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Special 510 (k) Summary of Safety and Effectiveness

**Name and
Address of
Submitter**

VISTAKON[®], Division of Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway, Suite 100
Jacksonville, Florida 32256

Contact: Susan Morris
Phone: (904) 443-1828

Date Prepared: September 1, 2006

**Device
Identification
and Class**

Common Name: Soft (hydrophilic) contact lenses for daily wear

Trade/Proprietary Name: VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear

Classification: Class II, under 21 CFR 886.5925

**Predicate
Device
Information**

The predicate devices are: 1) VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted, with UV Blocker for disposable daily wear, most recently cleared via K051900, 2) ACUVUE[®]2 COLOURS Brand (etafilcon A) Soft hydrophilic Contact Lens with UV Blocker for Daily Wear most recently cleared via K033969.

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Special 510 (k) Summary of Safety and Effectiveness, Continued

**Device
Description**

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker, for Daily Wear is available as a spherical lens, a bifocal lens, a toric lens, and a toric bifocal lens. The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Visibility Tinted with UV Blocker, for Daily Wear is tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling. The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens Cosmetically Tinted with UV Blocker for Daily Wear, contains a pigmented area that will mask or enhance the color of the natural iris. The lens is colored with one or more of the following color additives: iron oxides, titanium dioxide, phthalocyaninato (2-) copper, phthalocyanine green, vat orange 1 and Reactive Blue Dye #4. The cosmetically tinted lens is available in the following opaque colors: Blue, Gray, Green, Honey, Chestnut, Hazel and Sapphire. They are also available in the following enhancer colors: Blue, Green and Aqua.

In the VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker, for Daily Wear, a benzotriazole UV absorbing monomer is used to block UV radiation. The UV Blocking for VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear averages 97% in the UVB range of 280 nm to 315 nm. The UV Blocker for VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker for Daily Wear averages 82% in the UVA range of 316 nm to 380 nm. The UV Blocker for VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Cosmetically Tinted with UV Blocker for Daily Wear averages 81% in the UVA range of 316 nm to 380 nm.

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Special 510 (k) Summary of Safety and Effectiveness, Continued

Indications for Use

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear (spherical) is indicated for daily wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) BIFOCAL Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is indicated for daily wear for the correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) TORIC Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is indicated for daily wear for the correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism or less.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) BIFOCAL-TORIC Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is indicated for daily wear for the correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear helps protect against transmission of harmful UV radiation to the cornea and into the eye.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear may be prescribed for daily wear. Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection, and scheduled replacement (see "Wearing Schedule").

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Special 510 (k) Summary of Safety and Effectiveness, Continued

Indications for Use (continued)

When prescribed for frequent/planned replacement wear the VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is to be cleaned, rinsed, and disinfected each time the lens is removed. The etafilcon A contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

When prescribed for single-use disposable wear (See "Wearing Schedule") the VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is to be discarded after each removal.

Technological Characteristics

Comparison to Predicate Device

The table below shows a side-by-side comparison of the label claim characteristics of the modified device to the predicate device.

Property	Subject Device Label Claim	Predicate Device Label Claim
Water Content, %	58	58
Refractive Index @ 20° C	1.40	1.40
Dk-Fatt method, non- edge corrected (cm ² /sec)* (ml O ₂ /ml*mmHg)	28.0 x 10 ⁻¹¹	28.0 x 10 ⁻¹¹
Specific Gravity, (calc.)	0.98 - 1.13	0.98 - 1.13
Light Transmission	Minimum 85%	Minimum 85%
Base Curve Radius, mm	7.85 mm to 10.0 mm	7.85 mm to 10.0 mm
Diameter, mm	12.0 mm to 15.0 mm	12.0 mm to 15.0 mm
Power, Diopters	Varies with power: 0.06 mm to 1.00 mm	Varies with power: 0.06 mm to 1.00 mm
Center Thickness, mm	-20.0 D to + 20.0 D	-20.0 D to + 20.0 D

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Summary of Non-clinical Testing

The following tests were conducted as recommended by the FDA *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact lenses*, May 12, 1984:

- Toxicology Testing
 - Cytotoxicity using the ISO Agarose Overlay
 - ISO Ocular Irritation Study
 - USP & ISO Systemic Toxicity in Mice
 - Leachables
 - Physical/Chemical Testing
 - Stability Testing
 - Solution Compatibility Testing
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Clinical Testing

The technological characteristics, formulation, manufacturing, and sterilization processes are the same as the predicate device, therefore no clinical data is required.

Substantial Equivalence

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lenses for daily wear that are the subject of this 510(k) submission are equivalent to the predicate device. Successful results from chemical/physical, stability and toxicology tests confirm the lenses are within established finished product specifications, remain stable, and are non-toxic and biocompatible with the ocular environment.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vistakon
Division of Johnson & Johnson Vision Care, Inc.
c/o Susan Morris
Project Manager, Regulatory Submissions
7500 Centurion Parkway, Ste. 100
Jacksonville FL 32256

NOV 1 2006

Re: K062614

Trade/Device Name: Vistakon® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and
Visibility Tinted (Visibility and/or Cosmetically) with UV Blocker,
for Daily Wear (packaged in buffered saline with Povidone)

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) contact lens

Regulatory Class: Class II

Product Code: LPL

Dated: October 12, 2006

Received: October 17, 2006

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "MB Eydelman, M.D." The signature is written in a cursive style with a large, sweeping flourish at the end.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number ~~Unknown~~ K 06 2614

Device Name VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear

Indications for Use The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear (spherical) is indicated for daily wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) BIFOCAL Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is indicated for daily wear for the correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) TORIC Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is indicated for daily wear for the correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism or less.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) BIFOCAL-TORIC Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is indicated for daily wear for the correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.

The VISTAKON[®] (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear helps protect against transmission of harmful UV radiation to the cornea and into the eye.

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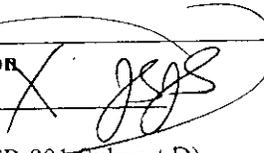
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Indications for Use Statement, Continued

The VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker, for Daily Wear is to be prescribed for daily wear. Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection, and scheduled replacement (see "Wearing Schedule").

When prescribed for frequent/planned replacement wear the VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker, for Daily Wear is to be cleaned, rinsed, and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

When prescribed for single-use disposable wear (See "Wearing Schedule") the VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker, for Daily Wear is to be discarded after each removal.

Prescription Use  (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use _____ (21 CFR 901 Subpart C)
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(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K062614