

OCT 16 2003

510(k) PREMARKET NOTIFICATION
VISTAKON® (galyfilcon A) Contact Lens

K 032340

Summary of Safety and Effectiveness

**Submitter
Information**

Company: VISTAKON®
Division of Johnson & Johnson Vision Care,
Inc.
7500 Centurion Parkway
Suite 100
Jacksonville, FL 32256

Contact Person: Jacqueline Zimovan
Project Leader
Regulatory & Clinical Affairs

Telephone: 904-443-1402
FAX: 904-443-1424

Date Prepared: July 28, 2003

**Identification of
the Device**

Common Name: Soft Contact Lens

Device Name: VISTAKON® (galyfilcon A) Contact Lens

Classification Name: Soft Hydrophilic Contact Lens, Daily Wear

Device Classification: Class II, 21 CFR 886.5925 (b) (1).

**Predicate
Device**

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

- Focus® NIGHT AND DAY™ (lotrafilcon A), FDA Group I.
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Summary of Safety and Effectiveness, Continued

Description of Device

- The VISTAKON® (galyfilcon A) Contact Lens Clear and Visibility Tint with UV blocker is available as a spherical lens, a multifocal lens, a toric lens and a toric-multifocal lens.
- The lens material, galyfilcon A, is a copolymer of 2-hydroxyethyl methacrylate and (3-methacryloxy-2-hydroxypropyloxy) propylbis(trimethylsiloxy)methylsilane and N,N-dimethylacrylamide, and polyvinylpyrrolidone and mPDMS-monomethacrylate (n=11), and 2-propenoic acid, 2-methyl-, 1,2-ethandiyl ester.
- The VISTAKON® (galyfilcon A) Contact Lens may be 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 transmittance characteristics are less than 1% in the UVB range of 280 – 315nm and less than 10% in the UVA range of 316 – 380nm.
- The VISTAKON® (galyfilcon A) Contact Lens is a hemispherical or hemitoric shell.
- The lens is supplied in a sterile state, packaged in a buffered saline solution with up to 0.01% methyl ether cellulose.
- The composition of the lens is 53% galyfilcon A and 47% water by weight when hydrated and stored in the buffered saline solution.

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Summary of Safety and Effectiveness, Continued

Indications for Use

Lens Design	Indication
Spherical	The VISTAKON® (galyfilcon A) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less.
Multifocal	The VISTAKON® (galyfilcon A) Multifocal Contact Lens 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 0.75D of astigmatism or less.
Toric	The VISTAKON® (galyfilcon A) Toric Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism or less.
Toric Multifocal	The VISTAKON® (galyfilcon A) Toric-Multifocal Contact Lens 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 10.00D of astigmatism or less.

- VISTAKON® (galyfilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.
- Eye care practitioners may prescribe the lens for single-use disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement, the lens may be disinfected using a chemical disinfection system only.

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Summary of Safety and Effectiveness, Continued

Technological Characteristics

The characteristics of the VISTAKON® (galyfilcon A) Contact Lens are compared to the characteristics of the predicate device, Focus® NIGHT & DAY™ (lotrafilcon A) Contact Lens, in the following tables.

Material Comparison		
	Focus® NIGHT AND DAY™ (lotrafilcon A) Contact Lens	VISTAKON® (galyfilcon A) Contact Lens
Material	lotrafilcon A	galyfilcon A
Type	Group I	Group I

Parameter Comparison				
	Focus® NIGHT AND DAY™ (lotrafilcon A) Contact Lens		VISTAKON® (galyfilcon A) Contact Lens	
Characteristics Comparison	Measured	Labeled	Measured	Labeled
Water Content, %	23	24	48	47
Refractive Index @ 20°C	1.4263	1.43	1.4055	1.41
Dk*, edge corrected	141.3	140	55.4	60
Dk*, non-edge corrected	167.6	NA	68.3	70
Base Curve, mm	8.47	8.4	8.35	8.3
Diameter, mm	13.8	13.8	14.11	14.0
Power, D	-1.11	-1.00	-1.03	-1.00

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Summary of Safety and Effectiveness, Continued

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All non-clinical toxicology tests were conducted in accordance with the GLP regulation (21 CFR Part 56). All other testing was conducted according to valid scientific protocols.

The results of the non-clinical testing on the VISTAKON® (galyfilcon A) Contact Lens demonstrate that:

- The lens material and extracts are not toxic and not irritating
 - Lens physical and material properties are consistent with currently marketed lenses.
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Clinical Testing

A three-month clinical study was completed to evaluate the safety and efficacy of the VISTAKON® (galyfilcon A) Contact Lens when worn by myopic patients on a daily wear basis. The clinical study was conducted in accordance with FDA's 1994 Guidance Document for Daily Wear Contact Lenses.

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, keratometry changes, reasons for discontinuations, and the number of reasons for unscheduled lens replacements.

Clinical evaluation demonstrated similar overall performance in the clinically relevant areas of vision, health, comfort and fit as compared to concurrent controls when used under daily wear conditions.

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Summary of Safety and Effectiveness, Continued

Conclusions Drawn from Studies

Validity of Scientific Data	Toxicology studies were conducted by a contract laboratory under Good Laboratory Practice Regulations. Microbiology, chemistry, shelf-life stability, and leachability studies were conducted by VISTAKON® laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7
Substantial Equivalence	Information presented in this Premarket Notification establishes that the VISTAKON® (galyfilcon A) Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.
Risk and Benefits	The risks of the subject device as 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.



OCT 16 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vistakon
c/o Ms. Jacqueline Zimovan
Project Leader
Regulatory and Clinical Affairs
P.O. Box 17700
Jacksonville, FL 32245-7700

Re: K032340
Trade/Device Name: VISTAKON® (galyfilcon A) Contact Lens
(Spherical, Toric, Multifocal and Toric-Multifocal)
(Clear and tinted with UV Blocker)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: July 28, 2003
Received: July 29, 2003

Dear Ms. Zimovan:

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) 594-4613. 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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

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

Enclosure

Statement of Indications for Use

510(k) Number: K032340

Device Name: VISTAKON® (galyfilcon A) Contact Lens Clear and Visibility Tint, with UV blocker

Indications for Use:

The VISTAKON® (galyfilcon A) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON® (galyfilcon A) Multifocal Contact Lens 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® (galyfilcon A) Toric Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D of astigmatism or less.

The VISTAKON® (galyfilcon A) Toric-Multifocal Contact Lens 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® (galyfilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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 lenses may be disinfected using a chemical disinfection system 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 _____

[Signature]

E. J. O. P.D.

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

510(k) Number K032340