SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: samfilcon A soft (hydrophilic) contact lens

Device Trade Name: Bausch + Lomb ULTRA (samfilcon A) Contact Lenses

Device Procode: LPM

Applicant's Name and Address: Bausch + Lomb, Inc.
1400 Goodman Street
Rochester, NY 14609

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P170035

Date of FDA Notice of Approval: April 30, 2018

II. INDICATIONS FOR USE

Single Vision Spherical (SVS) Vision Correction
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

Presbyopia Vision Correction
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens For Presbyopia is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner . The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for add powers ranging from +0.75D to +5.00D.

Astigmatism Vision Correction
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens For Astigmatism is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism up to 5.00 diopters.

III. CONTRAINDICATIONS

Do not use the Bausch + Lomb ULTRA (samfilcon A) Contact Lenses when any of the following conditions exist:

- Acute and 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)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) 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 Bausch + Lomb Ultra (samfilcon A) Soft (hydrophilic) Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Bausch + Lomb ULTRA (samfilcon A) Contact Lenses labeling.

V. DEVICE DESCRIPTION

Bausch + Lomb ULTRA (samfilcon A) Contact Lenses are is 46% water and 54% samfilcon A
material. The samfilcon A material is a hydrophilic copolymer of siloxane methacrylate, a siloxane cross-linker, and N-vinyl pyrrolidone. It is tinted blue for visibility with Reactive Blue Dye 246, a color additive that conforms to 21 CFR Part 73.3106. The Bausch + Lomb ULTRA (samfilcon A) Contact Lenses utilizes MoistureSeal® technology. In its hydrated state, the Bausch + Lomb ULTRA (samfilcon A) Contact Lens, when placed on the cornea acts as a refracting medium to focus light rays on the retina.

LENS PARAMETERS

The lens designs include spherical, toric, and multifocal lenses in the following parameter ranges:

Diameter	13.5mm to 15.0mm
Center Thickness	0.05mm to 0.75mm (varies with power)
Base Curve	7.8mm to 9.5mm
Power Range	+20.00D to -20.00D
Cylinder Power (Toric)	-0.75D to -5.00D

Cylinder Axis (Toric)	10° to 180° in 10° increments
Add Power (Multi-Focal)	+0.75D to +5.00D

The Ultra (samfilcon A) Contact Lens has the following physical properties:

Refractive Index:	1.411
Light Transmittance:	C.I.E. value – at least 95%
Water Content:	46%
Specific Gravity:	1.048
Oxygen Permeability:	$114 \times 10^{-11}[cm^3O_2(STP) \times cm]/(sec \times cm^2 \times mmHg)$@35°C (polarographic method)

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes. The currently available alternate practices and procedures for vision correction are other commercially available contact lenses approved for extended wear, spectacles, refractive keratoplasty, laser-assisted in-situ keratomileusis (LASIK), and corneal implants. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The Bausch + Lomb ULTRA (samfilcon A) Contact Lenses were cleared for daily wear use under 510(k) K131208 on September 11, 2013, Summary information is available on the FDA website at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K131208. The cleared lenses under K131208 are commercially available for daily wear in the United States, as well as in Canada, Mexico, European Union, South America, Australia, New Zealand, India, Russia, South Africa, United Arab Emirates, Asia Pacific, and many other countries worldwide. These lenses are not currently marketed for extended wear outside the United States. These lenses have not been withdrawn from the market for any reason related to the safety or effectiveness of the device.

VIII. PROBABLE ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The specific probable adverse reactions that may occur include the following:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)

- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

For the specific adverse events (AEs) that occurred during the Bausch + Lomb Ultra (samfilcon A) Contact Lens clinical study, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

A. Laboratory Studies

1. Biocompatibility

Non-clinical biocompatibility testing was conducted in accordance with FDA's *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses,* May 1994 and GLP regulation (21 CFR part 58) and applicable standards, which represents the basic level of biocompatibility testing for all contact lenses. These tests include: cytotoxicity, acute systemic toxicity, ocular irritation (<24 hours) and sensitization testing. To address biocompatibility issues related to the extended wear indication of greater than 24 hours, an ocular irritation study was conducted to support duration of exposure.

Non-clinical testing performed includes the following referenced standards:

- Biocompatibility testing per ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 9394

All test results met the pre-established acceptance criteria.
The testing performed on the Ultra (samfilcon A) extended wear soft contact lens demonstrates the lens is safe. Non-clinical testing included conformance to predetermined specifications.

Table 1: Biocompatibility – Ultra (samfilcon A) extended wear soft contact lens

Test Method	Acceptance	Results
Cytotoxicity – Direct Contact ISO 10993-5, clause 8.3	≤ grade 2 (mild reactivity)	The test article is considered non-cytotoxic; there was no evidence of causing cell lysis or cytotoxicity to L-929 cells (Grade 0 – no reactivity).
Cytotoxicity – MEM Elution ISO 10993-5: clause 8.2	≤ grade 2 (mild reactivity)	The test article extracts showed no evidence of causing cell lysis or cytotoxicity (Grade 0 – no reactivity).

Acute Systemic Toxicity ISO 10993-11, clause 5	Success was defined as follows: None of the Treated mice exhibited a significantly greater reaction than the control mice. <2 Treated mice died or exhibited abnormal behavior and <3 Treated mice exhibited weight loss of >2 grams	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.
Irritation – Ocular ISO 10993-10: Annex B.2	No significant irritation over the reagent control	There was no evidence of significant irritation in the test eye or control eye of any animal. The sodium chloride and sesame oil test article extracts are not considered irritants to the ocular tissue of the rabbit.
Sensitization - Guinea Pig Maximization ISO 10993-10: clause 7.5	Grade 0 reaction	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article is not considered a sensitizer in the guinea pig maximization test.
22 Day Ocular Irritation ISO 9394	Macroscopic ocular reaction grades (Draize scoring), minimal conjunctivitis (e.g. scores of 1) was not considered clinically significant. Biomicroscopic slit lamp data was evaluated in accordance with McDonald-Shadduck criteria. Lactic acid data was compared between groups to determine biological relevance.	No ocular irritation trends. Microscopic evaluation of the ocular tissue revealed that the test and control eyes were similar to each other and were essentially normal. The test and control values obtained in the corneal lactic acid analysis indicated that the samfilcon A contact lenses had no clinical effect on oxygen transport or corneal metabolism.

The Bausch + Lomb ULTRA (samfilcon A) Contact Lenses are packaged in a polypropylene blister pack. The materials were subjected to cytotoxicity, systemic toxicity and ocular irritation testing. A summary of the testing is provided below:

Table 2: Biocompatibility – Bausch + Lomb ULTRA (samfilcon A) Contact Lenses **packaging**

Test Method	Acceptance criteria	Results
Cytotoxicity – MEM Elution ISO 10993-5, clause 8.2	≤ grade 2 (mild reactivity	The test article extracts showed no evidence of causing cell lysis or cytotoxicity (Grade 0 – no reactivity).
Acute Systemic Toxicity ISO 10993-11, clause 5	Success was defined as follows: None of the Treated mice exhibited a significantly greater reaction than the control mice. <2 Treated mice died or exhibited abnormal behavior and <3 Treated mice exhibited weight loss of >2 grams	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.
Irritation – Ocular ISO 10993-10, Annex B.2	No significant irritation over the reagent control	No evidence of significant irritation in the test or control eye of any rabbit.

2. Physicochemical Tests

Physicochemical tests were performed to demonstrate long term safety and stability of the properties of the material used to manufacture the Ultra lens. See the following table for a summary of results.

Test	Purpose	Acceptance Criteria	Results
Preservative Uptake and Release	To determine the preservative uptake and release of the contact lens material	N/A	No significant uptake of either Polyaminopropyl Biguanide (PAPB) or Polyquaternium-1.
Compatibility	To determine compatibility	After 30-	Pass

with Lens Care Products	of contact lens care products with contact lenses	cycles, contact lens parameters should be within the finished product specifications	
Extractables – Leachability	To determine if any monomer, initiator, or tint leached out during extraction with water	N/A	No detectable levels of monomers, initiator, or tint were found in any of the purified water leachate.
Extractables - Soxhlet Extraction	The quantity of extractables from the Soxhlet extraction	N/A	The extractables ranged from 0.52% - 1.01% for water and 1.31% - 1.59% for n-hexane

3. Sterilization, Bioburden, and Shelf Life

The Bausch + Lomb ULTRA (samfilcon A) Contact Lenses are provided in a polypropylene blister and sealed with aluminum lid stock. The packaging solution is a sterile borate buffered saline with 0.5% poloxamine solution. The packaged lenses are steam sterilized in a validated autoclave. Each lens is labeled with the lens parameters, lot number and expiration date and placed in boxes with multiple packaging configurations and appropriate labeling.

Routine bioburden testing is performed prior to sterilization. This testing provides an assessment of the cleanliness of the devices being manufactured and the facility in general. The bioburden test method was validated in accordance with ISO Standard 11737-1:2006, "Sterilization of health care products – Microbiological methods – Part 1: Determination of the population of microorganisms on product."

The Bausch + Lomb ULTRA (samfilcon A) Contact Lenses are terminally sterilized by subjecting the finished device to moist heat sterilization. The moist heat sterilization cycle was validated using the overkill method (partial cycle approach) in accordance with Annex D of ISO Standard 17665-1:2006, "Sterilization of health care products –Moist heat – Part 1: Requirements for the development, validation and routine control of sterilization process for medical devices." The sterilization process for the device was validated to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Shelf life studies have been conducted to verify that the packaging for the Bausch + Lomb ULTRA (samfilcon A) Contact Lenses maintains a sterile barrier and adequately protects the device through the expiration date on the package label,

which is 3 years from the date of sterilization. Shelf life testing has also been conducted to verify that device physical and optical properties satisfy the requirements of the engineering drawings and product specification document through the 3 year labeled expiration date. All test samples satisfied all acceptance criteria (see **Table 4**).

Table 4: Sterility, Bioburden, and Shelf Life

Test	Purpose	Acceptance Criteria	Results
Bioburden testing	Evaluate the cleanliness of the manufacturing process and facility	Vegetative growth: Alert: ≥500 CFU/device Action: ≥1,000 CFU/device Spores: Alert: ≥10 CFU/device Action: ≥20 CFU/device	Pass
Moist Heat Sterilization Validation	Evaluate sterility	No positive biological indicators	Pass
Package Evaluation – Dye Penetration Testing	Evaluate whole package integrity	No evidence of dye across seal by a defined channel	Pass
Sterility testing	Evaluate sterility	Negative for growth	Pass
Shelf-life	To establish the expiration date	Finished Product Specifications	3 years

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the Bausch + Lomb Ultra (samfilcon A) Contact Lenses when worn for up to 7 days extended wear for the optical correction of refractive ametropia and presbyopia in persons with non-diseased eyes in the United States under IDE # G130282. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Subjects were treated between April 30, 2015 and August 3, 2016. The database for this PMA reflected data collected through August 3, 2016 and included 816 enrolled subjects. There were 406 subjects between the ages of 18 and 40 (812 eyes) in the

Bausch + Lomb Ultra investigational group and 410 subjects (820 eyes) in the Bausch + Lomb PureVision (balafilcon A) control group. There were 34 investigational sites. The study was a prospective, multi-center, two-arm cohort study, randomized, double-blinded, 12-month clinical study. Subjects were 1:1 randomized to one of the two study groups. Randomization was stratified by site.

For the primary safety analysis, the null hypothesis was that the proportion of subjects with serious or significant non-serious adverse events (AEs) in the Ultra lens group minus the proportion of subjects with serious or significant non-serious AEs in the PureVision lens group was 0.05 (5%) or more. The alternative hypothesis was that the difference in proportions was less than 0.05. If the null hypothesis was rejected, then the test lens would be statistically successful in demonstrating non-inferiority to the control lens.

For the primary effectiveness analysis, high contrast distance lens visual acuity (VA) was obtained at the Screening/Dispensing Visit, and at each follow-up visit. Scores were recorded as the number of letters correctly identified in the eye examination. VA was converted to the Log10 of the Minimum Angle of Resolution (logMAR) by using the score (number of letters), and the 12-Month visit VA was compared between treatment groups.

Continuous data were summarized using descriptive statistics: n, mean, median, standard deviation (SD), minimum, and maximum. Categorical data were presented by the total counts for each category and corresponding percentages.

Regarding sample size justification, when the sample size in each group is 326, a two-group large-sample normal approximation test of proportions with a one-sided 0.050 significance level will have 90% power to reject the null hypothesis that Ultra and PureVision are not equivalent in favor of the alternative hypothesis that the proportions in the two groups are equivalent, assuming that the expected difference in proportions is 0.000 and the proportion in the control group is 0.050. Accounting for a total discontinuation rate of up to 20%, at least 326 / (1.0 – 0.2) = 408 subjects were to be enrolled in each group for a total of approximately 816 subjects to be enrolled in the study.

Bausch + Lomb representatives monitored all study site locations to assess the data, quality, and study integrity in a manner consistent with applicable health authority regulations and the procedures adopted by Bausch + Lomb.

Monitoring visits and telephone consultations occurred as necessary, or per the monitoring plan, to verify that the rights and well-being of subjects were protected, the conduct of the investigation was in compliance with the currently approved protocol, the integrity of the data was maintained, the facilities remained acceptable, and test article accountability was ensured.

The control group was an active control; the control treatment, Bausch + Lomb PureVision (balafilcon A) Contact Lenses, is a legally marketed alternative with similar indications for use.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the Study to Evaluate the Safety and Effectiveness of a Silicone Hydrogel Soft Contact Lens When Worn on a 7-Day Extended Wear Basis was limited to subjects who met the following inclusion criteria. Study enrollment limitations included that subjects were required to be of legal age (at least 18) and no older than 40 on the date the Informed Consent Form was signed, subjects were required to be myopic and require lens correction from −0.50 diopters (D) to −6.00 D in each eye, and subjects were required to have clear central corneas and be free of any anterior segment disorders.

   Subjects were not permitted to enroll in the Study to Evaluate the Safety and Effectiveness of a Silicone Hydrogel Soft Contact Lens When Worn on a 7-Day Extended Wear Basis study if they met any of the following exclusion criteria: Subjects were participating in any drug or device clinical investigation within two weeks prior to entry into this study and/or during the period of study participation, subjects who had an active ocular disease or who were using any ocular medication, subjects who were not correctable to 42 letters (0.1 logMAR) in each eye with soft spherical contact lenses, subjects who were using any systemic medications that would, in the Investigator's opinion, affect ocular physiology or lens performance, subjects with any Grade 2 or greater finding during the slit lamp examination, and subjects with corneal infiltrates, of any grade.

2. Follow-up Schedule

   All subjects were evaluated according to the follow-up schedule below (**Table 5**):

Table 5
Follow-up Visit Schedule

Visit	Exam	Target	Visit Window
1	Screening/Dispensing	Day 1	
2	1-Day Follow-up	Day 2	
3	1-Week Follow-up	Day 7	Day 5-9
4	1-Month Follow-up	Day 30	Day 26-34
5	3-Month Follow-up	Day 90	Day 83-97
6	6-Month Follow-up	Day 180	Day 166-194
7	9-Month Follow-up	Day 270	Day 256-284
8	12-Month Follow-up	Day 365	Day 351-379

At the screening/dispensing visit, a slit lamp biomicroscope examination was conducted, a spherocylindrical refraction (and best spectacle corrected visual acuity (BSCVA)) was measured, and keratometry was performed. Following the contact lens fitting, symptoms/complaints were assessed, distance high contrast

visual acuity was measured, contact lens over-refraction and visual acuity were measured, and lens wettability, deposits, centration and movement were assessed.

During the follow-up visits, the slit lamp examination was repeated, symptoms/complaints were assessed, distance high contrast visual acuity was measured, change in visual acuity from baseline was determined, contact lens over-refraction and visual acuity were measured, and lens wettability, deposits, centration and movement were assessed. Contact lenses were replaced monthly. Adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints

With regards to safety,

- The primary safety endpoint was the rate of serious or significant non-serious adverse events during the 12-month follow-up.

Serious adverse events are those events that result in, or have potential to cause, either permanent impairment of an ocular function or damage to an ocular structure, and may necessitate medical or surgical intervention.

Serious adverse events may include any hazardous, sight-threatening conditions occurring after exposure to the test article, including the following:

- A presumed infectious ulcer (defined as a progressive erosion of the corneal tissue);
- Any central or paracentral (within 6mm of cornea) corneal event that results in permanent opacification (such as vascularization);
- Any serious adverse ophthalmic events including hypopyon and hyphema;
- Any neovascularization within the central 6 mm of the cornea;
- Permanent loss of two or more lines of BSCVA;
- All cases of iritis.

Significant Non-Serious Adverse Events include:

- Peripheral non-progressive non-infectious corneal ulcers;
- All symptomatic corneal infiltrative events;
- All cases of corneal staining greater than or equal to Grade 3;
- A temporary loss of two or more lines of BSCVA (for greater than or equal to 2 weeks);
- Neovascularization cases Grade 2 or greater;
- Any ocular event that necessitates temporary lens discontinuation of greater than or equal to 2 weeks.

Secondary safety endpoints included the proportion of eyes with slit lamp findings Grade 2 or greater; AEs and medically treated events; ungraded slit lamp findings; best-spectacle corrected VA line change from baseline; mean subjective

responses to comfort-related symptoms and complaints; lens wettability; lens deposits; centration and movement assessments; changes in keratometry; and changes in refraction.

With regards to effectiveness,

- The primary effectiveness endpoint was high contrast, distance visual acuity (VA) with dispensed lenses at the 12-Month Follow-up Visit.

- The secondary effectiveness endpoint was lens wear time reported as average extended lens wear time (days/week) since last visit.

The null hypothesis for each primary endpoint was that the Ultra lens is inferior to the PureVision lens using the predetermined threshold, or non-inferiority bound, for each endpoint. Rejecting the null hypothesis would provide evidence that the Test lens is at least as good as, or non-inferior to, the Control lens.

With regard to success/failure criteria, the applicant did not define any specific study success criteria beyond the safety and effectiveness endpoints.

The primary and secondary study endpoints were analyzed in two population groups: Dispensed eyes (all eyes dispensed contact lenses) and Eligible Dispensed eyes. Safety endpoints were analyzed using the Dispensed population, and effectiveness endpoints were analyzed using the Eligible Dispensed population.

B. Accountability of PMA Cohort

At the time of database lock, of 816 subjects enrolled in the PMA study, 100% (816) subjects were available for analysis at the completion of the study, the 12-month final visit evaluated for safety and effectiveness as the basis for the PMA submission.

Of the 816 subjects enrolled, 10 (20 eyes) were ineligible at baseline (2 [4 eyes] in the Ultra group and 8 [16 eyes] in the PureVision group). All of the ineligible subjects were discontinued. Of the 816 enrolled subjects, 669 (82.0%) eligible subjects (1,338 eyes) completed the study, 136 (16.7%) eligible subjects (272 eyes) were discontinued, and one (0.1%) eligible subject (2 eyes) was non-dispensed.

Subject accountability is presented in **Table 6**.

Table 6
Ultra Clinical Study Subject Accountability

	Ultra		PureVision		Total	
	n	**%**	**n**	**%**	**n**	**%**
Enrolled (N)	406		410		816	
Eligible at Baseline	404	99.5	402	98.0	806	98.8
--Completed study visit schedule and exited	340	83.7	329	80.2	669	82.0
--Discontinued	63	15.5	73	17.8	136	16.7
--Non-Dispensed	1	0.2	0		1	0.1
Ineligible at Baseline	2	0.5	8	2.0	10	1.2
--Completed study visit schedule and exited	0		0		0	
--Discontinued	2	0.5	8	2.0	10	1.2
--Non-Dispensed	0		0		0	

Percentages (n/N x 100) are based on the number of enrolled subjects within each treatment group.

Regarding reasons for discontinuation, 63 of the 406 Ultra subjects (15.5%), and 73 of the 410 PureVision subjects (17.8%) were discontinued. The major reasons for discontinuation included voluntary withdrawal (24 subjects (3%) for Ultra and 56 subjects (6.8% for PureVision) and lost to follow-up (26 subjects (3.2%) for Ultra and 32 subjects (3.9% for PureVision). Outcomes were similar for adverse events (7 subjects (0.9%) for Ultra and 4 subjects (0.5% for PureVision) and for study-related symptoms/ complaints (15 subjects (0.1%) for Ultra and 15 subjects (0.2% for PureVision). Reasons for discontinuation by eye are presented in **Table 7**.

Table 7
Reasons for Discontinuation by Eye (Dispensed Eyes)

Reason for Discontinuation	**Ultra N = 810 n (%)**	**PureVision N = 820 n (%)**	**Total N = 1630 n (%)**
Adverse event	7 (0.9)	4 (0.5)	11 (0.7)
Positive slit lamp findings	0	2 (0.2)	2 (0.1)
Study related symptoms/complaints	15 (1.9)	15 (1.8)	30 (1.8)
Unacceptable distance lens visual acuity (VA)	1 (0.1)	2 (0.2)	3 (0.2)
Unacceptable lens centration	0	0	0
Unacceptable lens movement	3 (0.4)	0	3 (0.2)
Ineligible at baseline	4 (0.5)	15 (1.8)	19 (1.2)
Inability to maintain recommended wearing schedule	10 (1.2)	4 (0.5)	14 (0.9)
Lack of motivation	0	4 (0.5)	4 (0.2)

Reason for Discontinuation	Ultra N = 810 n (%)	PureVision N = 820 n (%)	Total N = 1630 n (%)
Failure to follow subject instructions	2 (0.2)	2 (0.2)	4 (0.2)
Lost to follow-up	26 (3.2)	32 (3.9)	58 (3.6)
Instillation of a non-medically indicated solution not specified in the protocol	0	0	0
Pregnant	12 (1.5)	14 (1.7)	26 (1.6)
Other eye discontinued	10 (1.2)	5 (0.6)	15 (0.9)
Death	0	0	0
Voluntary withdrawal	24 (3.0)	56 (6.8)	80 (4.9)
Missed >2 follow-up visits	0	0	0
Investigator decision not in the best medical interest of the subject to continue the study	4 (0.5)	0	4 (0.2)
Other	12 (1.5)	7 (0.9)	19 (1.2)
Total	130 (16.0)	162 (19.8)	292 (17.9)

Percentages (n/N x 100) are based on the number of dispensed eyes in each treatment group.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a randomized, prospective, multi-center clinical study performed in the United States.

Table 8 presents the demographic data for the Ultra test group vs. the PureVision control group. Subject demographics were similar between the groups. The mean age was approximately 29 years for both lens groups, females represented more than half of both lens groups, and most subjects in both lens groups were white.

Table 8
Demographics (Eligible, Dispensed Subjects)

	Ultra N=403	PureVision N=402
Age (years)		
N	403	402
Mean (SD)	29.8 (6.2)	29.2 (6.1)
Median	30.0	29.0
Min, Max	18, 40	18, 40
Gender: n (%)		
Female	263 (65.3)	265 (65.9)
Male	140 (34.7)	137 (34.1)

Race: n (%)		
White	326 (80.9)	328 (81.6)
American Indian/ Alaska Native	2 (0.5)	1 (0.2)
Native Hawaiian/ Pacific Islander	0	0
Black/ African American	33 (8.2)	30 (7.5)
Asian	15 (3.7)	19 (4.7)
Other	23 (5.7)	17 (4.2)
Refuses to Answer	4 (1.0)	7 (1.7)

Demographics are reported for all eligible, dispensed subjects. Percentages (n/N x 100) are based on the number of subjects with responses.

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the dispensed cohort of 669 subjects available for the 12 month evaluation: 340 Ultra subjects and 329 PureVision subjects. The key safety outcomes for this study are presented below in Tables 9 to 24. Adverse effects are reported in Tables 9 and 10.

Adverse effects that occurred in the PMA clinical study:

There were no serious adverse events reported for either group.

Overall, 3.0% (24/810) of the Ultra eyes experienced significant non-serious adverse events during the study, compared to 2.4% (20/820) of the PureVision eyes; non-inferiority was met using a predetermined threshold of 5.0%. There were 3 incidents each (0.4%) of peripheral non-progressive non-infectious corneal ulcer associated with the Ultra test and PureVision control lens groups. The adverse events also included 17 (2.1%) Ultra and 8 (1.0%) PureVision incidents of symptomatic corneal infiltrative events, and 6 PureVision control lens ocular events that necessitated ≥2 weeks temporary lens discontinuation. The incidence rates of eyes with significant non-serious adverse events are presented in **Table 9.**

Table 9
Eyes with Significant Non-Serious Adverse Events

	Ultra	**PureVision**
	n (%)	**n (%)**
Dispensed Eyes (N)	810	820
Total Events	24	20
Eyes with an Event	24 (3.0)	20 (2.4)
Peripheral Non-Progressive Non-Infectious Corneal Ulcer	3 (0.4)	3 (0.4)
Symptomatic Corneal Infiltrative Event	17 (2.1)	8 (1.0)
Corneal Staining Greater than or equal to Grade 3	4 (0.5)	3 (0.4)
Temporary Loss of 2 or more lines of BSCVA	0	0
Neovascularizarion of Grade 2 or greater for ≥ 2 weeks	0	0
Ocular Event that necessitates temporary lens discontinuation	0	6 (0.7)

for ≥ 2 weeks		

Percentages (n/N x 100) are based on the number of dispensed eyes in each treatment group.

Other adverse events were grouped by graded findings ≥ Grade 2 and ungraded findings. There were 50 (6/2%) reports of upper lid tarsal conjunctival abnormalities associated with Ultra test lens compared to 73 (9.6%) with PureVision, and 12 (1.5%) Ultra test lens reports of corneal infiltrates compared to 6 (0.7%) with PureVision. **Table 10** summarizes the outcomes for Other Adverse Events.

Table 10
Other Adverse Events
(Dispensed Eyes Over All Follow-up Visits)

	Ultra N=808 n (%)	**PureVision N=816 n (%)**
Graded Findings >= Grade 2		
Asymptomatic corneal infiltrates	2 (0.2%)	1 (0.1%)
Upper lid tarsal conjunctival abnormalities	50 (6.2%)	73 (9.6%)
Corneal Infiltrates	12 (1.5%)	6 (0.7%)
Ungraded Findings		
Conjunctivitis	28 (3.5%)	30 (3.7%)

Percentages (n/N x 100) are based on the number of dispensed eyes in each treatment group.

Biomicroscopy findings for each dispensed eye, assessed at the Screening/ Dispensing Visit (baseline) and at each follow-up visit, were graded for severity on a scale from 0 (No Finding) to 4 (Severe Finding). Over All Follow-up Visits, ≥ Grade 2 findings were noted in 114 (14.1%) eyes in the Ultra group and 152 (18.6%) eyes in the PureVision group. **Table 11** provides comparisons between groups for eyes with slit lamp findings ≥ Grade 2.

Table 11
Graded Slit Lamp Findings Over All Follow-up Visits, Eyes with Findings ≥ Grade 2 (Dispensed Eyes)

Finding	**Ultra N=808 n (%)**		**PureVision N=816 n (%)**	
	Absent	**Present**	**Absent**	**Present**
Any Finding	694 (85.9)	114 (14.1)	664 (81.4)	152 (18.6)
Epithelial Edema	804 (99.5)	4 (0.5)	812 (99.5)	4 (0.5)
Epithelial Microcysts	808 (100.0)	0	815 (99.9)	1 (0.1)
Corneal Staining	775 (96.2)	31 (3.8)	739 (91.5)	69 (8.5)
Limbal Injection	783 (96.9)	25 (3.1)	799 (97.9)	17 (2.1)

Finding	Ultra N=808 n (%)		PureVision N=816 n (%)	
	Absent	Present	Absent	Present
Bulbar Injection	768 (95.0)	40 (5.0)	784 (96.1)	32 (3.9)
Corneal Infiltrates	796 (98.5)	12 (1.5)	810 (99.3)	6 (0.7)
Corneal Neovascularization	808 (100.0)	0	816 (100.0)	0
Upper Lid Tarsal Conjunctival Abnormalities	758 (93.8)	50 (6.2)	740 (90.7)	76 (9.3)

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores.

Table 12 presents Eyes with Device-Related Medically Treated Adverse Events. There were 14 (1.7%) Ultra test lens related events compared to 8 (1.0%) PureVision control lens related events.

Table 12
Eyes with Device-Related Medically Treated Adverse Events (Dispensed Eyes)

	Ultra N=810 n (%)	PureVision N=820 n (%)
Eyes with medically treated lens-related significant non-serious AEs		
Total Non-Missing	810	820
Yes	14 (1.7%)	8 (1.0%)
No	796 (98.3%)	812 (99.0%)
Missing	0	0

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores.

Ungraded slit lamp findings were marked as either present or absent for each eye. Over All Follow-up Visits, for Any Finding, there were 146 (18.1%) eyes in the Ultra group and 101 (12.4%) eyes in the PureVision group with ungraded slit lamp findings. Regarding anterior segment abnormalities, which included but were not limited to circumlimbal conjunctival staining, Grade 1-2 inferior papillae, pinguecula, and pterygium, there were 109 (13.5%) reports with the Ultra test lenses, compared to 60 (7.4%) with the PureVision control lenses. Also included were 9 (1.1%) Ultra test lens reported new corneal scars, compared to 3 (0.4%) PureVision control lens new corneal scars. In addition, regarding symptoms associated with corneal infiltrates, there were 19 (2.4%) Ultra test lens reported incidents, compared to 9 (1.1%) PureVision control lens incidents. **Table**

13 presents the ungraded slit lamp findings for the Ultra and PureVision groups, based upon all dispensed eyes.

Table 13
Ungraded Slit Lamp Findings (Dispensed Eyes)

	Eyes With Findings							
	Ultra N=810				PureVision N=820			
	Absent		Present		Absent		Present	
	n	%	n	%	n	%	n	%
Any Finding								
Screening/Dispensing	773	95.4	37	4.6	785	95.7	35	4.3
Over All Follow-up Visits	662	81.9	146	18.1	715	87.6	101	12.4
1-Day Follow-up Visit	772	96.3	30	3.7	796	98.5	12	1.5
1-Week Follow-up Visit	743	92.2	63	7.8	785	97.4	21	2.6
1-Month Follow-up Visit	743	94.1	47	5.9	756	95.7	34	4.3
3-Month Follow-up Visit	705	93.0	53	7.0	727	96.7	25	3.3
6-Month Follow-up Visit	677	94.0	43	6.0	705	96.3	27	3.7
9-Month Follow-up Visit	647	93.0	49	7.0	663	96.4	25	3.6
12-Month Follow-up Visit	645	94.6	37	5.4	638	97.0	20	3.0

Percentages (n/N x 100) are based on the number of eyes with non-missing scores in each treatment group.

High contrast distance BSCVA was obtained at the Screening/Dispensing Visit (baseline) and again at the Exit Visit. VA was calculated as the Log_{10} of the Minimum Angle of Resolution (logMAR) by converting the number of letters correctly identified to the logMAR equivalent. An eye was considered to have worsened 2 or more Snellen lines if the difference in logMAR VA $\geq$ 0.2 (exit BSCVA – baseline BSCVA). Over All Follow-up Visits, there were no eyes in either group with a 2 or more line decrease in BSCVA from baseline to exit (refer to **Table 14**).

Table 14
High Contrast Distance VA Line Change: Baseline BSCVA Versus Exit BSCVA (Dispensed Eyes)
Eyes With a 2 or More Line Decrease in VA

	Ultra N=810		PureVision N=820	
	Absent n (%)	Present n (%)	Absent n (%)	Present n (%)
Exit BSCVA	776 (100.0)	0	772 (100)	0

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores in each treatment group.

Symptoms/complaints were collected for each eye for each subject at the Screening/ Dispensing Visit after the study lens was inserted and at each scheduled visit based on the subject's experience with the study lenses. Subject symptoms and complaints were assessed on a scale from 0 to 100, with 0 denoting the most unfavorable symptoms/complaints; the rating scale included descriptors at 20-point intervals to help standardize subject responses. The outcomes indicated there were generally more reports of unfavorable symptoms/complaints associated with the PureVision lens group. **Table 15** presents the proportion of eyes with unfavorable symptoms/complaints (scores < 50) compared between the Ultra and PureVision groups, based upon all dispensed eyes.

Table 15
Summary of Unfavorable Symptoms/Complaints: Over All Follow-up Visits (Dispensed Eyes)

Symptoms/Complaints	**Ultra N=810 n (%)**	**PureVision N=820 n (%)**
Burning/Stinging Upon Insertion	28 (3.5)	48 (6.0)
Comfort Upon Insertion	29 (3.6)	46 (5.7)
Vision Upon Insertion	15 (1.9)	18 (2.2)
Overall Comfort	72 (8.9)	130 (15.9)
Comfort at End of Day	86 (10.6)	150 (18.4)
Dryness	106 (13.1)	208 (25.5)
Ease of Handling/Insertion	24 (3.0)	22 (2.7)
Ease of Handling/Removal	20 (2.5)	30 (3.7)
Itchiness	82 (10.1)	96 (11.8)
Lens Cleanness Upon Removal	42 (5.2)	86 (10.7)
Lens Handling	11 (1.4)	20 (2.5)
Overall Impression	45 (5.6)	93 (11.4)
Redness	86 (10.6)	65 (8.0)
Vision	35 (4.3)	64 (7.8)
Vision at End of Day	44 (5.4)	76 (9.3)
Vision in Low Light	32 (4.0)	67 (8.2)

Percentages (n/N x 100) are based on the number of eyes with non-missing scores in each treatment group. Scores are captured on a scale from 0 to 100, with 100 being the most favorable score. Unfavorable symptoms/complaints are defined as scores < 50.

Lens wettability was assessed at the Screening/Dispensing Visit on the newly dispensed lens and at each follow-up visit, using a scale of Optimal, Slight, Mild, Moderate and Severe. Over All Follow-up Visits, 294 (36.3%) eyes in the Ultra group exhibited suboptimal (< 100% of the anterior lens surface rated wettable)

lens wettability, compared to 308 (37.9%) eyes in the PureVision group. **Table 16** presents lens wettability over all follow-up visits.

Table 16
Lens Wettability Over All Follow-up Visits (Dispensed Eyes)

	Ultra N=810 n (%)	**PureVision N=820 n (%)**
Optimal: 100% of anterior lens surface is wettable	516 (63.7)	504 (62.1)
Slight: Presence of small (<0.1 mm), individual, discrete, non-wetting areas	196 (24.2)	205 (25.2)
Mild: Presence of single area of non-wetting between 0.1 mm and 0.5 mm in size	52 (6.4)	47 (5.8)
Moderate: Presence of several areas of non-wetting, each between 0.1 mm and 0.5 mm in size	45 (5.6)	47 (5.8)
Severe: Presence of one or more non-wetting areas greater than 0.5 mm in size	1 (0.1)	9 (1.1)

Percentages (n/N x 100) are based on the number of eligible, dispensed eyes with non-missing scores in each treatment group. Events with multiple visits in a visit category are counted once for the most severe lack of wettability. Over All Follow-up Visits summarizes the worst case over all follow-up visits.

Three qualities of lens deposits were assessed at the Screening/ Dispensing Visit (for the dispensed lenses) and at each follow-up visit. Type of deposits were captured as none, crystalline, crust-like, film, or spots; percent coverage of deposits were assessed as none, 1-25%, 26-50%, 51-75% or 76-100%; and degree of deposits were assessed as none, light, medium, or heavy. Over All Follow-up Visits, 60 (7.4%) eyes in the Ultra group and 83 (10.2%) eyes in the PureVision group had suboptimal lens deposits (a deposit degree rating of medium or heavy, regardless of the type or percent coverage). **Tables 17** and **18** present summaries of the proportions of eyes with suboptimal lens deposits.

Table 17
Eyes with Suboptimal Lens Deposits (Dispensed Eyes)

Visit	Ultra N=810		PureVision N=812	
	Absent n (%)	Present n (%)	Absent n (%)	Present n (%)
Over All Follow-up Visits	750 (92.6)	60 (7.4)	729 (89.8)	83 (10.2)

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores in each treatment group. The total scores are used for analysis. Suboptimal lens deposits are defined as a degree of deposits of medium or heavy.

Table 18
Lens Deposits: Over All Follow-Up Visits by Deposit Category (Dispensed Eyes)

	Ultra n (%)	PureVision n (%)
Total Non-missing (N)	810	812
None	334 (41.2)	313 (38.5)
Light	416 (51.4)	416 (51.2)
Medium	60 (7.4)	79 (9.7)
Heavy	0	4 (0.5)

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores in each treatment group. Over All Follow-up Visits summarizes the worst case over all follow-up visits.

Contact lens centration was assessed at the Screening/Dispensing Visit on the newly dispensed lens and at each follow-up visit, using the following scale:

- Excellent (fully centered);
- Good (slight decentration, no corneal exposure);
- Fair (decentration, intermittent corneal exposure);
- Poor (incomplete corneal coverage and/or edge lift).

Suboptimal lens centration was defined as any rating other than excellent. Over All Follow-up Visits, lens centration was reported as excellent in 715 (88.3%) eyes in the Ultra group and 737 (90.8%) eyes in the PureVision group (**Table 19**). Suboptimal lens centration is depicted in **Table 20.**

Table 19
Lens Centration Over All Follow-up Visits (Dispensed Eyes)

	Ultra n (%)	**PureVision n (%)**
Total Non-Missing (N)	810	812
Excellent (fully centered	715 (88.3)	737 (90.8)
Good (slight decentration, no corneal exposure)	89 (11.0)	71 (8.7)
Fair (decentration, intermittent corneal exposure)	2 (0.2)	3 (0.4)
Poor (incomplete corneal coverage and/or edge lift)	4 (0.5)	1 (0.1)

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores in each treatment group. Over All Follow-up Visits summarizes the worst case over all follow-up visits.

Table 20
Eyes with Suboptimal Lens Centration (Dispensed Eyes)

Visit	**Ultra N=810**		**PureVision N=820**	
	Absent n (%)	**Present n (%)**	**Absent n (%)**	**Present n (%)**
Screening/Dispensing	772 (95.5)	36 (4.5)	806 (98.3)	14 (1.7)
Over All Follow-up Visits	715 (88.3)	95 (11.7)	737 (90.8)	75 (9.2)

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores in each treatment group.

Contact lens movement was assessed at the Screening/Dispensing Visit on the newly dispensed lens and at each follow-up visit using the following scale:

- Adequate
- Excessive (> 0.6 mm)
- Insufficient (< 0.2 mm)
- Adherence

Over All Follow-up Visits, lens movement was reported as adequate for 730 (90.1%) eyes in the Ultra group and 771 (95.0%) eyes in the PureVision group (**Table 21**). Suboptimal lens movement is defined as a rating other than adequate. There were 80 (9.9%) eyes in the Ultra group and 41(5.0%) eyes in the PureVision group Over All Follow-up Visits with suboptimal lens movement. The majority of the Ultra suboptimal lens movement was due to insufficient movement; see **Table 22**. In addition, over All Follow-up Visits, there were 6 (0.7%) eyes in the Ultra group and 4 (0.5%) eyes in the PureVision groups with lens adherence.

Table 21
Suboptimal Lens Movement (Dispensed Eyes)

Visit	Ultra N=810		PureVision N=820	
	Absent n (%)	Present n (%)	Absent n (%)	Present n (%)
Over All Follow-up Visits	730 (90.1)	80 (9.9)	771 (95)	41 (5.0)

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores in each treatment group. The Total scores are used for analysis. Suboptimal lens movement is defined as a score other than Adequate.

Table 22
Lens Movement Over All Follow-up Visits (Dispensed Eyes)

	Ultra n (%)	PureVision n (%)
Total Non-Missing (N)	810	812
Adequate	730 (90.1)	771 (95.0)
Excessive (> 0.6 mm)	4 (0.5)	13 (1.6)
Insufficient (< 0.2 mm)	70 (8.6)	24 (3.0)
Adherence	6 (0.7)	4 (0.5)

Percentages (n/N x 100) are based on the number of dispensed eyes with non-missing scores in each treatment group. Over All Follow-up Visits summarizes the worst case over all follow-up visits where Adherence is considered most severe, followed by Insufficient and Excessive.

Table 23 summarizes keratometry changes from baseline to Exit Visit for all dispensed eyes. There were 25 eyes (3.2%) in the Ultra group and 19 eyes (2.5%) in the PureVision group with a change in keratometry (absolute value of ≥ 1.00 D).

Table 23
Keratometry Changes (Absolute Value) from Baseline to Exit Visit in the Meridian with the Largest Change (Dispensed Eyes)

	Ultra N=776 n (%)	PureVision N=772 n (%)
Diopters		
0.00-0.99	751 (96.8)	753 (97.5)
1.00-1.99	22 (2.8)	13 (1.7)
2.00-2.99	2 (0.3)	2 (0.3)
3.00-3.99	1 (0.1)	4 (0.5)
4.00-4.99	0	0
≥5.00	0	0
Missing	34	48

Percentages (n/N x 100) are based on the number of non-missing dispensed eyes with responses. Baseline measurements are obtained at the Screening/Dispensing Visit.

Table 24 summarizes spherocylindrical refraction changes from baseline to Exit Visit for all dispensed eyes. There were 2 eyes (0.3%) in the Ultra group and 5 eyes (0.6%) in the PureVision group with a change in refraction of ≥ 1.00 D.

Table 24
Spherocylindrical Refractive Changes (Absolute Value) from Baseline to Exit Visit (Dispensed Eyes)

	Ultra N=776	**PureVision N=772**
Spherocylindrical Refractive Absolute Change (D)		
Mean (SD)	0.10 (0.16)	0.11 (0.17)
Median	0.00	0.00
Min, Max	0.00, 1.00	0.00, 1.00
Categorical Summary: n (%)		
0.00 - 0.99D	774 (99.7%)	767 (99.4%)
1.00 - 1.99D	2 (0.3%)	5 (0.6%)
2.00 - 2.99D	0	0
3.00 - 3.99D	0	0
4.00 - 4.99D	0	0
≥5.00	0	0

Percentages (n/N x 100) are based on the number of non-missing dispensed eyes in each treatment group with responses. Spherocylindrical refraction, or Mean Refractive Spherical Equivalent (MRSE) is calculated as sphere measurement + (cylinder measurement/2).

2. Effectiveness Results

The analysis of effectiveness was based on the Eligible, Dispensed cohort of 658 subjects at the 12-month time point.

Key effectiveness outcomes are presented in Tables 25 to 29.

The primary effectiveness endpoint was high contrast, distance visual acuity (VA) with dispensed lenses at the 12-Month Follow-up Visit. All eyes dispensed study lenses for eligible subjects were included in the analysis under the treatment they actually received. High contrast distance lens VA was obtained at the Screening/ Dispensing Visit, and at each follow-up visit. Scores were recorded as the numbers of letters correctly identified in the eye examination. VA was converted to the Log10 of the Minimum Angle of Resolution (logMAR) by using the score (number of letters). The Ultra lens was found to be non-inferior to the PureVision lens with regard to distance high contrast lens VA with a non-inferiority margin of 0.06. VA at the 12-Month visit was comparable between treatments (**Table 25**). Approximately 97% of subject eyes in the clinical study achieved at least 20/25 with the Bausch + Lomb ULTRA (samfilcon A) contact lens.

Table 25
High Contrast Distance logMAR Lens VA at the 12-Month Follow-up Visit
(Eligible, Dispensed Eyes)

Ultra		PureVision	
n	**LSMean (SE)**	**n**	**LSMean (SE)**
667	−0.063 (0.002)	649	−0.048 (0.002)

Analyses are based on the number of eligible, dispensed eyes with non-missing scores in each treatment group.
LSMean = Least Square Mean

The secondary effectiveness endpoint was lens wear time reported as average extended lens wear time (days/week) since last visit. For this parameter, the subjects in both groups reported mean extended wearing times of 6.7 days per week over all visits (see **Table 26**).

Table 26
Average Weekly Wear Time (Days per Week)
(Eligible, Dispensed Subjects)

Visit	Ultra		PureVision	
	n	**LSMean (SE)**	**n**	**LSMean (SE)**
Over All Follow-up Visits	400	6.7 (0.031)	396	6.7 (0.031)

Over All Follow-up Visits is based on the average weekly wear time over all follow-up visits.

With regard to the line change in visual acuity from baseline over all follow-up visits, Over All Follow-up Visits, 25 (3.0%) eyes in the Ultra group and 30 (3.8%) eyes in the PureVision group experienced a worsening of ≥ 2 lines (≥ 10 letters) from Dispensing Lens VA at any time point. **Table 27** presents the line change in visual acuity from baseline over all follow-up visits.

Table 27
High Contrast Distance Lens VA Line Change: Screening/Dispensed Lens VA versus Follow-up Lens VA Over All Follow-up Visits (Eligible, Dispensed Eyes)

Line Change	Ultra N=806 n (%)	PureVision N=796 n (%)
-9	1 (0.1)	0
-8	0	0
-7	0	0
-6	0	0
-5	0	0
-4	2 (0.2)	2 (0.3)
-3	2 (0.2)	3 (0.4)
-2	20 (2.5)	25 (3.1)
-1	198 (24.6)	261 (32.8)

No Change	575 (71.3)	500 (62.8)
1	7 (0.9)	5 (0.6)
2	1 (0.1)	0
3	0	0
4	0	0

Percentages (n/N x 100) are based on the number of eligible, dispensed eyes with non-missing scores in each treatment group. Positive line changes reflect improved VA. Over All Follow-up Visits summarizes the worst case over all the follow-up visits.

Contact Lens Performance was evaluated at all visits for a number of parameters, based upon a scale of 0 (no symptoms) to 4 (severe symptoms: the lens was very irritating or annoying, and could not be tolerated). For each performance parameter, a categorical parameter was defined as unfavorable if the evaluation was a 3 (moderate) or a 4 (severe), and favorable if the evaluation was 0-2 (no, slight, or mild symptoms).

Over All Follow-up Visits, there were differences between the Ultra group and PureVision group in the proportion of eyes with unfavorable lens performance ratings, as there was a higher proportion of eyes with unfavorable lens performance ratings for the PureVision group for Discomfort, Spectacle Blur, Variable Vision, Blurred Vision, and Lens Needs Cleaning. Over All Follow-up Visits, there were similar proportions of eyes between the two groups with unfavorable lens performance ratings for the remaining parameters which were assessed in **Table 28**.

Table 28
Eyes with Unfavorable Lens Performance Ratings Over All Scheduled Follow-up Visits (Eligible, Dispensed Eyes)

Lens Performance Parameter	**Ultra N=805 n (%)**	**PureVision N=800 n (%)**
Discomfort	128 (15.9)	181 (22.6)
Excessive Tearing	24 (3.0)	16 (2.0)
Photophobia	21 (2.6)	11 (1.4)
Halos	9 (1.1)	13 (1.6)
Itching/Burning	67 (8.3)	68 (8.5)
Spectacle Blur	8 (1.0)	24 (3.0)
Variable Vision	22 (2.7)	39 (4.9)
Blurred Vision	43 (5.3)	66 (8.3)
Lens Needs Cleaning	48 (6.0)	88 (11.0)
Handling	12 (1.5)	22 (2.8)

Only data from scheduled visits are used. Percentages (n/N x 100) are based on the number of eyes with non-missing scores in each treatment group. An unfavorable performance is a score of 3 or 4.

At the start of each follow-up visit, as part of the worn lens evaluation, the subject was asked whether they used rewetting drops. The frequency (count and percent) of subjects using rewetting drops is provided with percent based on the total non-missing responses. Over All Follow-up Visits, 722 (89.6%) eyes in the Ultra group used rewetting drops compared to 748 eyes (93.5%) in the PureVision group (**Table 29**).

Table 29
Rewetting Drop Usage Over All Follow-up Visits
(Eligible, Dispensed Eyes)

Used Rewetting Drops	
Ultra **N=806** **n (%)**	**PureVision** **N=804** **n (%)**
Yes (%)	**Yes (%)**
722 (89.6)	748 (93.5)

Summaries are based on usage reported at scheduled visits. The percentages (n/N x 100) are based on the number of total non-missing eyes.

3. Subgroup Analyses

In this premarket application, there were no preoperative characteristics that were evaluated for potential association with outcomes.

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 34 investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

An Overnight Corneal Swelling Study was conducted to demonstrate the percentage change in overnight average central 2mm corneal thickness was not more than 2% greater with overnight wear of the Bausch + Lomb Ultra (samfilcon A) contact lens compared to no contact lens wear in the same eye of the same participants.

The applicant also conducted two feasibility clinical studies to evaluate the comfort and fitting characteristics on the Ultra Contact Lens when treated with OPTI-FREE PureMoist Multi-Purpose Disinfecting Solution.

No issues regarding device safety or lack of effectiveness were raised by the results from these studies.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) 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. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The overall effectiveness of the Bausch + Lomb Ultra (samfilcon A) contact lens was demonstrated based upon the 12-month results of the IDE clinical investigation.

The primary effectiveness endpoint was high contrast, distance visual acuity (VA) with dispensed lenses at the 12-Month Follow-up Visit. At the 12-Month Follow-up Visit, mean LogMAR was -0.063 for the Ultra test lens and -0.048 for the PureVision control lens, indicating comparable outcomes. Approximately 97% of subject eyes in the clinical study achieved at least 20/25 with the Bausch + Lomb ULTRA (samfilcon A) contact lens.

The secondary effectiveness endpoint was lens wear time reported as average extended lens wear time (days/week) since last visit. The average wearing time since the last visit was 6.7 (±0.031) days for both the Ultra and the PureVision groups over all follow-up visits.

With regard to the line change in visual acuity from baseline, Over All Follow-up Visits, 25 (3.0%) eyes in the Ultra group and 30 (3.8%) eyes in the PureVision group experienced a worsening of ≥ 2 lines (≥ 10 letters) from Dispensing Lens VA.

Over All Follow-up Visits, there were significant differences between the Ultra group and PureVision group in the proportion of eyes with unfavorable lens performance ratings. There was a higher proportion of eyes with unfavorable lens performance ratings for the PureVision group for Discomfort, Spectacle Blur, Variable Vision, Blurred Vision, and Lens Needs Cleaning. Over All Follow-up Visits, the proportions of eyes with unfavorable lens performance ratings were similar between treatment groups or the remaining parameters which were assessed.

Regarding the usage of rewetting drops, the frequency of subjects using rewetting drops was determined with percent based on the total non-missing responses. Over All Follow-up Visits, 722 (89.6%) eyes in the Ultra group used rewetting drops compared to 748 eyes (93.5%) in the PureVision group.

The effectiveness results from the PMA clinical trial provided evidence that the study outcomes met the acceptance criteria.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory studies as well as data collected in the pivotal clinical study conducted to support PMA approval as described above.

The primary safety endpoint was the rate of serious or significant non-serious adverse events during the 12-month follow-up. There were no serious adverse events reported for either lens group.

Overall, 3.0% (24/810) of the Ultra eyes experienced significant non-serious adverse events during the study, compared to 2.4% (20/820) of the PureVision eyes; non-inferiority was met using a predetermined threshold of 5.0%.

Biomicroscopy findings for each dispensed eye were graded for severity on a scale from 0 to 4. Over All Follow-up Visits, ≥ Grade 2 findings were noted in 114 (14.1%) eyes in the Ultra group and 152 (18.6%) eyes in the PureVision group.

Ungraded slit lamp findings were reported. Over All Follow-up Visits, for Any Finding there were 146 (18.1%) eyes in the Ultra group and 101 (12.4%) eyes in the PureVision group with ungraded slit lamp findings.

High contrast distance BSCVA was obtained at the Screening/Dispensing Visit (baseline) and at the Exit Visit. An eye was considered to have worsened 2 or more Snellen lines if the difference in logMAR VA ≥ 0.2 (exit BSCVA – baseline BSCVA). Over All Follow-up Visits, there were no eyes in either group with a 2 or more line decrease in BSCVA from baseline to exit.

Symptoms/complaints were collected for each eye for each subject at the Screening/ Dispensing Visit following lens insertion and at follow-up. The outcomes indicated there were generally more reports of unfavorable symptoms/complaints associated with the PureVision lens group.

Lens wettability was assessed at the Screening/Dispensing Visit on the newly dispensed lens and at each follow-up visit, using a scale of Optimal, Slight, Mild, Moderate, and Severe. Over All Follow-up Visits, the proportion of eyes with suboptimal lens wettability, 294 (36.3%) eyes in the Ultra group, was comparable to the 308 (37.9%) eyes in the PureVision group.

Suboptimal degree of lens deposits was defined as a deposit degree rating of medium or heavy, regardless of the type or percent coverage. Over All Follow-up Visits, 60 (7.4%) eyes in the Ultra group and 83 (10.2%) eyes in the PureVision group had suboptimal lens deposits.

Contact lens centration was assessed at the Screening/Dispensing Visit on the newly dispensed lens and at each follow-up visit, using a scale of Excellent to Poor. Suboptimal lens centration was defined as any rating other than excellent. Over All Follow-up Visits, lens centration was reported as excellent in 715 (88.3%) eyes in the Ultra group and 737 (90.8%) eyes in the PureVision group.

Contact lens movement was assessed at the Screening/Dispensing Visit on the newly dispensed lens and at each follow-up visit. Over All Follow-up Visits, lens movement was reported as adequate for 730 (90.1%) eyes in the Ultra group and 771 (95.0%) eyes in the PureVision group. There were 80 (9.9%) eyes in the Ultra group and 41 (5.0%) eyes in the PureVision group Over All Follow-up Visits with suboptimal lens movement. The majority of the Ultra suboptimal lens movement was due to insufficient movement.

Keratometry changes from baseline to Exit Visit were determined for all dispensed eyes. There were 25 eyes (3.2%) in the Ultra group and 19 eyes (2.5%) in the PureVision group with a change in keratometry (absolute value of $\geq$ 1.00 D).

Regarding spherocylindrical refraction changes from baseline to Exit Visit for all dispensed eyes, there were 2 eyes (0.3%) in the Ultra group and 5 eyes (0.6%) in the PureVision group with a change in refraction of $\geq$ 1.00 D.

The safety results from the PMA clinical trial provided evidence that the study outcomes met the acceptance criteria.

C. Benefit-Risk Determination

The probable benefits of the device are based on data collected in a clinical study conducted to support PMA approval and other clinical studies as described above. The benefits of the subject device include vision correction, as well as the convenience of wearing contact lenses overnight, i.e., without removal, for up to 1 week.

Additional factors to be considered in determining probable risks and benefits for the Bausch + Lomb Ultra (samfilcon A) Soft (hydrophilic) Contact Lens include:

a. The results of the clinical study can be considered generalizable to the intended market or target patient population.

b. Clinical data were collected using a study design that included randomized treatment and masking of subjects and evaluators.

c. Medical adverse events and complications (e.g., risks of infection, inflammation, corneal edema, etc.) are similar to those associated with most other extended wear contact lenses.

1. Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

In conclusion, given the available information above, the data support that for the visual correction of refractive ametropia, the probable benefits of the Bausch + Lomb Ultra (samfilcon A) Contact Lens outweigh the probable risks.

D. Overall Conclusions

The data in this premarket application support the reasonable assurance of safety and effectiveness of the subject device when used in accordance with the Indications for Use. The effectiveness endpoints related to adequate high contrast, distance visual acuity and lens wearing time were met, demonstrating the ability of the Bausch + Lomb Ultra (samfilcon A) Contact Lenses to correct ametropia as well as to provide acceptable lens comfort. The incidence rates of eyes with significant non-serious adverse events were comparable between the two lens groups.

XIV. CDRH DECISION

CDRH issued an approval order on April 30, 2018.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

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

Post-approval Requirements and Restrictions: See approval order.