEAR LENSES WHILE SLEEPING. CLINICAL STUDIES HAVE SHOWN THAT THE RISK OF SERIOUS ADVERSE REACTIONS IS INCREASED WHEN THESE LENSES ARE WORN OVERNIGHT.**
- **STUDIES HAVE SHOWN THAT CONTACT LENS WEARERS WHO ARE SMOKERS HAVE A HIGHER INCIDENCE OF ADVERSE REACTIONS THAN NONSMOKERS.**
- **IF A PATIENT EXPERIENCES EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES AND PROMPTLY CONTACT HIS OR HER EYECARE PRACTITIONER.**

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

NOTE: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV-light has not been established at this time

PRECAUTIONS:

Records processed under FOIA Request 2024-2530; Released by CDRH on 05-16-2024

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use; and the patient should wait at least 1 hour before replacing the lenses.
- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses**.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may damage the lenses. Follow the lens care directions for CARE FOR A DRIED OUT (DEHYDRATED) LENS if lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on CARE FOR A STICKING LENS. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** and those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during water activities and other sports.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eyecare practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assess the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Serious corneal damage may result from wearing a lens which has been soaking in a conventional hard contact lens solution containing preservatives and chemicals which should not be used with any soft (hydrophilic) contact lenses.
- Eye irritation may occur within a short time after putting on a hypertonic lens. Removal of the lens will relieve the irritation.
- Patients must adhere to the recommended care procedures for the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses**. Failure to follow these procedures may result in the development of serious ocular infections.
- The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** should be removed before sleeping. The lens should also be removed before swimming or in the presence of noxious and irritating vapors. Lens wearers may experience irritation in areas of high environmental pollution.

ADVERSE EFFECTS:

The patient should be informed that the following problems may occur:

- Eye pain;
- Eyes sting, burn, or itch (irritation);
- Comfort is less than when lens was first placed on eye;
- Abnormal feeling of something in the eye (foreign body, scratched area);
- Excessive watering (tearing) of the eyes;
- Unusual eye secretions;
- Redness of the eyes;
- Reduced sharpness of vision (poor visual acuity);
- Blurred vision, rainbows, or halos around objects;
- Sensitivity to light (photophobia);
- Dry eyes;
- If a lens becomes less comfortable than when it was first placed it on the cornea, it may indicate the presence of a foreign body. The lens should be removed immediately and the eye examined; if any eye abrasion, ulceration, irritation, or infection is present, a physician should be consulted immediately.
- When visual blurring occurs, the lens must be removed until the condition subsides. Clean, rinse and disinfect the lens before reinsertion.
- Rainbows or halos around objects, or blurring of the vision may occur if you wear your lenses continuously for too long a time. Removal of the lenses and a rest period of at least one hour generally relieves these symptoms.
- Excessive tearing, unusual eye secretions, and light sensitivity are not normal; if these symptoms occur, the patient should be examined to determine the cause.

FITTING:

Conventional methods of fitting hydrophilic contact lenses apply to the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses**. For a detailed description of the fitting techniques, refer to the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens Professional Fitting Guide**, copies of which are available from:

Specialty UltraVision
307 Orchard City Drive, Suite 100
Campbell, California 95008

(408) 341 0700 or (888) 29 ULTRA

WEARING SCHEDULE:

Daily Wear: (Less than 24 hours, while awake)

There may be a tendency for the patient to overwear the lenses initially. Therefore, the importance of adhering to the initial daily wearing schedule should be stressed to the patient.

Care must be taken on the initial visit to ensure that the patients is supplied with the recommended chemical disinfecting accessory products and fully understands all care and handling instructions for the lenses. As with any contact lens, regular follow-up visits are necessary to ensure patient health and compliance with instruction.

Day	Continuous Hours
1	4
2	6
3	8
4	10
5	12
6	14
7	All waking hours

Studies have not been completed to show that **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are safe to wear during sleep. Do not wear **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** while sleeping.

*WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.

LENS CARE:

The eyecare practitioner should recommend a care system suitable for use with **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses**. The patient should follow the eyecare practitioner's specific instructions carefully.

NOTE: DO NOT MIX OR ALTERNATE COMPONENTS OF DISINFECTING AND STORAGE SYSTEMS UNLESS INSTRUCTED TO DO SO BY THE EYECARE PRACTITIONER.

Patients must wash and rinse hands thoroughly and dry with a lint free towel before handling contact lenses.

Cleaning and Disinfecting: **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** must be BOTH cleaned and disinfected each time the lens is removed from the eye. One procedure does not replace the other.

Cleaning is necessary to remove mucus and film from the lens surface. This can be accomplished by using a recommended daily cleaner. Excessive deposits may damage the lens; therefore, if this occurs, evaluation of the lens care procedure should be made. Cleaning with a recommended enzymatic contact lens cleaner on a weekly basis is recommended to remove and prevent buildup of protein deposits from constituents normally found in tears.

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh, unexpired lens care solutions. Never re-use solution.
- Use the recommended system of lens care, either chemical (not heat), or oxidation (hydrogen peroxide) and carefully follow instructions on solution labeling.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.

NOTE: Heat (thermal) Disinfection is not recommended for use with the Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens.

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfecting.
- The eye care practitioner should recommend a care system that is appropriate for the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eye care practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfecting again before use. The patient should consult the package insert or the eye care practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh disinfecting/storage solution. Replace lens case at regular intervals as recommended by the lens care manufacturer or the eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable
- **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses cannot be heat (thermally) disinfected.**

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the eyecare practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfecting solution labeling.
- Do not heat the disinfecting solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eye.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storage solution for at least one hour or until the lens again feels soft and pliable.
- Clean, rinse and disinfect the rewetted lens using the lens care system recommended by the eye care practitioner.
- If after soaking, the lens does not become soft or the surface remains dry, DO NOT PLACE THE LENS ON THE EYE. Contact the eye care practitioner.

CARE FOR A STICKING (NONMOVING) LENS:

Very rarely, a lens may adhere to an eye as a result of the patient sleeping while wearing the lens or wearing a hypotonic lens. If a lens adheres for any reason, patients may be instructed to apply a few drops of a recommended saline or lubricating solution and wait until the lens moves freely before removing the lens. If nonmovement of the lens continues, the patient should immediately consult their eyecare practitioner.

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patients should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each lens is supplied sterile in a blister pack containing buffered saline solution. The blister pack is labeled with the base curve, diopter power, cylinder and axis (for toric lenses), diameter, tint, lot number, and expiration date of the product.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens** should be reported to:

Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, California 95008

(408) 341 0700 or (888) 29 ULTRA

Issued November, 2000

IGEL VISIONCARE PTE LTD

September 18, 2000

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Reference: Letter of Reference on behalf of Specialty UltraVision to permit the FDA to reference Igel Vision Care Pte Ltd's 510(k) K984523 for the Igel®56 UV(hefilcon C) soft (Hydrophilic) Contact Lens for Daily Wear (clear or visitint, spherical and toric, cast molded)

To Whom It May Concern:

Igel Vision Care Pte Ltd. hereby grants permission for Specialty UltraVision, Inc. to reference all of the information contained within the company's premarket notification K984523, which received marketing clearance on February 16, 1999. The product covered in the application is the Igel®56 UV(hefilcon C) soft (Hydrophilic) Contact Lens for Daily Wear, indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism, for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in not-aphakic persons with non-diseased eyes on a daily wear basis. The referenced 510(k) submission received marketing clearance for a cast molded Igel®56 UV(hefilcon C) soft (Hydrophilic) Contact Lens for Daily Wear.

Should there be additional information needed with respect to this permission, please contact the undersigned at the address on this letterhead.

Sincerely,

(b)(6)

Wong Hoe Leong
President