

# Summary of 510(k) Submission

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## Summary

The 510(k) submission summary consists of these sections

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## Name and address of submitter

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Date Prepared: November 14, 1996

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## Identification of Device

- Trade name: VISTAKON (genfilcon A) Contact Lens, clear and with visibility tint.
- Common or usual name: Soft (hydrophilic) Contact Lens (daily wear)
- FDA Classification: Class II

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## Predicate Device

Optima FW (polymacon) Visibility Tinted Contact Lens

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**Description of Device** The VISTAKON (genfilcon A) Soft (hydrophilic) Contact Lens is available as a spherical lens, a spherical multifocal lens and an astigmatic (toric) lens. The lens material (genfilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with tetraethylene glycol dimethacrylate and ethylene glycol dimethacrylate. The VISTAKON Contact Lens with visibility tint is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. The VISTAKON Contact Lens is a hemispherical shell.

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**Intended Use** The VISTAKON Contact Lens (spherical) is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00 D of astigmatism or less.

The VISTAKON MULTIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic or non-aphakic persons with non-diseased eyes who may have 0.75 D of astigmatism or less.

The VISTAKON TORIC Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D of astigmatism or less.

Eye care practitioners may prescribe the lens for single-use disposable wear or for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement (see WEARING SCHEDULE). When prescribed for frequent/planned replacement, the lens may be disinfected using a chemical disinfection system only.

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**Characteristics** The VISTAKON (genfilcon A) Contact Lens is classified into FDA Group I for contact lens materials. The predicate device was chosen from FDA Group I. The VISTAKON (genfilcon A) Contact Lens is compared to the predicate device in the following table.

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	VISTAKON (genfilcon A) Contact Lens with visibility tint		Optima FW Visibility Tinted Contact Lens	
	Measured	Label	Measured	Label
Water Content, %	47.5	48	41.2	38.6
Refractive Index @ 20°C	1.43	1.43	1.44	1.43
Dk, non-edge corrected	14.1	13.0	7.5	8.5*
Color (if tinted)	light blue	light blue	light blue	light blue
Base Curve, mm	8.6	8.6	8.4	8.7
Diameter, mm	14.0	14.0	14.0	14.0
Power, D	-0.99	-1.00	-0.98	-1.00

Dk units =  $\times 10^{-11}$  (cm<sup>2</sup>/sec) (ml O<sub>2</sub>/ml x mm Hg)

\*edge correction method not identified in Bausch & Lomb labeling

### Non clinical Studies

Included as non clinical studies are

- chemistry,
- toxicology, lenses and package,
- microbiology

### Chemistry

Material property data were generated on the subject device and the predicate device. The data for both devices reflect properties of Group I lenses. The lens care product manufacturers have previously shown compatibility of Group I lenses with their products.

The shelf-life stability for VISTAKON (genfilcon A) Contact Lenses is based upon approved stability protocols from N18-033. The initial shelf-life of the lens will be declared based on the data generated under one of these protocols. Shelf-life will not be claimed until a minimum of six months of real time data have been collected and found to be acceptable.

Studies were conducted to determine the leachable materials from the subject and predicate devices. The results indicate that, at the levels of detection reported, there are no significant differences between the subject device and the predicate device.

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**Toxicology,  
genfilcon A lens  
material**

In accordance with the May 1994 Guidance Document for Daily Wear contact lenses, toxicology studies have been conducted on the VISTAKON (genfilcon A) soft (hydrophilic) contact lenses, clear and with visibility tint.

1. The Ocular Irritation study indicates the extracts would not be considered ocular irritants under the conditions of the study.
  2. The USP Systemic Toxicity study indicates the extracts would not be considered systemically toxic under the conditions of the study.
  3. The Cytotoxicity study indicates that the lens is not cytotoxic under the conditions of the study.
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**Toxicology,  
package  
materials**

No additional toxicology studies have been conducted on the plastic primary packaging materials, as the materials are the same as those previously tested and reported under N18-033.

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**Microbiology**

The lens sterilization process, moist heat sterilization, has been validated to deliver a minimum SAL of  $10^{-6}$ . The lens care product manufacturers have established a reasonable assurance of disinfection efficacy of their care products with the lens groups for which they are approved. The lens will be presented in the same primary package currently used for other products approved under N18-033. There are shelf-life stability data which support lens sterility throughout the shelf-life claimed for the product.

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**Clinical studies**

The safety of the lens material in the spherical design has been confirmed through a clinical trial for daily wear contact lens materials with a new USAN name according to the Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses (May 1994). The study evaluated at least 50 patients with a 2:1 ratio of subject device to predicate device for three (3) months. Parameters measured included adverse reactions, symptoms, problems and complaints, slit lamp evaluations, visual acuity, lens wear time, fit assessment and discontinuations. The VISTAKON (genfilcon A) trial contact lens was found to be safe and effective for its intended use and at least substantially clinically equivalent to the predicate device.

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**Conclusions  
drawn from  
studies**

**1. Validity of Scientific Data**

Toxicology studies were conducted by a contract laboratory under Good Laboratory Practice Regulations. Microbiology, chemistry, shelf-life stability, and leachables studies were conducted by in-house laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

**2. Safety and Effectiveness**

The data presented in this Premarket Notification support the safety and effectiveness of the subject device when used in accordance with the labeled directions for use and for the requested indication. The subject device has been shown to be substantially equivalent to the predicate device.

**3. Risk and Benefits**

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

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