AUG 1 2 2005 K051900

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) 443-1428

Date Prepared: July 12, 2005

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 Visibility Tinted with UV Blocker for Daily Disposable Wear
Classification:	Class II, under 21 CFR 886.5925

Predicate Device Information

The predicate device is the 1-DAY ACUVUE® Brand (etafilcon A) Contact Lens, Clear and Visibility Tinted, with UV Blocker for disposable daily wear most recently cleared via K013973.

Device Description

The VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker for Daily Disposable Wear is available as a spherical lens, spherical multifocal lens and an astigmatic (toric) 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 trimethacrylate. The VISTAKON® Contact Lens with visibility tint is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 5 % in the UVB range of 280 to 315 nm and less than 30 % in the UVA range of 316 to 380 nm. The lens is a hemispherical shell.

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Indications for Use

The VISTAKON (etafilcon A) Soft (hydrophilic) Contact Lens (spherical), Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with not diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON (etafilcon A) Soft (hydrophilic) Bifocal Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is indicated for daily wear for the correction of distance and near vision in presbyopic, aphakic or not-aphakic persons with non-diseased eyes who may have 0.75 D of astigmatism or less.

The VISTAKON (etafilcon A) Soft (hydrophilic) Toric Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes who are hyperopic or myopic and may have 10.00 D of astigmatism or less.

The VISTAKON (etafilcon A) Soft (hydrophilic) Toric Bifocal Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic or not aphakic persons with non-diseased who may have 10.00 D of astigmatism or less.

VISTAKON (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear help protect against transmission of harmful UV radiation to the cornea and into the eye.

The VISTAKON (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is to be prescribed for Daily Disposable Wear and is to be discarded after each removal.

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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 – 1.12	0.98 - 1.12
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

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

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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 Lens, Clear and Visibility Tinted with UV Blocker for Daily Disposable 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2005

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

Re: K051900
Trade/Device Name: Vistakon (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable 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: MVN; LPL
Dated: July 12, 2005
Received: July 13, 2005

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 (301) 827-8910. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting 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 K051900
Device Name	VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens Clear and Visibility Tinted with UV Blocker for Daily Disposable Wear
Indications for Use	The VISTAKON (etafilcon A) Soft (hydrophilic) Contact Lens (spherical), Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with not diseased eyes who may have 1.00D or less of astigmatism. The VISTAKON (etafilcon A) Soft (hydrophilic) Bifocal Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is indicated for daily wear for the correction of distance and near vision in presbyopic, aphakic or not-aphakic persons with non-diseased eyes who may have 0.75 D of astigmatism or less. The VISTAKON (etafilcon A) Soft (hydrophilic) Toric Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes who are hyperopic or myopic and may have 10.00 D of astigmatism or less. The VISTAKON (etafilcon A) Soft (hydrophilic) Toric Bifocal Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic or not aphakic persons with non-diseased who may have 10.00 D of astigmatism or less. VISTAKON (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear help protect against transmission of harmful UV radiation to the cornea and into the eye. The VISTAKON (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker, for Daily Disposable Wear is to be prescribed for Daily Disposable Wear and is to be discarded after each removal.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary Ann Burns

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

~~510(k) Number~~ K051900

Prescription Use ✓ (Per 21 CFR 801.109)		OR	Over-the-Counter Use