SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name:	lenefilcon A hydrophilic contact lens
Device Trade Name:	VISTAKON (lenefilcon A) Soft (hydrophilic) Contact Lenses (Clear and Visibility Tinted with UV Blocker) for Extended Wear
Applicant's Name and Address:	VISTAKON Division of Johnson & Johnson Vision Care, Inc. P.O. Box 10157 Jacksonville, FL 32247-0157
Date(s) of Panel Recommendation:	None

Premarket Approval Application (PMA) Number: P990085

Date of Quality System Good Manufacturing Inspection: February 2, 2001

Date of Notice of Approval to Applicant: February 16, 2001

II. INDICATIONS FOR USE

The VISTAKON Spherical (lenefilcon A) Contact Lens is indicated for daily and extended wear for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes. The lens is indicated for daily wear in aphakic persons. The lens may be worn by persons who have astigmatism of 1.00 diopter or less which does not interfere with visual acuity.

The VISTAKON BIFOCAL (lenefilcon A) Contact Lens is indicated for daily and extended wear for the correction of distance and near vision in presbyopic, not-aphakic persons with non-diseased eyes. The lens is indicated for daily wear in aphakic persons. The lens may be worn by persons who have astigmatism of 1.00 diopter or less which does not interfere with visual acuity.

The VISTAKON TORIC (lenefilcon A) Contact Lens is indicated for daily and extended wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and have astigmatism of 10.00 diopters or less. The lens is indicated for daily wear in aphakic persons.

The VISTAKON TORIC BIFOCAL (lenefilcon A) Contact Lens is indicated for daily and extended wear for the correction of distance and near vision in presbyopic not-aphakic persons with non-diseased eyes that have astigmatism of 10.00 diopters or less. The lens is indicated for daily wear in aphakic persons.

VISTAKON (lenefilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses may be prescribed for either daily wear or extended wear from 1 – 7 days between removals for cleaning and disinfection or disposal, as recommended by the eye care practitioner. Eye care practitioners may prescribe the lens either for single-use disposable wear or frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system recommended for soft (hydrophilic) contact lenses.

The subject lenses were cleared for daily wear under K983912 on January 26, 1999.

III. CONTRAINDICATIONS

Do not use the VISTAKON (lenefilcon A) Contact Lenses when any of the following conditions exists:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the VISTAKON Contact Lens
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the VISTAKON (lenefilcon A) Soft (hydrophilic) Contact Lens labeling (Attachment 1)

V. DEVICE DESCRIPTION

The VISTAKON (lenefilcon A) Soft (hydrophilic) Contact Lenses are available in spherical, bifocal, toric, and toric bifocal designs. The lens material is 55% water and

45% lenefilcon A, a copolymer of 2-hydroxyethyl 2-methyl-2-propenoate and glycerol monomethacrylate cross-linked with poly (oxy-1,2-ethanediyl) (4) bis (2-methyl-2-propenoate).

The lens may be prescribed for extended wear in spherical lens powers ranging from +8.00 D to –13.00 D, and toric lens powers from +8.00 D to –10.00 D sphere with cylinder powers from –0.25 D to –10.00 D. Bifocal lens add powers range from +0.25 D to +5.00 D

VI. ALTERNATIVE PRACTICES AND PROCEDURES

The alternative practices and procedures to correcting vision include other daily wear and extended wear contact lenses, rigid gas permeable daily wear and extended wear contact lenses, spectacles, and corrective surgeries such as radial keratotomy, photorefractive keratectomy and LASIK.

VII. MARKETING HISTORY

The subject device has not been marketed in the United States or any other country for extended wear.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse effects on health associated with extended wear contact lenses are included in the device labeling. Please refer to page 6 of this summary for a list of adverse reactions which were observed during the clinical study.

IX. SUMMARY OF PRECLINICAL STUDIES

The objective of the preclinical studies were to provide reasonable assurance of the safety of the VISTAKON (lenefilcon A) Soft (hydrophilic) Contact Lenses prior to clinical testing.

Biocompatability Studies

The following toxicology tests were performed: Primary Ocular Irritation Test, Cytotoxicity Test, Acute Systemic Toxicity and Leachables Testing. The test results raise no acute toxicological concerns and support the safety of the study lens for its intended use.

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Physical and Chemical Characterization Studies:

The physical/optical properties of the lens are:

% Water Content	55
Oxygen Permeability (Dk): $(cm^2/sec)(ml.mmHG) \times 10^{-11}$	16.4
% Light Transmittance	95% Clear, 85% Tinted

Mechanical Properties:

Refractive Index:	1.43
Specific Gravity	1.05 – 1.19

Solution Compatibility Studies:

The subject device is a group II (high water content, non-ionic material) contact lens. Currently marketed lens care solutions have been tested with group II lenses. The applicant provided information from 13 brief (2 to 4 week) small scale studies. These studies enrolled only 14 to 37 subjects each, and were conducted to evaluate the role of biguanide preserved solutions on the presence of superficial punctate keratitis (SPK). Although the prevalence of SPK observed in some of these studies was higher than anticipated, the results were inconclusive.

Shelf-life Stability Studies

An expiration date of 4 years has been established for sterilized lenses.

X. SUMMARY OF CLINICAL STUDIES

Objective

The objective of this clinical trial was to evaluate the safety and effectiveness of the subject device for not-aphakic extended wear from 1 to 7 days.

Study Design

This clinical trial was a prospective, randomized, controlled, multi-center clinical trial lasting one year. A total of 457subjects (914 eyes) (305 test subjects and 152 control subjects) were enrolled at 18 investigative sites throughout the United States. There were 10 subjects enrolled but not dispensed lenses because they did not meet the eligibility criteria. Subjects were randomized to wear either the test or control lens bilaterally for one year. The control lens used in this study was a group IV, 55% water content lens currently marketed for extended wear.

For the purposes of this study, extended wear meant that lenses were to be applied and worn around the clock, including during sleep for no more than 7 days/6 nights. Weekly extended wear meant at the end of any six (6) nights of extended wear, the patient had to remove the lens for one night prior to beginning a new cycle of lens wear. All subjects used the Opti-Free Multi-Purpose Solution as the lens care regimen when lenses were removed.

Follow-up visits were to be scheduled at day 1, week 1, month 1, 3, 6, 9 and 12. Primary safety data collected during the study included:

- Adverse events
- Slit lamp findings
- Subjective symptoms and problems
- Keratometric and refractive changes
- Visual acuity

The primary efficacy data collected during the study included:

- Lens wearing time
- Discontinuations
- Lens Replacements

Subjects were eligible for study participation if they were at least 18 years old, signed informed consent, and complied with inclusion and exclusion criteria specified in the protocol.

Demographic Data

The study population consisted of subjects representative of the general population attending offices for contact lens care. Of the subjects enrolled, 305 test and 152 control subjects were dispensed lenses. Lens power ranged from –2.00 D to –5.00 D.

Gender distribution for the enrolled subjects consisted of 301 females and 166 males enrolled into the clinical study and ranged in age from 18 to 60 years. Although the potential exists for minor differences in physiological response by gender for the target population, minimal number of clinically significant findings does not indicate that gender differences are of clinical importance for this device.

Data Analysis and Results

Adverse Reactions

Adverse events were defined as including, but not limited to a hazardous, sight threatening condition such as: corneal ulcer, iritis, other ocular infections, inflammations, corneal scarring, or permanent loss of vision.

There were 125 adverse reactions (50 in the control group and 75 in the trial group) reported for 40 control eyes and 64 trial eyes during the clinical study. In some cases, multiple adverse reactions were reported for eyes in both groups. There were no adverse reactions reported as serious/severe for the trial group. Adverse reactions were reported as follows:

Finding	No. Events	
	Control Group	Trial Group
Infiltrates	8	3
Abrasion	3	2
Corneal ulcer	6	0
Conjunctivitis	21	41
CLARE	5	3
Iritis	5	1
Hypoxia	2	0
GPC	6	13
Foreign body	1	0
Keratitis	4	9
Uvitis	0	2
SPK	0	2
Bacterial infection	0	1

There were no adverse reactions reported as severe in the Trial group. All adverse reactions in this group were reported as mild or moderate.

Slit Lamp Findings

Slit lamp exam results were graded 0 to 4. There were 10 non-serious events (3 control, 7 trial) requiring treatment. There was no apparent trend over time for either group. Findings were not statistically different between the 2 groups. For eyes that completed the study positive slit lamp findings greater than grade 2 were:

corneal edema –0.11% had grade 3+ (control 0.28%).
staining – 0.03% had grade 3+ (control 0.39%).
vascularization – 0% had grade 3+ (control 0%).
injection – 0.19% had grade 3+ (control 0.39%)
infiltrate- 0% had grade 3+ (control 0.06%). No corneal ulcers in trial eyes that completed the study.
tarsal abnormalities – 0.03% had grade 3+ (control 0.11%).
"other" –most prevalent grade 3 findings were conjunctivitis or lid edema, grade 2 were compression rings. 0.27% had grade 3+ (control 0.62%).

In each case for both groups the conditions resolved with no damage to the eyes with the exception of one eye with a grade 3 infiltrate having a scar after treatment. All visual acuities were restored to acuities prior to the events occurring.

Symptoms/Problems/Complaints

There were 29 non-serious events (10 control, 19 trial) that required treatment; none resulted in damage to eye. Among completed eyes, dryness was most prevalent (15.5% trial, 10.5% control), followed by blurred vision (5% trial, 5.4% control) and discomfort (4.5% trial, 5.1% control). Among discontinued eyes, dryness was most prevalent (10.5% trial, 10.5% control), followed by discomfort (5.6% trial, 8.7% control) and other (6.3% trial, 5.3% control). There were no statistically significant differences in tearing, photophobia, halos, itch/burning, spectacle blur, and other

The trial lenses and control lenses performed similarly with respect to patient reported symptoms, problems and complaints. The most frequently reported symptom was dryness for both groups.

Keratometric/Refractive Changes

Keratometry Changes: There were 2 reports in the trial group of mire clarity change from baseline to final exam, but no associated change in BCVA. K measurement changes were substantially clinically equivalent between trial and control groups. Mean K change at the final exam was 0.31/0.34D for completed controls, and 0.34/0.36D for completed trial eyes.

Refractive Changes: Refractive changes were substantially clinically equivalent between trial and control groups. Of completed eyes at 12 months, mean change was 0.22D control and 0.23D trial eyes. Discontinued eyes also had similar mean refractive changes, 0.13D control and 0.12D trial eyes.

Visual Acuity

Visual acuity was reported initially and at each follow-up visits for subjects in both the Control and Trial groups of the study. At the final visit 60.6% of eyes in the Control

group had visual acuity of 20/20 or better and 87.4% had visual acuity better than 20/40. In the Trial group 72.8% had 20/20 or better and 93.4% had better than 20/40 final visual acuity. In the Trial group there were no eyes with final visual acuity worse than 20/40

Wearing Time

The primary effectiveness endpoint was the percentage of subjects in each group able to successfully maintain the extended wear schedule. For subjects in the Trial group, 85.8% were able to wear lenses for 7 days. For subjects in the Control group, 83.8% were able to wear lenses for 7 days. There are no statistically significant differences for wearing time between the two lens groups with both having an average lens wearing time of 6.87 days.

Discontinued Patients

There were 82 eyes (27%) discontinued from the Control group and 146 eyes (23.9%) discontinued from the Trial group. Multiple reasons were cited for discontinuance. The main reasons for discontinuing the study were as follows:

Reason	Control	Trial
Protocol violation	6.6%	6.9%
Lost-to-follow-up	5.9%	4.3%
Discomfort	3.3%	3.3%

Reasons for discontinuance were comparable in both groups.

Lens Replacements

Of the 304 lenses dispensed in the Control group and 610 lenses dispensed in the Trial group, there were 175 lenses (57.6%) replaced in the Control group and 531 lenses (87.0%) replacements in the Trial group. The most prevalent reasons for replacement were as follows:

Reason	Control	Trial
Torn	17.4%	56.4%
Comfort	15.8%	11.6%
Visual acuity	9.2%	4.8%

There was a higher rate of unscheduled replacements for the trial group early in the study due to lenses adhering to the blister packages, but this was remedied (trial and control similar rates) once the packaging design was modified.

XI. CONCLUSIONS DRAWN FROM STUDY

The results of the preclinical and clinical studies provide reasonable assurance of the safety and effectiveness of the VISTAKON (lenefilcon A) soft contact lens for the patient population, refractive conditions and specified duration of wear.

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII CDRH DECISION

FDA issued an approval order on February 16, 2001. The applicant's manufacturing facility was inspected on February 2, 2001 and was found to be in compliance with the device Quality System Regulations.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling

Hazards to Health from Use of the Device: See the Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.

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