

<b>CIBA Vision</b>	CIBA Vision® Corporation 11460 Johns Creek Parkway Duluth, GA USA 30155
	<b>SEE3™ (Iotrafilcon A) Soft Contact Lens</b>
<b>510(k) Summary of Safety and Substantial Equivalence</b>	

510(k) Summary K970746

**1. Submitter Information:**

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**2. Device Name:**

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: SEE3™ (Iotrafilcon A)
- Classification Name: Daily Wear  
Soft (hydrophilic) Contact Lens
- Device Classification: Class II {21 CFR 886.5925 (b) (1)}

**3. Predicate Device:**

The predicate lens was selected to address both intended use (daily wear) and material type (FDA Group I: low water, nonionic polymer):

- Cibasoft® (tefilcon), FDA Group I, low water, nonionic soft contact lenses for daily wear;  
CIBAVision® Corporation - PMAs P810005, P820086

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#### 4. Description of Device:

The SEE3™ (Iotrafilcon A) soft contact lens is a new soft contact lens suitable for daily wear. The lens material is 24% water and 76% Iotrafilcon A, a silicone containing hydrogel treated with a plasma coating.

The SEE3™ (Iotrafilcon A) contact lens is available in a spherical lens design of the following dimensions:

- Chord Diameter: 14.0 mm
- Center Thickness: 0.05 to 0.35 mm (varies with power)
- Base Curve: 8.8 mm
- Power Range: -20.00D to +20.00D
- Powers Available: -5.00D to +5.00D (0.25D steps),  
-8.00, -5.50, +5.50, +6.00D

A clear lens has the following properties:

- Specific gravity: 1.08
- Refractive index: 1.43 (hydrated)
- Light transmittance:  $\geq 99\%$
- Water content: 24 % by weight in normal saline
- Oxygen permeability:  $140 \times 10^{-11}$   
[(cm<sup>2</sup>/sec)(ml O<sub>2</sub>/ml·mmHg)]  
measured at 35°C, Coulometric method.

Lenses are supplied sterile in sealed glass vials containing isotonic phosphate buffered saline solution. The compatibility and package integrity of the glass vial packaging system has been demonstrated and successfully used for other marketed lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Vial containers are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical stability of the lens and package integrity (ability to maintain sterility). Stability study data currently supports a twelve (12) month shelf-life for the SEE3™ (Iotrafilcon A) soft contact lens in sealed glass vials. Shelf-life studies are ongoing to determine extension of expiration dating.

#### 5. Indications for Use:

SEE3™ (Iotrafilcon A) soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non aphakic persons with non-diseased eyes.

The lenses may be prescribed for daily wear with removal for cleaning and disinfection and monthly replacement. SEE3™ (Iotrafilcon A) lenses may be cleaned using a chemical, not heat, disinfection system.



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**6. Description of Safety and Substantial Equivalence:**

A series of nonclinical tests and clinical studies were performed to demonstrate the safety and effectiveness of the SEE3™ (Iotrafilcon A) contact lens, and establish substantial equivalence to a currently marketed, predicate (control) lens. All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(k) Guidance Document for Class II Contact Lenses* and in conformance to applicable device regulations. Results demonstrate the lens is non-toxic and biocompatible, and has material characteristics comparable to or better than other currently marketed soft contact lenses. Clinically, the lens has performed satisfactorily in a daily wear investigation. Results from all tests demonstrate the substantial equivalence to previously FDA approved, and currently marketed predicate (control) lenses.

**Nonclinical Testing:**

A series of *in vitro* and *in vivo* preclinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens. All nonclinical toxicology tests were conducted in accordance with the GLP regulation (21 CFR Part 58).

The results of the nonclinical testing on the SEE3™ (Iotrafilcon A) contact lens demonstrate that:

- The lens material and extracts are not toxic and non irritating.
- Lens physical and material properties are consistent with industry marketed lenses.
- The lens material remains unaffected, with respect to lens properties, by exposure to chemical cleaning and disinfection systems. The amount of preservatives in the tested care regimens show similar uptake and release profiles to the predicate device.

**Clinical Testing:**

The SEE3™ (Iotrafilcon A) contact lens was investigated in daily wear clinical study. The three month clinical evaluation was conducted in accordance with current Good Clinical Practices and published regulations (21 CFR Parts 50, 56, 312, 812). The study assessed the safety and effectiveness, and clinical performance as compared to a predicate control lens.

Clinical evaluation of the SEE3™ (Iotrafilcon A) lens demonstrated similar overall performance in the clinically relevant areas of vision, health, comfort and fit to compared to concurrent controls when used under daily wear conditions.



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**SEE3™ (lotrafilcon A) Soft Contact Lens**

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**Substantial Equivalence:**

The SEE3™ (lotrafilcon A) contact lens is similar to other daily wear soft contact lenses in terms of water content (24% water) and ionic characteristics (FDA Group I: low water, nonionic), clinical performance, and indications for use. In addition, the lenses may be disinfected using a chemical, not heat, disinfection regimen.

Any differences which may exist between the (lotrafilcon A) contact lens and other Group I soft hydrophilic plastic contact lenses does not adversely effect the safety and effectiveness of the device.