JAN 26 1999

K983912

Summary of 510(k) Submission

Summary

The 510(k) submission summary consists of these sections

- Name and address of submitter
- Identification of device
- Predicate device
- Description of device
- Intended use

- Characteristics
- Non clinical studies
- Clinical studies
- Conclusions drawn from studies
- Flow Chart for 510(k) Daily Wear Contact Lens Materials

Name and address of submitter

Vistakon, Johnson & Johnson Vision Products, Inc.
4500 Salisbury Road, Suite 300
Jacksonville, Florida 32216
Contact: Sharon A. Briggs
Phone: 904/443-1471
Date Prepared: November 2, 1998

Identification of Device

- Trade name: VISTAKON (lenefilcon A) Contact Lens Clear and Visibility tint with UV blocker.
- Common or usual name: Soft (hydrophilic) Contact Lens (daily wear)
- FDA Classification: Class II

Predicate Device

NewVues® (vifilcon A) Soft Contact Lens

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Summary of 510(k) Submission, Continued

Description of Device

The VISTAKON (lenefilcon A) Soft (hydrophilic) Contact Lens is available as a spherical lens, a multifocal lens, a toric lens and a toric multifocal lens. The lens material (lenefilcon A) is a copolymer of 2-hydroxyethyl 2-methyl-2 propenoate and 2-propenic acid, 2-methyl-2,3-dihydroxypropyl ester cross-linked with poly (oxy-1,2-ethanediyl) (4) bis (2-methyl-2-propenoate). The VISTAKON Contact Lens Visibility Tint with UV Blocker 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 transmittance characteristics are less than 1% in the UVB range of 280nm to 315nm and less than 10% in the UVA range of 316nm to 380nm. The VISTAKON Contact Lens is a hemispherical or hemitoric shell.

Intended Use

Spherical lens	The VISTAKON Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00 D of astigmatism or less.
Multifocal lens	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.
Toric lens	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.
Toric Multifocal lens	The VISTAKON TORIC 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 10.00D 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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Summary of 510(k) Submission, Continued

Characteristics

The VISTAKON (lenefilcon A) Contact Lens is classified into FDA Group II for contact lens materials. The predicate device is classified into FDA Group IV. The predicate device was chosen because the water content and Dk value are the same as the subject device, the predicate device is available in similar base curve and diameter configurations and both subject and predicate devices are visibility tinted. The characteristics of the VISTAKON (lenefilcon A) Contact Lens are compared to the characteristics of the predicate device in the following table.

	VISTAKON (lenefilcon A) Contact Lens Visibility Tint with UV Blocker		**NewVues® (vifilcon A) Soft Contact Lens**	
	Measured	Label	Measured	Label
Water Content, %	55	55	56	55
Refractive Index @ 20°C	1.41	1.41	#1.41	1.415
Dk, edge corrected	17	16	18	16
Dk, non-edge corrected	22	21	22	16
Color (if tinted)	Blue	Blue	Blue	Blue
Base Curve, mm	8.86	8.84	8.5	8.5
Diameter, mm	14.10	14.05	14.3	14.0
Power, D	-0.79	-0.74	-1.02	-1.00

Dk units = x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg)
* edge correction method not identified in CIBA Vision® labeling
# calculated from water content

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 II and Group IV lenses, respectively. The lens care product manufacturers have previously shown compatibility of Group II and Group IV lenses with their products.

The shelf-life stability for VISTAKON (lenefilcon A) Contact Lenses is based upon stability protocols included with this notification or referenced. Studies were conducted to determine the leachable monomers from the subject device.

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Summary of 510(k) Submission, Continued

Toxicology, lenefilcon A lens material

In accordance with the May 1994 Guidance Document for Daily Wear contact lenses, toxicology studies have been conducted on the VISTAKON (lenefilcon A) soft (hydrophilic) Contact Lenses Clear and Visibility Tint with UV blocker. The results are summarized below:

Cytotoxicity Test	The negative controls and the positive controls performed as anticipated. Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity. The test article was not cytotoxic and passed this ISO study.
Ocular Irritation Study in the Rabbit	Under the conditions of this study, there was no evidence of significant irritation in the test eye or control eye of any rabbit. The SC and CSO test article extracts would not be considered irritants to the ocular tissue of the rabbit.
Acute Systemic Toxicity in the Mouse	Under the conditions of this study, there was no mortality or evidence of significant systemic toxicity from the extracts. Each test article extract met the ISO requirements.

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.

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. There are shelf-life stability data that support lens sterility throughout the shelf-life claimed for the product.

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,

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Summary of 510(k) Submission, Continued

Clinical studies	problems and complaints, slit lamp evaluations, visual acuity, lens wear time, fit assessment and discontinuations. The VISTAKON (lenefilcon A) trial contact lens was found to be at least substantially clinically equivalent to the predicate device.	
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 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.
	Substantial Equivalence	The data presented in this Premarket Notification support the subject device is as safe, as effective and performs as well as or better than 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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 1999

Ms. Sharon A. Briggs
Group Leader, Regulatory Submissions
Vistakon
Johnson and Johnson Vision Prouducts, Inc.
P.O. Box 10157
Jacksonville, FL 32247

Re: K983912
Trade Name: VISTAKON (lenefilcon A) Soft (hydrophilic) Contact Lenses Clear and Visibiltiy Tint with UV Blocker (Cast molded, Spherical, Toric, Multifocal Designs for daily wear)
Regulatory Class: II
Product Code: 86 LPL
Dated: November 2, 1998
Received: November 3, 1998

Dear Ms. Briggs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K983912

Device Name: VISTAKON (lenefilcon A) Contact Lens, clear and visibility tint with UV Blocker

Indications for Use:

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

(Optional Format 3 - 10 - 09)
(Posted July 1, 1998)

Mei-Chun Shih

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983912

Prescription Use ✓
(Per 21 CFR 801.109)