SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Ophthalmic Excimer Laser System Ophthalmic Refractometer
Device Trade Name:	***iDESIGN***® Refractive Studio and ***STAR S4 IR***® Excimer Laser Systems
Device Procode:	LZS
Applicant's Name and Address:	AMO Manufacturing USA, LLC 510 Cottonwood Dr Milpitas, CA 95035
Date of Panel Recommendation:	None
Premarket Approval (PMA)	
Application Number:	P930016/S057
Date of FDA Notice of Approval:	September 9, 2019

The original ***iDESIGN***® ***Advanced WaveScan Studio*** System was approved with the ***STAR S4 IR***® Excimer Laser System for wavefront-guided laser assisted in situ keratomileusis (LASIK) for the correction of myopic refractive errors on May 6, 2015 in P930016/S044, for the correction of mixed astigmatic refractive errors on November 14, 2016 in P930016/S045, for the correction of hyperopic refractive errors on June 30, 2017 in P930016/S048, and for wavefront-guided monovision LASIK with ***iDESIGN***® Refractive Studio System in myopic patients with presbyopia on June 15, 2018 in P930016/S053. This supplement expands the indication for use to include wavefront-guided photorefractive keratectomy (PRK). This supplement also includes a new updated software (v 2.1) for the ***iDESIGN***® Refractive Studio system.

II. INDICATIONS FOR USE

The ***STAR S4 IR***® Excimer Laser System and the ***iDESIGN***® Refractive Studio is indicated for wavefront-guided photorefractive keratectomy (PRK) in patients:

- With myopia, with or without astigmatism, as measured by ***iDESIGN***® Refractive Studio System with spherical equivalent up to -8.00 D, and cylinder up to -3.00 D.
- With agreement between manifest refraction (adjusted for optical infinity) and ***iDESIGN***® Refractive Studio System refraction as follows:
  - Spherical Equivalent: Magnitude of the difference is less than 0.625 D.
  - Cylinder: Magnitude of the difference is less than or equal to 0.5 D.
- in patients 18 years of age or older,
- with refractive stability (a change of ≤ 1.0 D in manifest refraction spherical equivalent for a minimum of 12 months prior to surgery) and
- with wavefront capture diameter of at least 4 mm.

III. CONTRAINDICATIONS

iDESIGN® System driven PRK surgery is contraindicated:

- in patients with any type of active connective tissue disease or autoimmune disease.
- in patients with signs of keratoconus, abnormal corneal topography, and degenerations of the structure of the cornea.
- in patients with significant dry eyes. If the patients have severely dry eyes, PRK may increase the dryness. This may or may not go away. Severe eye dryness may delay healing of the flap or interfere with the surface of the eye after surgery. It may result in poor vision after PRK.
- in patients whose corneal thickness would cause anticipated treatment to violate the posterior 250 microns (μm) of the corneal stroma.
- in patients with uncontrolled diabetes.
- in patients with active eye infection or active inflammation
- in patients with recent herpes eye infection or problems resulting from past infection

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the ***STAR S4 IR***® Excimer Laser System and ***iDESIGN***® Refractive Studio system labeling.

V. DEVICE DESCRIPTION

A. *iDESIGN*® Refractive Studio

The ***iDESIGN***® Refractive Studio measures the refractive error and wavefront aberrations of the human eye using a high-definition Hartmann-Shack wavefront sensor. The measurements can be used to determine the regular (sphero-cylindrical) refractive errors and irregularities (aberrations) that may cause decreased or blurry vision in the human eye.

The ***iDESIGN***® Refractive Studio system optical head projects a beam of light onto the retina. The light reflects through the optical path of the eye and into the Hartmann-Shack wavefront device. The reflected beam is imaged by a lenslet array onto the charge coupled device (CCD). Each lens of the array gathers light information (deflection information) from a different region of the pupil to form an image of the light that passes through that region of the pupil. An array of spots is imaged on the CCD sensor. The system compares the locations of the array of spots gathered from the CCD to the theoretical ideal (the ideal plane wave).

The ***iDESIGN***® Refractive Studio system software uses these data to compute refractive errors of the eye and wavefront aberrations using Fourier Transform analysis. The target treatment shape is automatically calculated by the ***iDESIGN***® System from the wavefront data. Once the target shape is established, the software generates the commands for the laser to create the target shape on the cornea.

B. STAR S4 IR® Excimer Laser System

The ***STAR S4 IR***® Laser System is a 193 nm excimer laser system that delivers spatially scanning ultraviolet pulses of variable shape and size on to the cornea. Pulse shapes may be circles of variable diameter or slits of variable width and orientation. The range of diameters and slit widths available during treatments is 0.65 mm to 6.5 mm. An auto-centering dual camera infrared eye tracking system, together with the delivery system, aligns the treatment to the eye, and compensates for eye movements during laser correction to maximize the corneal reshaping accuracy. An operating microscope is used to observe the patient procedures and to facilitate accurate focus and laser beam alignment. A debris-removal system is designed to evacuate the debris plume that occurs during ablation. The operating chair and fixation LED align the patient, while a video camera and monitor record the patient treatment.

The variable spot scanning (VSS) feature of the laser, used for ***iDESIGN*®** procedure treatments, delivers variable diameter ultraviolet pulses to precise locations by the scanning delivery system. The VSS algorithm optimizes the ablation pattern by choosing the best combination of beam diameters and locations to achieve a target shape. Wavefront-guided treatments using the ***STAR S4 IR***® and ***iDESIGN***® systems utilize an automated iris registration system. The angle of rotation of the patient's eye under the

laser is determined by comparing features of the iris on the aberrometer image to the same features located in the image of the iris taken using the ***STAR S4 IR***® system camera.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of myopia:

- Glasses or contact lenses.
- Implantable lens surgery (phakic intraocular lens).
- Wavefront-guided or corneal topography-assisted LASIK.
- LASIK, refractive lenticule extraction, or PRK using manifest refraction.

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 ***iDESIGN***® Refractive Studio has been distributed in United States, Canada, Japan, India, Italy, Ireland, Great Britain, and Turkey. The ***STAR S4 IR***® Excimer Laser and ***iDESIGN***® ***Refractive Studio*** systems have been distributed in over 60 countries including Argentina, Australia, Austria, Bangladesh, Belgium, Bolivia, Brazil, Bulgaria, Cameroon, Canada, Chile, China, Colombia, Costa Rica, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Finland, France, Germany, Greece, Hong Kong, Hungary, India, Iraq, Indonesia, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Korea, Kuwait, Lebanon, Malaysia, Martinique, Mexico, Mongolia, Netherlands, New Zealand, Norway, Oman, Paraguay, Peru, Philippines, Poland, Russian Federation, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Taiwan, Thailand, Tunisia, Turkey, United Arab Emirates, United Kingdom, United States, Venezuela, and Vietnam. Neither of these devices have been withdrawn from any country or market for reasons of safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (i.e., complications) associated with the use of the device: decrease in best corrected visual acuity (vision that is corrected with glasses or contact lenses), over-correction or under-correction that may require eyeglasses or contact lens wear, increase in astigmatism, a reduction in the refractive correction over time (regression), unintentional imbalance between the two eyes (anisometropia) that may cause headaches, eye strain, double vision and/or difficulty judging distance or depth perception, patients around 40 years of age or older may need glasses for close work such as reading due to presbyopia, foreign body sensations, pain (including chronic eye pain that is resistant to therapy referred to as neuropathic pain), dry eyes, halos, glare, starbursts, hazy

vision, blurred vision, distortion, double or multiple images (ghost images, images that appear to have a shadow), fluctuating vision, difficulty focusing, difficulty with night driving, eye pain or soreness, feeling of something in the eye, grittiness, light sensitivity, decreased ability to see in low-light conditions (e.g., reading a street sign at dusk), corneal damage (scarring, swelling, cloudiness, haziness, irregular shape, bulging of the cornea (ectasia)), corneal epithelial defect, corneal erosion, corneal ulceration or perforation, corneal decompensation, persistent corneal edema, corneal infection and corneal inflammation, drooping eyelid (ptosis) that may require surgical intervention, increased intraocular pressure, cataract, and retinal detachment.

Also, there may be difficulty with for future ophthalmic assessments, such as appropriate intraocular lens selection for implantation during cataract surgery and intraocular pressure (IOP) assessments.

For the specific adverse events that occurred in the pivotal clinical trial, please see **Section X** (Summary of Primary Clinical Study) below.

IX. SUMMARY OF NONCLINICAL STUDIES

iDESIGN® Refractive Studio

Non-clinical testing was performed to verify and validate the version 2.1 software incorporated into *iDESIGN*® Refractive Studio to ensure the system meets its design requirements. Supplemental Use Case Testing was conducted for the user interface changes of the PRK indication, and the slow Autorefraction option.

STAR S4 IR® Excimer Laser System

Since there were no changes to the hardware in this supplement, the hardware verification testing performed and submitted previously is still applicable. For a summary of the nonclinical studies, please refer to the SSED of the original PMA P930016 (https://www.accessdata.fda.gov/cdrh_docs/pdf/p930016.pdf) and P930016/S44 (https://www.accessdata.fda.gov/cdrh_docs/pdf/P930016S044b.pdf).

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of wavefront-guided photorefractive keratectomy (PRK) using the ***iDESIGN***® Refractive Studio and ***STAR S4 IR***® Excimer Laser System for patients with myopia, with or without astigmatism, as measured by ***iDESIGN***® Refractive Studio with spherical equivalent up to -10.00 D, and cylinder up to -4.00 D in the US under IDE G150113. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between February 2016 and August 2017. The database for this Panel Track Supplement reflected data collected through November 24, 2017* and included 167 subjects. There were 7 investigational sites.

The study was a single-arm, 1-year, prospective, multicenter, bilaterally-treated, open-label, non-randomized clinical study. As refractive stability was reached at 6 months (and confirmed at 9 months), the key safety and effectiveness endpoints are evaluated at 6 months. At the time of database closure for this analysis, 322 eyes (96.4%; 322/334) were evaluated at 6 months, 228 eyes (68.3%; 228/334) were evaluated at 9 months, and 184 eyes (55.1%; 184/334) were evaluated at 12 months.

Descriptive statistics (including sample size [n], mean, standard deviation [SD], minimum, maximum, as appropriate) and frequency distributions were used to summarize clinical outcomes. Confidence intervals for binomial proportions were computed using the Clopper-Pearson exact method. All confidence intervals, statistical tests, and resulting p-values were based on two-sided analyses and assessed at a 0.05 significance level. For continuous variables, statistical tests assuming normality were generally used. However, the data were reviewed to evaluate whether the normality assumption was appropriate. When found not to be appropriate, the corresponding non-parametric tests were used.
For visual acuity data, Early Treatment Diabetic Retinopathy Study (ETDRS) letter scores were converted to LogMAR values prior to analysis. For refractive data, the sphere component of the manifest refraction (as tested at 4.0 m) was adjusted for optical infinity by adding -0.25 D to the sphere magnitude. Similarly, manifest refraction spherical equivalent (MRSE) was calculated using the adjusted manifest sphere value. Additionally, all refractions were converted to minus cylinder format and adjusted for vertex distance (standardized to 12.5 mm).
Outcomes stratifications of the key effectiveness and safety endpoints were conducted by age, gender, race, site, preoperative contact lens wear, preoperative iDesign spherical equivalent (IDSE), preoperative iDesign sphere (IDS), preoperative iDesign cylinder (IDC), wavefront capture diameter, iris registration status, and clinically significant protocol deviations. Additionally, covariate analyses of the effect on key study endpoints for any factors found to have statistically significant differences among stratification categories were conducted.

Per ANSI Z80.11-2012, Annex E, the sample size calculation is to be based on the probability of observing an adverse event at a rate greater than or equal to the expected rate but less than or equal to an acceptable target. This study was powered to detect the percentage of eyes losing 2 or more lines of BSCVA at 3 months. In the approved indication for the original ***STAR S4 IR***® System wavefront-guided LASIK Myopia clinical study (PMA P930016-S016, approved 05/23/03), the percentage of eyes losing 2 or more lines of BSCVA at 3 months was 0.3% (1/318, 95% exact CI (0.00%, 1.7%)). Using the binomial distribution with an alpha of 0.05, 80% power and a sample size of n=300 eyes, a rate of at least 1% can be detected. Adding 15% for loss due to attrition yields a sample size of 334 eyes (167 subjects) to be treated in order to achieve 300 evaluable eyes at the

* The vector analysis included on Table 33 was based on 324 evaluable patients at the 6-month time-point at final database lock on August 24, 2018.

point of refractive stability. Adding an additional 50% to account for screen failures allowed approximately 334 subjects to be enrolled.

Sample size was also calculated for the contrast sensitivity substudy. The sample size calculation for the substudy was based on ANSI guidance (ANSI Z80.11) using non-inferiority approach. With a sample size of 65, a paired t-test with a 0.05 one-sided significance level would have over 90% power to detect the paired difference in mean contrast sensitivity was no less than 0.15 below zero when the expected mean difference was 0, assuming the non-inferiority margin equals 0.15 and the standard deviation of the differences was 0.40.

1. Subject Selection and Eligibility Criteria

Enrollment in this study was limited to subjects who met the following eligibility criteria. Subjects who agreed to participate provided informed consent and underwent the required screening procedures to determine eligibility. To qualify for enrollment, subjects were to meet all eligibility criteria for both eyes and intend to have bilateral PRK for the treatment of myopic refractive errors. In general, eyes were to be healthy with myopic refractive errors of up to -10.00 D of spherical equivalent with cylinder between 0.00 and -4.00 D, as measured using the ***iDESIGN***® aberrometer.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in this study was limited to patients who met the following inclusion criteria.

i. Subject Inclusion Criteria

- Signed informed consent and HIPAA authorization.
- At least 18 years of age.
- The refractive error, based on the ***iDESIGN*®** displayed refraction selected for treatment ("4.0 Rx calc" at 12.5 mm), must be myopia with or without astigmatism with sphere up to -8.00 D, and cylinder between 0.00 D and -4.00 D with a maximum spherical equivalent (SE) of -10.00 D.
- Anticipated residual stromal bed thickness of at least 250 microns.
- Distance best spectacle corrected visual acuity (BSCVA) of 20/20 or better.
- BSCVA ≥ 2 lines (≥ 10 letters) better than distance uncorrected visual acuity (UCVA).
- Less than or equal to 0.75 D difference between cycloplegic and manifest refraction sphere.
- A stable refractive error over the last 12 months as defined by a change of ≤1.00 D in MRSE.
- Demonstration of refractive stability for subjects with contact lens wear within the last 4 weeks: rigid contact lenses must be removed for at least 4 weeks and soft contact lenses for at least 2 weeks prior to the first refraction used to establish stability.
- Agreement between manifest refraction (adjusted for optical infinity) and ***iDESIGN*®** System refraction chosen for treatment

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Women who are pregnant, breast-feeding, or intend to become pregnant, or not using an adequate method of birth control over the course of the study.
- Concurrent use of systemic (including inhaled) medications that may impair healing (e.g. corticosteroids).
- History of any of the following medical conditions, or any other condition that could affect wound healing: collagen vascular disease, autoimmune disease, immunodeficiency diseases, ocular herpes zoster or herpes simplex, endocrine disorders (including, but not limited to unstable thyroid disorders and diabetes), lupus, rheumatoid arthritis, and diabetes (regardless of type, duration, severity or control).
- Subjects with a cardiac pacemaker, implanted defibrillator or other implanted electronic device.
- History of prior intraocular or corneal surgery (including cataract extraction), active ophthalmic disease or abnormality (including, but not limited to, symptomatic blepharitis, recurrent corneal erosion, severe dry eye syndrome or symptoms, neovascularization > 1 mm from limbus), retinal detachment/repair, clinically significant lens opacity, clinical evidence of trauma, corneal opacity within the central 9 mm and visible on topography, at risk for developing strabismus, or with ocular hypertension, intraocular pressure (IOP) >21 mmHg at screening or evidence of glaucoma or propensity for narrow angle glaucoma.
- Evidence of keratoconus, corneal dystrophy or irregularity, or abnormal topography.
- Desire to have monovision.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations as follows:

Clinical Study Visit Schedule

VISIT	EXAM	VISIT WINDOW
1	Preoperative Exam	Within 120 days prior to surgery
2	Operative	0-120 days after preoperative exam
3	1 day	1-2 day postoperative
4	1 week	5-8 days postoperative
5	1 month	3-6 weeks postoperative
6	3 months	10-14 weeks postoperative
7	6 months	20-26 weeks postoperative
8	9 months	35-43 weeks postoperative
9	12 months	44-60 Weeks postoperative

Note: 1 month = 4 weeks, 1 week = 7 days

Study procedures included uncorrected distance visual acuity (monocular and binocular), best spectacle corrected distance visual acuity (monocular), contrast sensitivity, manifest

refraction, cycloplegic refraction, anterior segment examination, Schirmer I tear test, IOP, corneal pachymetry, keratometry, corneal topography, dilated fundus examination, non-directed ocular/visual symptoms query ***iDESIGN***® System measurements (refraction, aberrometry, topography, keratometry, and pupillometry), and binocular subjective questionnaires. Adverse events and complications were recorded at all visits.

In this study, all eyes were targeted for emmetropia. Surface PRK treatments were calculated using ***iDESIGN***® software version 1.3.

Preoperatively, study procedures included:

- Subjective non-directed ocular/visual symptoms
- Binocular Subjective Questionnaires: Ocular Surface Disease Index (OSDI), Patient Reported Visual Symptom Questionnaire (PRVSQ for PRK/LASIK), National Eye Institute Refractive Error Quality of Life - 42 (NEI-RQL-42) and exploratory Satisfaction Questionnaire
- ***iDESIGN***® System Measurement (refraction, aberrometry, topography, keratometry, pupillometry)
- Keratometry
- Corneal topography
- Distance UCVA – (monocular and binocular)
- Manifest refraction
- Distance BSCVA
- Contrast sensitivity substudy
- Anterior segment examination
- Schirmer I Tear Test
- Intraocular pressure (applanation tonometry)
- Pachymetry (ultrasound)
- Cycloplegic refraction
- Dilated fundus examination

Postoperatively, the parameters measured during the study included:

- Non-directed ocular/visual symptoms
- Binocular Subjective Questionnaires: OSDI, PRVSQ for PRK/LASIK, NEI RQL 42 and exploratory Satisfaction Questionnaire
- ***iDESIGN***® System Measurement (refraction, aberrometry, topography, keratometry, pupillometry)
- Keratometry
- Corneal topography
- Distance UCVA – (monocular and binocular)
- Manifest refraction
- BSCVA; (if ≥ 2-line loss in BSCVA at 3 months or later, a rigid contact lens over refraction or pin-hole visual acuity should be obtained)
- Anterior segment examination
- Contrast sensitivity substudy
- Schirmer I Tear Test

- Intraocular pressure (applanation tonometry)
- Pachymetry (ultrasound) (1 and 12-months only)
- Cycloplegic refraction (6 and 12-months only)
- Dilated fundus examination (6 and 12-months only)
- AEs, complications, and device deficiencies/complaints were recorded at all visits.

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

3. Clinical Endpoints

With regard to safety:

Primary Safety Endpoint Targets

1. Maintenance of BSCVA-lines lost
   - <5% of eyes with a loss of >2 lines of BSCVA from preoperative
   - <1% of eyes with haze beyond 6 months with loss >2 lines of BSCVA
2. Maintenance of BSCVA-preservation 20/40
   - <1% of eyes with a BSCVA of 20/20 or better preoperatively had BSCVA of worse than 20/40 postoperatively
3. Induced manifest refractive astigmatism
   - <5% of eyes with induced manifest refractive astigmatism >2.00 D
4. Serious, device-related adverse events
   - <1% of eyes with serious, device-related adverse events per type of event

With regard to effectiveness:

Primary Effectiveness Endpoint Targets

1. Monocular UCVA
   - ≥ 85% of eyes with a UCVA of 20/40 or better
2. MRSE within 0.50 D of target
   - ≥ 50% of eyes with an MRSE within 0.50 D of intended correction
3. MRSE within 1.00 D of target
   - ≥ 75% of eyes with an MRSE within 1.00 D of intended correction
4. Refractive stability
   - ≥ 95% of eyes achieve refractive stability.

The targets were to be evaluated at the point of postoperative refractive stability.

The point of refractive stability in the study was determined when the following criteria were met:
•At least 95% of the treated eyes have a change ≤1.00 D of MRSE and manifest cylinder (MRC) between refractions performed at 1 month and 3 months after surgery or any two refractions performed at least 3 months apart.

•The mean rate of change in MRSE and MRC, as determined by a paired analysis, is ≤0.5 D per year (0.04 D/month) over the same time period.
•The mean rate of change in MRSE and MRC decreases monotonically over time, with a projected asymptote of zero or a rate of change attributable to normal aging.
•The 95% confidence interval for the mean rate of change includes zero or a rate of change attributable to normal aging.
•Stability is confirmed at least 3 months after the stability time point by a statistically adequate subgroup.

B. Accountability of PMA Cohort

At the time of database lock, of the 334 eyes enrolled in the PMA study, 96.4% (322) of eyes are available for analysis at the 6-month post-operative visit, the point of postoperative refractive stability.

Table 1 presents the accountability for the 334 eyes treated in this study. All 167 subjects were treated bilaterally.

TABLE 1
Accountability

Accountability All Treated Eyes (N=334)	1 Day		1 Week		1 Month		3 Month		6 Month		9 Month		12 Month	
Subject status	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Available for Analysis	334	100.0	334	100.0	332	99.4	328	98.2	322	96.4	228	68.3	184	55.1
- In Interval (included in analysis)	334	100.0	332	99.4	330	98.8	310	92.8	300	89.8	222	66.5	180	53.9
- Out of Interval (included in analysis)	0	0.0	2	0.6	2	0.6	18	5.4	22	6.6	6	1.8	4	1.2
Missing Eyes	0	0.0	0	0.0	2	0.6	6	1.8	10	3.0	20	6.0	22	6.6
- Discontinued	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
- Missed visit	0	0.0	0	0.0	0	0.0	4	1.2	2	0.6	2	0.6	0	0.0
- Not seen but accounted for	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
- Lost-to-follow-up	0	0.0	0	0.0	2	0.6	2	0.6	8	2.4	18	5.4	22	6.6
Active	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6	86	25.7	128	38.3
- Active (not yet in visit interval)	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6	58	17.4	104	31.1
- In interval or Past interval (form not yet received)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	28	8.4	24	7.2
Percent Accountability* (ANSI Z80.11-2012)	.	100.0	.	100.0	.	99.4	.	98.2	.	97.0	.	91.9	.	89.3

*Percent Accountability = (Available for Analyses * 100)/(Enrolled [treated] - Discontinued - Active)

C. Study Population Demographics and Baseline Parameters

The demographics and eligibility criteria of the study population are typical for a contemporary refractive study performed in the US with the exception of gender/sex. Although females are not equally represented in the study, the outcomes from the study are transferable to the typical refractive surgical population because females are adequately represented in the study. Subgroup analyses (**Section X, D.3**) show that all key safety and effectiveness targets were met when stratified by age, sex/gender, and race.

Subject demographics are presented in **Table 2**. The mean age of the study subjects were 26.6 years (SD 5.41) and ranged from 19 to 47 years. The majority of subjects were White (65.9%; 110/167). The subject population consisted of more males (68.3%) than females (31.7%). The majority of subjects (97.0%; 162/167) did not wear contact lenses within the 4 weeks prior to the screening visit.

TABLE 2
Demographic Characteristics

Category	Classification	All Subjects (N=167)
Gender	Male	114 (68.3%)
	Female	53 (31.7%)
Race	American Indian/Alaska Native	3 (1.8%)
	Asian (Includes Indian)	12 (7.2%)
	Black or African American	22 (13.2%)
	White	110 (65.9%)
	Other[a]	20 (12.0%)
Age (Years)	Mean	26.6[b]
	SD	5.41
	Min	19
	Max	47
Preoperative CL Wear[c]	No	162 (97.0%)
	Soft	5 (3.0%)
	Rigid/Toric	0 (0.0%)
	Soft/Toric	0 (0.0%)

[a] Other includes Hispanic and Mixed.
[b] There were 54 eyes from subjects 18-21 years old.
[c] Within the 4 weeks (28 days) prior to the screening visit.

Table 3 presents the mean preoperative manifest and ***iDESIGN*®** System measured refractive error for the 334 treated eyes. Mean preoperative refractive measurements were consistent between ***iDESIGN*®** and manifest refractions with almost no difference in means (all within 0.05 D of each other).

TABLE 3
Preoperative Manifest and *iDESIGN*® System Refractive Errors
All Treated Eyes (N=334)

	Variable	Mean	Std Dev	Median	Minimum	Maximum
Manifest Refraction	**MRS**	-3.58	1.96	-3.25	-8.25	-0.25
	MRC	-1.00	0.84	-0.75	-4.00	0.00
	MRSE	-4.08	1.97	-3.75	-8.75	-0.63
iDesign Refraction	**IDS**	-3.56	1.96	-3.23	-7.99	-0.07
	IDC	-1.05	0.83	-0.80	-3.98	-0.03
	IDSE	-4.09	1.97	-3.69	-8.99	-0.64

MRS = manifest refractive sphere
MRC = manifest refractive cylinder
MRSE = manifest refractive spherical equivalent
IDS = iDesign sphere
IDC = iDesign cylinder
IDSE = iDesign spherical equivalent

Tables 4 and **Table 5** present the preoperative refractive error bin distributions for the study population based on preoperative ***iDESIGN*®** System measurements.

TABLE 4
Preoperative Refractive Error Stratified by *iDESIGN*® Sphere and Cylinder
All Treated Eyes (N=334)

	iDesign Cylinder					
	0 to ≥-0.5 D	**<-0.5 to ≥-1 D**	**<-1 to ≥-2 D**	**<-2 to ≥-3 D**	**<-3 to ≥-4 D**	**Total**
iDesign Sphere	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**
≤0 to ≥-1 D	8 2.4%	5 1.5%	2 0.6%	4 1.2%	4 1.2%	**23 6.9%**
<-1 to ≥-2 D	19 5.7%	22 6.6%	16 4.8%	8 2.4%	2 0.6%	**67 20.1%**
<-2 to ≥-3 D	12 3.6%	17 5.1%	22 6.6%	7 2.1%	2 0.6%	**60 18.0%**
<-3 to ≥-4 D	19 5.7%	17 5.1%	17 5.1%	1 0.3%	2 0.6%	**56 16.8%**
<-4 to ≥-5 D	13 3.9%	17 5.1%	9 2.7%	4 1.2%	0 0.0%	**43 12.9%**
<-5 to ≥-6 D	15 4.5%	9 2.7%	8 2.4%	2 0.6%	3 0.9%	**37 11.1%**
<-6 to ≥-7 D	9 2.7%	7 2.1%	8 2.4%	3 0.9%	1 0.3%	**28 8.4%**
<-7 to ≥-8 D	6 1.8%	4 1.2%	8 2.4%	2 0.6%	0 0.0%	**20 6.0%**
Total	**101 30.2%**	**98 29.3%**	**90 26.9%**	**31 9.3%**	**14 4.2%**	**334 100%**

% Percentage is calculated by dividing the total number of eyes in the bin (n)/ by the total number of eyes N (334)

TABLE 5
Preoperative Refractive Error Stratified by *iDESIGN*®
Spherical Equivalent (SE) and Cylinder, All Treated Eyes (N=334)

	iDesign Cylinder					
	0 to ≥-0.5 D	**<-0.5 to ≥-1 D**	**<-1 to ≥-2 D**	**<-2 to ≥-3 D**	**<-3 to ≥-4 D**	**Total**
iDesign SE	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**
≤0 to ≥-1 D	3 0.9%	2 0.6%	0 0.0%	0 0.0%	0 0.0%	**5 1.5%**
<-1 to ≥-2 D	21 6.3%	18 5.4%	6 1.8%	3 0.9%	0 0.0%	**48 14.4%**
<-2 to ≥-3 D	12 3.6%	13 3.9%	20 6.0%	7 2.1%	5 1.5%	**57 17.1%**
<-3 to ≥-4 D	20 6.0%	25 7.5%	21 6.3%	7 2.1%	2 0.6%	**75 22.5%**
<-4 to ≥-5 D	11 3.3%	14 4.2%	11 3.3%	3 0.9%	1 0.3%	**40 12.0%**
<-5 to ≥-6 D	13 3.9%	15 4.5%	10 3.0%	4 1.2%	2 0.6%	**44 13.2%**
<-6 to ≥-7 D	14 4.2%	6 1.8%	10 3.0%	2 0.6%	1 0.3%	**33 9.9%**
<-7 to ≥-8 D	4 1.2%	5 1.5%	7 2.1%	2 0.6%	3 0.9%	**21 6.3%**
<-8 to ≥-9 D	3 0.9%	0 0.0%	5 1.5%	3 0.9%	0 0.0%	**11 3.3%**
Total	**101 30.2%**	**98 29.3%**	**90 26.9%**	**31 9.3%**	**14 4.2%**	**334 100%**

% Percentage is calculated by dividing the number of eyes in the bin (n)/ by the total number of eyes N (334)

D. Safety and Effectiveness Results

As refractive stability was achieved at 6 months, and confirmed at 9 months, the key safety and effectiveness study endpoints were evaluated at 6 months for all treated eyes (N = 334).

1. Safety Results

The analysis of safety was based on the safety cohort of 334 treated eyes with 322 available at 6 months. The key safety outcomes for this study are presented below in **Tables 6 to 8**. Adverse effects are reported in **Table 9**.

a) *Less than 5% of eyes with a loss of >2 lines BSCVA from preoperative:* At 6 months, 1/322 eyes (0.3%) lost >2 lines of BSCVA, meeting the safety criterion of <5% of eyes with a loss of >2 lines of BSCVA.
b) *Less than 1% of eyes with haze beyond 6 months with a loss of >2 lines BSCVA from preoperative:* One eye (0.3%, 1/322 eyes) had haze beyond 6 months and lost >2 lines of BSCVA, meeting the safety criterion of <1% of eyes with haze beyond 6 months with a loss of >2 lines BSCVA from preoperative.
c) *Less than 1% of eyes with a BSCVA of 20/20 or better preoperatively that have a BSCVA of worse than 20/40 postoperatively:* No eyes (0%; 0/322) had preoperative BSCVA of 20/20 or better but worse than 20/40 postoperatively at 6 months, meeting the safety endpoint target of <1% of eyes with preoperative BSCVA of 20/20 or better having BSCVA worse than 20/40 postoperatively.
d) *Less than 5% of eyes with induced manifest refractive astigmatism >2.00 diopters*: At 6 months, no eyes (0%; 0/322) had induced manifest refractive astigmatism >2.00 D, meeting the safety criterion of <5% of eyes with induced manifest refractive astigmatism >2.00 D.
e) *Less than 1% of eyes with serious, device-related AEs per type*: Serious, devise-related AEs occurred ≤ 0.9% per type, meeting the target rate of <1% per type.

TABLE 6
Summary of Study Safety Endpoints Over Time – All Eyes

Safety Variable	1 Month (N=332) n %	3 Months (N=328) n %	6 Months (N=322) n %	9 Months (N=228) n %	12 Months (N=184) n %
Loss of > 2 lines BSCVA from preoperative[a]	3 0.9%	0 0%	1[f] 0.3%	0 0%	0 0%
Haze beyond 6 months with loss >2 lines of BSCVA[b]			1[f] 0.3%	0 0%	0 0%
BSCVA of 20/20 preoperative and 20/40 postoperative[c]	0 0%	0 0%	0 0%	0 0%	0 0%
Induced manifest refractive astigmatism >2.00 D[d]	0 0%	0 0%	0 0%	0 0%	0 0%
			Cumulative		
Serious, device-related adverse events[e]	≤ 0.9% of eyes with each type of serious, device-related adverse event (corneal infiltrate 0.6% [2/334], corneal erosion 0.6% [2/334], corneal haze (visually significant or potentially affecting vision) 0.9% [3/334])				

Note: Shaded areas represent time frames outside event definition.
% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per time period (N) [= (n / N) x 100%].
[a] Safety endpoint target: <5% of eyes with a loss of >2 lines (logMAR change of >0.24) of BSCVA from preoperative
[b] Safety endpoint target: <1 % of eyes with haze beyond 6 months with loss >2 lines (logMAR change of >0.24) of BSCVA
[c] Safety endpoint target: <1 % of eyes with BSCVA of 20/20 or better preoperative have BSCVA of worse than 20/40 postoperative. All eyes had preoperative BSCVA of 20/20 or better
[d] Safety endpoint target: <5% of eyes with induced manifest refractive astigmatism >2.00 D
[e] Safety endpoint target: <1% of eyes for each type of serious, device-related adverse events
[f] One eye had haze and a decrease in BSCVA of 2 lines from preoperative BSCVA of 20/16 to 20/25 at 6 months: BSCVA improved to 20/12.5 at 9 months.

f) *BSCVA Preservation*

Table 7 shows that 99.7% of eyes in the clinical study had 20/20 or better BSCVA at 6 months after treatment.

TABLE 7
BSCVA Before and After Treatment – All Eyes

Visual Acuity	Preoperative (N=334)		1 Month (N=332)		3 Months (N=328)		6 Months (N=322)		9 Months (N=228)		12 Months (N=184)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/10 or better	12	3.6%	13	3.9%	72	22.0%	82	25.5%	58	25.4%	55	29.9%
20/12.5 or better	167	50.0%	139	41.9%	245	74.7%	256	79.5%	184	80.7%	149	81.0%
20/16 or better	315	94.3%	271	81.6%	322	98.2%	319	99.1%	228	100%	182	98.9%
20/20 or better	**334**	**100%**	**326**	**98.2%**	**328**	**100%**	**321**	**99.7%**	**228**	**100%**	**184**	**100%**
20/25 or better	334	100%	331	99.7%	328	100%	322	100%	228	100%	184	100%
20/32 or better	334	100%	332	100%	328	100%	322	100%	228	100%	184	100%
20/40 or better	**334**	**100%**	**332**	**100%**	**328**	**100%**	**322**	**100%**	**228**	**100%**	**184**	**100%**

% Percentage is calculated by dividing the number of eyes in the cell (n) by the total number of eyes per time period (N).

The change in lines of BSCVA postoperatively compared to preoperatively for all eyes is presented in **Table 8**. At 6 months, 97.2% (313/322) of eyes had either no change or an improvement in BSCVA compared to preoperative. One eye (0.3%; 1/322) had a decrease in BSCVA of >2 lines at 6 months vs. preoperative, meeting the safety endpoint target for BSCVA lines lost of <5% of eyes with a loss of >2 lines of BSCVA.

TABLE 8
Change in BSCVA Over Time vs. Preoperative – All Eyes

LogMAR Change	Acuity Change	1 Month (N=332)		3 Months (N=328)		6 Months (N=322)		9 Months (N=228)		12 Months (N=184)	
		n	%	n	%	n	%	n	%	n	%
<-0.24	**Increase >2 lines**	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
≥-0.24 to <-0.14	**Increase =2 lines**	1	0.3%	6	1.8%	10	3.1%	10	4.4%	18	9.8%
≥-0.14 to <-0.04	**Increase =1 line**	40	12.0%	134	40.9%	151	46.9%	124	54.4%	108	58.7%
≥-0.04 to ≤0.04	**No Change**	196	59.0%	174	53.0%	152	47.2%	90	39.5%	56	30.4%
>0.04 to ≤0.14	**Decrease =1 line**	77	23.2%	13	4.0%	8	2.5%	4	1.8%	2	1.1%
>0.14 to ≤0.24	**Decrease =2 lines**	15	4.5%	1	0.3%	0	0.0%	0	0.0%	0	0.0%
>0.24	**Decrease >2 lines**	3	0.9%	0	0.0%	1	0.3%	0	0.0%	0	0.0%
Not Reported		0		0		0		0		0	
Total		332		328		322		228		184	

% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per time period (N).

One eye had a decrease in BSCVA from the 20/16 line preoperatively to the 20/25 line at 6 months postoperatively (Decrease > 2 lines). BSCVA improved to the 20/12.5 line at 9 months postoperatively.

g) Adverse effects that occurred in the PMA clinical study:

A summary of serious and non-serious AEs is presented in **Table 9**. During the study, the most frequently reported AEs were corneal edema at 1 month (rate of 3%; 10/334); all resolved by 3 months. At the stability time point of 6 months, AEs included haze beyond 6 months with loss of 2 lines or greater (≥10 letters) BSCVA and decrease in BSCVA of greater than or equal to 2 lines (≥10 letters) not due to irregular astigmatism (both 0.3%, 1/322; same eye), corneal haze potentially affecting vision (0.6%, 2/322; both eyes of same subjects), corneal erosion (0.3%; 1/322), and anterior uveitis (0.3%; 1/322).

A total of 11 serious ocular AEs occurred in 11 eyes of 10 subjects.

- Four serious, non-device related AEs occurred in 4 eyes of 4 subjects: retinal detachment (n = 1), anterior uveitis (n = 1), and corneal abrasion (n = 2).

- Seven serious, device-related AEs (SADEs) occurred in 7 eyes of 6 subjects: corneal infiltrate (n = 2 eyes), corneal haze (n = 3 eyes), and corneal erosion (n = 2 eyes). The rate of each type of serious, device-related adverse event was <1% (corneal infiltrate: 0.6%, 2/334; corneal erosion: 0.6%. 2/334; corneal haze: 0.9%, 3/334), meeting the safety endpoint for serious, device-related AEs. All seven SADEs have resolved.

TABLE 9
Summary of Adverse Events Over Time – All Eyes

	<1 Month (N=334)		1 Month (N=332)		3 Months (N=328)		6 Months (N=322)		9 Months (N=228)		12 Months (N=184)		Cumulative[a] (N=334)	
Adverse Event	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Corneal infiltrate or ulcer	2	0.6	0	0.0	1	0.3	0	0.0	0	0.0	0	0.0	3	0.9
Any persistent corneal epithelial defect at 1 month or later[b]			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema at 1 month or later[c]			10	3.0	0	0.0	0	0.0	0	0.0	0	0.0	10	3.0
IOP with increase >10 mmHg above baseline on two consecutive examinations or an IOP >30 mmHg on two consecutive examinations	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Haze beyond 6 months with loss of 2 lines or greater (≥10 letters)							1[d]	0.3	0	0.0	0	0.0	1[d]	0.3
Decrease in BSCVA of greater than or equal to 2 lines (≥10 letters) not due to irregular astigmatism, at 3 months or later					0	0.0	1[d]	0.3	0	0.0	0	0.0	1[d]	0.3
Retinal detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.5	1	0.3
Retinal vascular accidents	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ocular penetration	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Severe glare, dry eye, or halos at 3 months or later					0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal melt	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Glaucoma or ocular hypertension	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Severe allergic reaction to study medication	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any other vision-threatening event (Serious)														
Corneal haze potentially affecting vision	0	0.0	0	0.0	0	0.0	2[e]	0.6	0	0.0	0	0.0	2[e]	0.6
Corneal abrasion	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6
Corneal erosion	0	0.0	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	2	0.6
Anterior uveitis	0	0.0	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	1	0.3
Other adverse events (Non-serious)														
Corneal erosion	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.3
Chronic dry eye[f]	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6
Headaches	0	0.0	0	0.0	2	0.6	0	0.0	0	0.0	0	0.0	2	0.6

Note: Shaded areas represent time frames outside event definition.

% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per time period (N).

[a] Cumulative includes unscheduled visits.

[b] Defined as corneal epithelial defect as a result of surgery that persisted at 1 month or later.

[c] Includes only cases involving primary cases of corneal edema (i.e., does not include cases of edema secondary to corneal infiltrate, corneal erosion, and corneal abrasion)

[d] Same eye (#30352)

[e] Both eyes from same subject (#2051)

[f] Chronic Dry Eye diagnosis was not based the on protocol-defined dry eye definition (subject score of ≥ 33 on the OSDI in combination with a Schirmer score of ≤ 5 mm).

h) *Complications*

Table 10 presents a summary of complications (per the statistical plan and consistent with the ANSI Guidance Document for Corneal Reshaping, Z80.11-2012) over time.

The highest frequencies of reports of complications occurred between 1 week and <1 month. Corneal edema was reported in 34.7% of eyes (116/334); most reports were Grade 1 (82.8%; 96/116). Ghosting/diplopia was reported by 44.3% of subjects (74/167; via a PRVSQ PRO questionnaire) prior to 1 month; rates decreased over time. During the study, other complications included pain (highest rate at 6 months: 3.4%, 11/322), foreign body sensation (highest rate at 3 months: 1.5%, 5/328), corneal erosion (also reported as AEs; cumulative rate of 0.9%; 3/334) and peripheral corneal epithelial defect (cumulative rate of 0.9%; 3/334). Transient light sensitivity syndrome was not reported at any time.

TABLE 10
Summary of Complications Over Time – All Eyes

Complication	1 Week to <1 Month (N=334)		1 Month (N=332)		3 Months (N=328)		6 Months (N=322)		9 Months (N=228)		12 Months (N=184)		Cumulative[a] (N=334)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Corneal edema between 1 week and 1 month after the procedure	116[b]	34.7												
Peripheral corneal epithelial defect at 1 month or later			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	0.9
Corneal erosion at 1 month or later			0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	3[c]	0.9
Foreign body sensation at 1 month or later			0	0.0	5	1.5	2	0.6	1	0.4	0	0.0	10	3.0
Pain at 1 month or later			5	1.5	9	2.7	11	3.4	1	0.4	0	0.0	28	8.4
Ghost/diplopia (PRSVQ PRO)[d]	74	44.3	47	28.3	15	9.1	7	4.3	4	3.5	2	2.2	96	57.5
Transient light sensitivity syndrome	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Note: Shaded blank areas represent time frames outside complication definition.

% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per time period (N).

[a] Cumulative includes unscheduled visits.

[b] Between 1 week and 1 month, there were 96 Grade 1 reports, 14 Grade 2 reports, two Grade 3 reports, and 4 reports of edema being present, but the rating was not recorded.

[c] Reported as a serious and/or device-related adverse events; Two cases documented as SADEs, one of which occurred and was treated by a primary care doctor between the 1- and 3-month study visits (no associated medical finding available at the time of occurrence); the other case was noted as corneal erosion at the time of occurrence (6 months). A third case was documented as an ADE with the medical finding of epithelial defect at an unscheduled visit between 3 and 6 months.

[d] Complications based on subject-based PRVSQ Question 5a "Over the last 7 days, how often did you experience multiple or double vision?". The n-values over time are as follows: n=167 at <1 month; n=166 at 1 month; n=164 at 3 months; n=161 at 6 months; n=114 at 9 months; n=92 at 12 months; n=167 for cumulative)

i) *Intraoperative Complications*

All treated eyes (100.0%, 334/334) underwent uneventful treatment procedures with no intraoperative complications.

Of the 334 treated eyes, most eyes (95.8%, 320/334) were treated with iris registration engaged for the duration of treatment. Fourteen eyes (4.2%, 14/334) underwent treatment without iris registration engaged across three sites.

j) *Patient Reported Outcomes (PRO) Measures and Questionnaires (PRVSQ for PRK/LASIK, NEI-RQL-42, OSDI, and Patient Satisfaction)*

The results of the Patient Reported Visual Symptom Questionnaire (PRVSQ) PRO (**Table 11**), National Eye Institute Refractive Error Quality of Life Instrument (NEI-RQL) (**Table 12**), Ocular Surface Disease Index (OSDI) (**Table 13** and **Table 14**), and patient satisfaction with vision (**Table 15**) are shown on the next pages.

The PRVSQ questionnaire asked patients to rank the frequency (never, rarely, sometimes, often, always) and level of bother ('not bothered', 'slightly', 'moderately', 'very', 'extremely') of their visual symptoms over the last 7 days. The results of the PRVSQ at 6 months (**Table 11**) indicated that the most reported visual symptom was sensitivity to light (55.9%; 90/161) followed by starbursts (35.4%; 57/161), glare (33.5%; 54/161), halos (26.7%; 43/161), fluctuating vision (18%; 29/161) and multiple/double vision (4.3%; 7/161). Overall, however, most subjects (≥ 90%) were either not bothered or slightly bothered by symptoms or did not experience the visual symptom. There were no reports of extreme bother with any symptom at 6 months.

Mean scores from the NEI-RQL (**Table 12**) are presented at preoperative and 6 months across all measures.

OSDI questionnaire within-subject category status change (**Table 14**) shows that the majority of subjects that were Normal at preoperative remained Normal at 6 months.

Most subjects (98.8%; 159/161) indicated being 'completely' or 'very' satisfied when asked to rate their overall satisfaction with present vision at 6 months (**Table 15**).

TABLE 11
PRVSQ Optical Visual Symptoms All Subjects at 6 Months[a]: Key Results

Symptom	Percentage of subjects experiencing[b]	Percentage of subjects often/always experiencing	Percentage of subjects did not experience[c] or not bothered or slightly bothered	Highest bother rating and percentage of subjects	Percentage of subjects with limitation/ difficulty
Halos	26.7% (43/161)	3.1% (5/161)	99.4% (160/161)	Moderate 0.6% (1/161)	0.6% (1/161)
Glare	33.5% (54/161)	2.5% (4/161)	96.3% (155/161)	Moderate 3.7% (6/161)	0.6% (1/161)
Starbursts[d]	35.4% (57/161)	4.9% (8/161)	96.3% (155/161)	Moderate 3.7% (6/161)	0.0% (0/161)
Sensitivity to Light	55.9% (90/161)	8.7% (14/161)	90.0% (145/161)	Very 1.9% (3/161)	3.7% (6/161)
Multiple/ Double Vision	4.3% (7/161)	0% (0/161)	99.4% (160/161)	Moderate 0.6% (1/161)	0.0% (0/161)
Fluctuating Vision	18.0% (29/161)	1.2% (2/161)	98.1% (158/161)	Moderate 1.9% (3/161)	2.5% (4/161)

[a] The questionnaire asked patients to rank the frequency and level of bother of their visual symptoms over the last 7 days both before and at 6 months after treatment.
[b]Total subjects indicating rarely, sometimes, often and always experiencing the given symptom
[c] Includes subjects that did not experience the symptom or not reported.
[d] One subject not reported

TABLE 12
Mean Scores of NEI-RQL-42 Questionnaire Measures
6 Month vs Preoperative (N=161 Subjects)

Measure	Preoperative	6 Month
Clarity of vision	87.86	94.00
Expectations	4.35	91.15
Near vision	74.26	91.91
Far vision	83.60	96.94
Diurnal fluctuations	88.72	95.73
Activity limitations	54.90	98.95
Glare	77.80	86.02
Symptoms	87.79	89.06
Dependence on correction	39.93	97.88
Worry	44.57	85.71
Suboptimal correction	95.50	99.92
Appearance	38.96	96.65
Satisfaction with correction	62.36	95.78

NEI-RQL scores range from 0 to 100, higher scores represent better health. The changes in scores may not necessarily represent a clinically meaningful improvement or worsening in the NEI-RQL scores.

TABLE 13
OSDI Dry Eye Severity Categories Over Time – All Subjects

OSDI Severity Category (scores)	Preoperative (N=167)		1 Month (N=166)		3 Month (N=164)		6 Month (N=161)		9 Month (N=114)		12 Month (N=92)	
	n	%	n	%	n	%	n	%	n	%	n	%
Normal (0-12)	138	82.6	95	57.2	132	80.5	140	87.0	107	93.9	86	93.5
Mild (13-22)	13	7.8	32	19.3	22	13.4	13	8.1	6	5.3	5	5.4
Moderate (23-32)	6	3.6	19	11.4	8	4.9	5	3.1	0	0.0	0	0.0
Severe (33-100)	10	6.0	20	12.0	2	1.2	3	1.9	1	0.9	1	1.1

% Percentage is calculated by dividing the number of subjects in the cell (n) / by the total number of subjects per time period (N).

TABLE 14
OSDI Within-Subject Category Status Change from Preoperative to 6 months

Preoperative OSDI Status	6M OSDI Status									
	Normal		Mild		Moderate		Severe		Total	
	n	%	n	%	n	%	n	%	n	%
Normal	123	90	9	7	3	2	1	1	136	100
Mild	8	67	4	33	0	0	0	0	12	100
Moderate	4	80	0	0	0	0	1	20	5	100
Severe	6	67	0	0	2	22	1	11	9	100

% Percentage is calculated by dividing the number of subjects in the cell (n) / by the total number of subjects per category (N).

TABLE 15
Patient Satisfaction with Visual Quality – All Subjects

Category	Satisfaction	Preop (N=167)[a] n	Preop (N=167)[a] %	1 Month (N=166) n	1 Month (N=166) %	3 Month (N=164) n	3 Month (N=164) %	6 Month (N=161) n	6 Month (N=161) %	9 Month (N=114)[b] n	9 Month (N=114)[b] %	12 Month (N=92) n	12 Month (N=92) %
Q1. Please rate your satisfaction with your present vision when not wearing glasses or contacts	Completely satisfied	0	0.0	59	35.5	117	71.3	127	78.9	91	79.8	80	87.0
	Very satisfied	0	0.0	77	46.4	42	25.6	32	19.9	22	19.3	9	9.8
	Somewhat satisfied	0	0.0	24	14.5	4	2.4	1	0.6	0	0.0	2	2.2
	Neither satisfied or dissatisfied	2	1.2	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0
	Somewhat dissatisfied	14	8.4	4	2.4	0	0.0	0	0.0	0	0.0	0	0.0
	Very dissatisfied	57	34.1	1	0.6	0	0.0	0	0.0	1	0.9	1	1.1
	Completely dissatisfied	94	56.3	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0
Q2. Please rate your satisfaction with your present vision when wearing glasses or contacts	Completely satisfied	22	13.2	7	4.2	7	4.3	10	6.2	9	7.9	4	4.3
	Very satisfied	64	38.3	9	5.4	1	0.6	4	2.5	4	3.5	1	1.1
	Somewhat satisfied	61	36.5	6	3.6	5	3.0	0	0.0	1	0.9	1	1.1
	Neither satisfied or dissatisfied	10	6.0	1	0.6	2	1.2	1	0.6	0	0.0	0	0.0
	Somewhat dissatisfied	8	4.8	2	1.2	1	0.6	0	0.0	0	0.0	0	0.0
	Very dissatisfied	3	1.8	4	2.4	1	0.6	2	1.2	1	0.9	2	2.2
	Completely dissatisfied	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	Not applicable, I never wear glasses or contacts	0	0.0	137	82.5	147	89.6	144	89.4	98	86.0	83	90.2
Q3. Please rate your OVERALL satisfaction with your present vision	Completely satisfied	6	3.6	59	35.5	116	70.7	128	79.5	94	82.5	79	85.9
	Very satisfied	21	12.6	79	47.6	44	26.8	31	19.3	19	16.7	11	12.0
	Somewhat satisfied	59	35.3	24	14.5	3	1.8	1	0.6	0	0.0	1	1.1
	Neither satisfied or dissatisfied	20	12.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0
	Somewhat dissatisfied	32	19.2	3	1.8	0	0.0	0	0.0	0	0.0	0	0.0
	Very dissatisfied	15	9.0	0	0.0	0	0.0	1	0.6	1	0.9	1	1.1
	Completely dissatisfied	14	8.4	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0

% Percentage is calculated by dividing the number of subjects in the cell (n) / by the total number of subjects per time period (N).
Cumulative including unscheduled visit.
[a] At the preoperative visit, one subject marked two answers for Question 2: "Neither satisfied or dissatisfied" and "Somewhat dissatisfied"
[b] At the 9-month visit, one subject did not mark an answer for Question 2.
"n" represents total number of subjects.

k) *Contrast Sensitivity*

The changes in monocular best corrected contrast sensitivity from preoperative to 6 months using a non-parametric approach are presented in **Table 16**. At 6 months, median increases in contrast sensitivity from preoperative ranged between 0.07 and 0.14 log units under mesopic without glare conditions, between 0.04 and 0.16 log units under mesopic with glare conditions, and between 0.07 to 0.15 log units under photopic without glare conditions. Under all three lighting conditions, median changes in contrast sensitivity vs. preoperative were positive, indicating an increase (improvement) in contrast sensitivity postoperatively.

TABLE 16
Contrast Sensitivity Change (Log Units) from Preoperative to 6 Months Using Non-Parametric Analysis (N=72 Eyes)

Lighting Condition	Spatial Frequency	Mean	SD	25th Percentile	Median 50th Percentile	75th Percentile
Mesopic without glare	**1.5 cpd**	0.10	0.19	0.00	0.07	0.22
	3.0 cpd	0.10	0.23	0.00	0.14	0.23
	6.0 cpd	0.14	0.19	0.00	0.08	0.25
	12.0 cpd	0.11	0.33	-0.08	0.08	0.26
Mesopic with glare	**1.5 cpd**	0.04	0.20	-0.07	0.04	0.19
	3.0 cpd	0.08	0.22	-0.07	0.07	0.15
	6.0 cpd	0.13	0.24	0.00	0.08	0.29
	12.0 cpd	0.17	0.35	-0.07	0.16	0.35
Photopic without glare	**3.0 cpd**	0.08	0.20	-0.07	0.07	0.22
	6.0 cpd	0.12	0.20	0.00	0.14	0.23
	12.0 cpd	0.18	0.32	-0.00	0.15	0.40
	18.0 cpd	0.15	0.37	-0.09	0.15	0.35

l) *Higher Order Aberrations*

As shown in **Table 17**, analyses of higher order aberration (HOA) at 5 mm standardized wavefront diameter showed that HOA root mean square (RMS) minimally increased postoperatively. The small increase in total HOA RMS was associated with small increases in mean coma (ranging from 0.01 to 0.04 µm) and mean spherical aberration (0.02 µm).

TABLE 17
Preoperative and 6-month Higher Order Aberrations (HOA) (µm)
Eyes with 5 mm Standardized Wavefront Diameters

	Preoperative (N=326) Mean +/- SD	6 Months (N=302) Mean +/- SD
Total HOA RMS	0.16 +- 0.05	0.19 +- 0.08
Coma	0.10 +- 0.05	0.12 +- 0.08
Trefoil	0.08 +- 0.05	0.07 +- 0.04
Spherical Aberration	0.05 +- 0.03	0.07 +- 0.06

m) *Schirmer I Tear Test*

At 6 months, the mean Schirmer score was 20.79 mm (SD 9.31), and the mean change in Schirmer score from preop was 0.11 mm (SD 7.73). At 6 months, 89.7% (288/322) had Schirmer scores of ≥10 mm (normal) and 3.4% (11/322) eyes had Schirmer scores of ≤5 mm (severe dryness; **Table 18**); however, there were no AEs of dry eyes (predefined as a Schirmer score of ≤ 5 mm at 3 months or later and an OSDI score of ≥33).

TABLE 18
Schirmer Score Distribution Over Time – All Eyes

	Preoperative (N=334)		3 Month (N=328)		6 Month (N=322)		12 Month (N=184)	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**
≤5 mm (severe dry)	8	2.4	13	4.0	11	3.4	6	3.3
>5 mm to <10 mm	33	9.9	27	8.2	23	6.9	24	13.0
≥10 mm (normal)	293	87.7	288	87.8	288	89.7	154	83.7

% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per time period (N).

n) *Additional Anterior Segment Evaluation Findings*

The anterior segment was also evaluated for corneal clarity (**Table 19**) and changes in IOP. At 6 months, most eyes were noted with clear corneal clarity (score of 0) (90.1%; 290/322), 7.8% of eyes (25/322) were noted with faint/trace haze (score of 0.5), 1.9% (6/322) of eyes had mild haze (score of 1), and 1 eye (0.3%) had moderate haze (score of 2). At 6 months, the mean IOP was 12.33 mmHg (SD 2.05), and most eyes (90.1%; 290/322) had no change or decrease in IOP compared to preoperative. No eyes had an IOP >30 mmHg at any visit.

TABLE 19
Corneal Clarity Over Time – All Eyes

Corneal Clarity	Preop (N=334)		1 Day (N=334)		1 Week (N=334)		1 Month (N=332)		3 Month (N=328)		6 Month (N=322)		9 Month (N=228)		12 Month (N=184)		Cumulative (N=334)	
(Grade)	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Clear (0)	332	99.4	321	96.1	311	93.1	295	88.9	275	83.8	290	90.1	212	93.0	176	95.7	334	100.0
Faint/Trace Haze (0.5)	2	0.6	13	3.9	21	6.3	35	10.5	51	15.5	25	7.8	12	5.3	8	4.3	90	26.9
Mild Haze (1)	0	0.0	0	0.0	2	0.6	2	0.6	2	0.6	6	1.9	4	1.8	0	0.0	11	3.3
Moderate Haze (2)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1[a]	0.3	0	0.0	0	0.0	1	0.3
Dense Haze; Opacity prevents refraction; AC visible (3)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dense Haze: Anterior chamber not visible (4)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
--Haze present, but rating not recorded	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per time period (N) [= (n/N).x 100%]
Cumulative including unscheduled visit.

[a] This eye had moderate haze (score of 2) and a loss of >2 lines of BSCVA that was reported as a serious, device-related adverse event. Preoperative BSCVA for this eye was 20/16 (LogMAR -0.14); at 6 months, BSCVA was 20/25 (LogMAR 0.14). At the 9-month visit, corneal haze was noted as mild and BSCVA had returned to 20/16 (LogMAR -0.14)

o) *Device Failures and Replacements*

There were no ***iDESIGN®*** System failures during the course of this study. Three ***iDESIGN®*** Systems were returned due to inconsistencies with the patient fixation and target appearance and brightness. These inconsistencies did not have any impact on the safety or effectiveness in this population as treatment plans in the study required strict agreement between ***iDESIGN®*** system and manifest refractions.

2. Effectiveness Results

The analysis of effectiveness was based on 322 eyes at the 6-month time point. Key effectiveness outcomes are presented in **Table 20**.

a) *Greater than or equal to 85% of eyes have UCVA of 20/40 or better:* At 6 months, the primary study endpoint of UCVA of 20/40 or better was achieved in 100% (322/322) of eyes monocularly, exceeding the endpoint target of 85% of eyes with 20/40 or better UCVA. Overall, the proportions of eyes that achieved UCVA of 20/40 or better exceeded the target rate (85%) at all postoperative study visits.

b) *Greater than or equal to 50% of eyes have MRSE within 0.50 D of intended correction:* At 6 months, the point of refractive stability, 85.4% (275/322) of eyes had an MRSE within 0.50 D of target (emmetropia), exceeding the study endpoint target of ≥ 50% within 0.50 D.

c) *Greater than or equal to 75% of eyes have MRSE within 1.00 D of intended correction:* At 6 months, the point of refractive stability, 96.3% (310/322) of eyes had an MRSE within 1.00 D, exceeding the study endpoint target of ≥ 75% within 1.00 D.

TABLE 20
Summary of Key Effectiveness Endpoints Over Time – All Eyes

Effectiveness Variable	1 Month (N=332) n %	3 Months (N=328) n %	6 Months (N=322) n %	9 Months (N=228) n %	12 Months (N=184) n %	Target
UCVA 20/40 or better[a]	328 98.8%	328 100%	322 100%	228 100%	184 100%	*≥85%*
MRSE +/- 0.50 D[b]	223 67.2%	274 83.5%	275 85.4%	185 81.1%	157 85.3%	*≥50%*
MRSE +/- 1.00 D[c]	310 93.4%	316 96.3%	310 96.3%	221 96.9%	182 98.9%	*≥75%*

% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per time period (N) [= (n/N).x 100%].

The key effectiveness endpoints at 6 months stratified by preoperative IDSE, IDS, and IDC are presented in **Tables 21-23**.

The key effectiveness variables at 6 months stratified by preoperative IDC are presented in **Table 23**. All preoperative IDC diopter bins achieved the effectiveness endpoint targets

TABLE 21
Outcomes Stratification Analysis
Effect of Preoperative iDesign Spherical Equivalent (IDSE) Groups at 6 Months

	Preoperative IDSE										
Safety/Effectiveness Endpoints	**≥-1.0 D to ≤0.0 D (n=5)**	**≥-2.0 D to <-1.0 D (n=46)**	**≥-3.0 D to <-2.0 D (n=54)**	**≥-4.0 D to <-3.0 D (n=74)**	**≥-5.0 D to <-4.0 D (n=36)**	**≥-6.0 D to <-5.0 D (n=44)**	**≥-7.0 D to <-6.0 D (n=33)**	**≥-8.0 D to <-7.0 D (n=19)**	**≥-9.0 D to <-8.0 D (n=11)**	**Total (N=322)**	
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	***Target***
UCVA 20/40 or better	5 100%	46 100%	54 100%	74 100%	36 100%	44 100%	33 100%	19 100%	11 100%	322 100%	*≥85%*
MRSE +/- 0.50 D	5 100%	42 91.3%	52 96.3%	66 89.2%	36 100%	34 77.3%	22 66.7%	12 63.2%	6 54.5%	275 85.4%	*≥50%*
MRSE +/- 1.00 D	5 100%	46 100%	54 100%	73 98.6%	36 100%	39 88.6%	32 97.0%	16 84.2%	9 81.8%	310 96.3%	*≥75%*
BSCVA Worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<1%*
Loss of >2 Lines BSCVA*	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	0 0.0%	1 0.3%	*<5%*
Haze with Loss of >2 Lines BSCVA*	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Induced Astigmatism >2D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<5%*
Serious Device related AE: Corneal Infiltration	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.8%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Serious Device related AE: Corneal Erosion	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.3%	1 3.0%	0 0.0%	0 0.0%	2 0.6%	*<1%*

Preoperative IDSE											
Safety/Effectiveness Endpoints	**≥-1.0 D to ≤0.0 D (n=5)**	**≥-2.0 D to <-1.0 D (n=46)**	**≥-3.0 D to <-2.0 D (n=54)**	**≥-4.0 D to <-3.0 D (n=74)**	**≥-5.0 D to <-4.0 D (n=36)**	**≥-6.0 D to <-5.0 D (n=44)**	**≥-7.0 D to <-6.0 D (n=33)**	**≥-8.0 D to <-7.0 D (n=19)**	**≥-9.0 D to <-8.0 D (n=11)**	**Total (N=322)**	
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	***Target***
Serious Device related AE: Corneal Haze	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	2 18.2%	3 0.9%	*<1%*

Percentages calculated based on non-missing values.
*Defined as change in logMAR >0.24.

TABLE 22
Outcomes Stratification Analysis
Effect of Preoperative iDesign Preoperative iDesign Sphere (IDS) Groups at 6 Months

Preoperative IDS										
Safety/Effectiveness Endpoints	**≥-1.0 D to ≤0.0 D (n=22)**	**≥-2.0 D to <-1.0 D (n=64)**	**≥-3.0 D to <-2.0 D (n=59)**	**≥-4.0 D to <-3.0 D (n=54)**	**≥-5.0 D to <-4.0 D (n=40)**	**≥-6.0 D to <-5.0 D (n=37)**	**≥-7.0 D to <-6.0 D (n=27)**	**≥-8.0 D to <-7.0 D (n=19)**	**Total (N=322)**	
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	***Target***
UCVA 20/40 or better	22 100%	64 100%	59 100%	54 100%	40 100%	37 100%	27 100%	19 100%	322 100%	*≥85%*
MRSE +/- 0.50 D	20 90.9%	61 95.3%	54 91.5%	48 88.9%	36 90.0%	26 70.3%	18 66.7%	12 63.2%	275 85.4%	*≥50%*

Safety/Effectiveness Endpoints	Preoperative IDS									
	≥-1.0 D to ≤0.0 D (n=22)	**≥-2.0 D to <-1.0 D (n=64)**	**≥-3.0 D to <-2.0 D (n=59)**	**≥-4.0 D to <-3.0 D (n=54)**	**≥-5.0 D to <-4.0 D (n=40)**	**≥-6.0 D to <-5.0 D (n=37)**	**≥-7.0 D to <-6.0 D (n=27)**	**≥-8.0 D to <-7.0 D (n=19)**	**Total (N=322)**	
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	***Target***
MRSE +/- 1.00 D	22 100%	64 100%	59 100%	51 94.4%	39 97.5%	35 94.6%	24 88.9%	16 84.2%	310 96.3%	*≥75%*
BSCVA Worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<1%*
Loss of >2 Lines BSCVA*	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.7%	0 0.0%	0 0.0%	1 0.3%	*<5%*
Haze with Loss of >2 Lines BSCVA*	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.7%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Induced Astigmatism >2D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<5%*
Serious Device related AE: Corneal Infiltration	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.5%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Serious Device related AE: Corneal Erosion	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	2 5.4%	0 0.0%	0 0.0%	2 0.6%	*<1%*
Serious Device related AE: Corneal Haze	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.7%	0 0.0%	2 10.5%	3 0.9%	*<1%*

Percentages calculated based on non-missing values.
*Defined as change in logMAR >0.24.

TABLE 23
Outcomes Stratification Analysis Effect of Preoperative iDesign Cylinder (IDC) Groups at 6 Months

	Preoperative IDC						
Safety/Effectiveness Endpoints	**≥-0.5 D to ≤0.0 D (n=99)**	**≥-1.0 D to <-0.5 D (n=94)**	**≥-2.0 D to <-1.0 D (n=86)**	**≥-3.0 D to <-2.0 D (n=29)**	**≥-4.0 D to <-3.0 D (n=14)**	**Total (N=322)**	
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	***Target***
UCVA 20/40 or better	99 100%	94 100%	86 100%	29 100%	14 100%	322 100%	*≥85%*
MRSE +/- 0.50 D	85 85.9%	85 90.4%	71 82.6%	24 82.8%	10 71.4%	275 85.4%	*≥50%*
MRSE +/- 1.00 D	97 98.0%	91 96.8%	82 95.3%	28 96.6%	12 85.7%	310 96.3%	*≥75%*
BSCVA Worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<1%*
Loss of >2 Lines BSCVA*	1 1.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<5%*
Haze with Loss of >2 Lines BSCVA*	1 1.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Induced Astigmatism >2D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<5%*
Serious Device related AE: Corneal Infiltration	0 0.0%	1 1.1%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Serious Device related AE: Corneal Erosion	1 1.0%	1 1.1%	0 0.0%	0 0.0%	0 0.0%	2 0.6%	*<1%*
Serious Device related AE: Corneal Haze	1 1.0%	0 0.0%	2 2.3%	0 0.0%	0 0.0%	3 0.9%	*<1%*

Percentages calculated based on non-missing values.
*Defined as change in logMAR >0.24.

d) *UCVA*

Table 24 presents monocular UCVA outcomes over time. At 6 months, the point of refractive stability, 100% (322/322) of eyes had UCVA of 20/40 or better and 99.4% (320/322) of eyes had UCVA of 20/20 or better. Similar information was provided for binocular UCVA (see **Table 25** below)

TABLE 24
Monocular UCVA Over Time All Eyes

LogMAR Value	Acuity	Preoperative (N=334) n % (95% CI)	1 Month (N=332) n % (95% CI)	3 Months (N=328) n % (95% CI)	6 Months (N=322) n % (95% CI)	9 Months (N=228) n % (95% CI)	12 Months (N=184) n % (95% CI)
≤ -0.06	20/16 or better	0 0.0% (- , -)	171 51.5% (46.0, 57.0)	290 88.4% (84.4, 91.7)	296 91.9% (88.4, 94.7)	208 91.2% (86.8, 94.6)	175 95.1% (90.9, 97.7)
≤ 0.04	20/20 or better	2 0.6% (0.1, 2.1)	265 79.8% (75.1, 84.0)	325 99.1% (97.4, 99.8)	320 99.4% (97.8, 99.9)	226 99.1% (96.9, 99.9)	184 100% (98.4, 100)
≤ 0.14	20/25 or better	3 0.9% (0.2, 2.6)	314 94.6% (91.6, 96.8)	328 100% (99.1, 100)	320 99.4% (97.8, 99.9)	227 99.6% (97.6, 100)	184 100% (98.4, 100)
≤ 0.34	20/40 or better	19 5.7% (3.5, 8.7)	328 98.8% (96.9, 99.7)	328 100% (99.1, 100)	322 100% (99.1, 100)	228 100% (98.7, 100)	184 100% (98.4, 100)
≤ 0.74	20/100 or better	96 28.7% (23.9, 33.9)	332 100% (99.1, 100)	328 100% (99.1, 100)	322 100% (99.1, 100)	228 100% (98.7, 100)	184 100% (98.4, 100)
> 0.74	Worse than 20/100	238 71.3% (66.1, 76.1)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)
Not Reported	Not reported	0	0	0	0	0	0

Percentage is calculated based on non-missing values [(n/N).x 100%].

TABLE 25
Binocular UCVA Over Time Safety Population

LogMAR Value	Acuity	Pre-Op (N=167) n % (95% CI)	1 Month (N=166) n % (95% CI)	3 Months (N=164) n % (95% CI)	6 Months (N=161) n % (95% CI)	9 Months (N=114) n % (95% CI)	12 Months (N=92) n % (95% CI)
<=-0.06	20/16 or better	1 0.6% (0.0, 3.3)	128 77.1% (70.0, 83.3)	161 98.2% (94.7, 99.6)	160 99.4% (96.6, 100)	112 98.2% (93.8, 99.8)	92 100% (96.8, 100)
<= 0.04	20/20 or better	3 1.8% (0.4, 5.2)	155 93.4% (88.5, 96.6)	164 100% (98.2, 100)	161 100% (98.2, 100)	114 100% (97.4, 100)	92 100% (96.8, 100)
<= 0.14	20/25 or better	8 4.8% (2.1, 9.2)	165 99.4% (96.7, 100)	164 100% (98.2, 100)	161 100% (98.2, 100)	114 100% (97.4, 100)	92 100% (96.8, 100)
<= 0.34	20/40 or better	27 16.2% (10.9, 22.6)	166 100% (98.2, 100)	164 100% (98.2, 100)	161 100% (98.2, 100)	114 100% (97.4, 100)	92 100% (96.8, 100)
<= 0.74	20/100 or better	72 43.1% (35.5, 51.0)	166 100% (98.2, 100)	164 100% (98.2, 100)	161 100% (98.2, 100)	114 100% (97.4, 100)	92 100% (96.8, 100)
> 0.74	Worse than 20/100	95 56.9% (49.0, 64.5)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)
Not Reported	Not Reported	0	0	0	0	0	0

[a] Confidence Interval is calculated based on Clopper-Pearson Exact method.
[b] Percentage is calculated based on non-missing values [(n/N).x 100%].

Table 26 presents the differences in postoperative UCVA achieved compared to preoperative BSCVA. At 6 months, 81.4% (262/322) of eyes achieved the same or better acuity level postoperatively without correction as preoperatively with correction.

TABLE 26
Postoperative Monocular UCVA Compared to Preoperative Monocular BSCVA
All Eyes (N=332)

LogMAR Change	Acuity Change	1 Month (N=332) n %	3 Months (N=328) n %	6 Months (N=322) n %	9 Months (N=228) n %	12 Months (N=184) n %
<-0.24	**>2 lines better**	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
≥-0.24 to <-0.14	**2 lines better**	0 0.0%	1 0.3%	5 1.6%	3 1.3%	6 3.3%
≥-0.14 to <-0.04	**1 line better**	16 4.8%	62 18.9%	88 27.3%	76 33.3%	70 38.0%
≥-0.04 to ≤0.04	**Equal**	91 27.4%	197 60.1%	169 52.5%	117 51.3%	91 49.5%
>0.04 to ≤0.14	**1 line worse**	131 39.5%	61 18.6%	55 17.1%	27 11.8%	14 7.6%
>0.14 to ≤0.24	**2 lines worse**	56 16.9%	7 2.1%	3 0.9%	3 1.3%	3 1.6%
>0.24	**>2 lines worse**	38 11.4%	0 0.0%	2 0.6%	2 0.9%	0 0.0%
Not Reported		0	0	0	0	0

% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per time period (N).

e) *Accuracy of Manifest Refraction*

At 6 months post-operative, 85.4% (275/322) of eyes were within 0.50 D, and 96.3% (310/322) within 1.0 D of attempted correction (emmetropia). **Table 27** presents the accuracy of MRSE over time for all treated eyes. At 6 months, 1 eye (0.3%; 1/322) was undercorrected >1.00 D and 11 eyes (3.4%; 11/322) were overcorrected >1.00 D, of which 1 eye (0.3%; 1/322) was overcorrected >2.00 D.

TABLE 27
Accuracy of MRSE: Intended vs. Achieved Outcome

	Preoperative (N=334)	1 Month (N=332)	3 Months (N=328)	6 Months (N=322)	9 Months (N=228)	12 Months (N=184)
MRSE	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**
+/- 0.50 D	0 0.0% (- , -)	223 67.2% (61.8, ,72.2)	274 83.5% (79.1, ,87.4)	275 85.4% (81.1, ,89.1)	185 81.1% (75.4, ,86.0)	157 85.3% (79.4, ,90.1)
+/- 1.00 D	6 1.8% (0.7, 3.9)	310 93.4% (90.1,, 95.8)	316 96.3% (93.7,, 98.1)	310 96.3% (93.6, ,98.1)	221 96.9% (93.8, ,98.8)	182 98.9% (96.1, ,99.9)
+/- 2.00 D	62 18.6% (14.5, 23.2)	331 99.7% (98.3, 100)	328 100% (99.1, 100)	321 99.7% (98.3, 100)	228 100% (98.7, 100)	184 100% (98.4, 100)
Not Reported	0	0	0	0	0	0
Undercorrected						
> 1.00 D		16 4.8% (2.8, 7.7)	2 0.6% (0.1, 2.2)	1 0.3% (0.0, 1.7)	1 0.4% (0.0, 2.4)	1 0.5% (0.0, 3.0)
> 2.00 D		0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)
Overcorrected						
> 1.00 D		6 1.8% (0.7, 3.9)	10 3.0% (1.5, 5.5)	11 3.4% (1.7, 6.0)	6 2.6% (1.0, 5.6)	1 0.5% (0.0, 3.0)
> 2.00 D		1 0.3% (0.0, 1.7)	0 0.0% (- , -)	1 0.3% (0.0, 1.7)	0 0.0% (- , -)	0 0.0% (- , -)

Percentage is calculated based on non-missing values [(n/N).x 100%].

f) *Stability Outcome*

- Refractive stability is defined by the following criteria (per ANSI Z80.11-2012 and Study Protocol):
  - At least 95% of the treated eyes have a change ≤1.00 D of MRSE and MRC between refractions performed at 1 month and 3 months after surgery or any two refractions performed at least 3 months apart.
  - The mean rate of change in MRSE and MRC, as determined by a paired analysis, is ≤0.50 D per year (0.04 D/month) over the same period.
  - The mean rate of change in MRSE and MRC decreases monotonically over time, with a projected asymptote of zero or a rate of change attributable to normal aging; and,
  - The 95% confidence interval for the mean rate of change includes zero or a rate of change attributable to normal aging.
  - Stability is confirmed at least 3 months after the stability time point by a statistically adequate subgroup.

i. Stability of MRSE

Table 28 presents the stability of MRSE across visits for all eyes with at least two consecutive study visits. **Table 29** presents the stability of MRSE across visits for all eyes with data at 1, 3, 6, and 9 months. The defined criteria for refractive stability were met at the 6-month visit and confirmed at the 9-month visit. At least 95.0% of eyes had ≤1.00 D change in MRSE between 3 and 6 months and between 6 and 9 months, meeting the criterion of at least 95% of the treated eyes having a change of ≤1.00 D in MRSE at any two refractions performed at least 3 months apart.

TABLE 28
Stability of Manifest Refraction Spherical Equivalent (MRSE)
Consecutive Cohort[a]

Distributions	**Between 1 and 3 Months (N=328 Eyes) n %**	**Between 3 and 6 Months (N=318 Eyes) n %**	**Between 6 and 9 Months (N=226 Eyes) n %**	**Between 9 and 12 Months (N=182 Eyes) n %**
Change in MRSE by ≤1.00 D	312 95.1%	311 97.8%	216 95.6%	181 99.5%
Change in MRSE by ≤0.50 D	256 78.0%	281 88.4%	180 79.6%	163 89.6%
Mean Outcomes	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**
Mean Change in MRSE	0.16 +/- 0.51 (0.10, 0.21)	0.07 +/- 0.39 (0.02, 0.11)	0.00 +/- 0.50 (-0.07, 0.06)	-0.01 +/- 0.35 (-0.06, 0.04)
Mean Change Per Month	0.08	0.02	0.00	0.00

[a]Includes only eyes with data at two consecutive visits.
Change defined as current visit value minus previous visit value.
Percentage is calculated from (n/N).x 100%.

TABLE 29
Stability of Manifest Refraction Spherical Equivalent (MRSE)
Consistent Cohort[a]

Distributions	Between 1 and 3 Months (N=224 Eyes) n %	Between 3 and 6 Months (N=224 Eyes) n %	Between 6 and 9 Months (N=224 Eyes) n %
Change in MRSE by ≤1.00 D	212 94.6%	217 96.9%	214 95.5%
Change in MRSE by ≤0.50 D	172 76.8%	195 87.1%	178 79.5%
Mean Outcomes	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**
Mean Change in MRSE	0.17 +/- 0.54 (0.10, 0.24)	0.09 +/- 0.42 (0.03, 0.14)	0.00 +/- 0.50 (-0.07, 0.06)
Mean Change Per Month	0.08	0.03	0.00

Change defined as current visit value minus previous visit value.
[a]Includes only eyes with data at 1, 3, 6, and 9 Months visits.
Percentage is calculated from (n/N).x 100%.

ii. *Stability of Refractive Cylinder*

Table 30 presents the stability of absolute (non-vector) cylinder across visits for all eyes with at least two consecutive study visits. **Table 31** presents the stability of absolute (non-vector) cylinder across visits for all eyes with data at 1, 3, 6, and 9 months. At least 95.0% of eyes had ≤1.00 D change in manifest refractive cylinder (MRC) between 3 and 6 months and between 6 and 9 months, meeting the criterion of at least 95% of the treated eyes having a change of ≤1.00 D in MRC at any two refractions performed at least 3 months apart.

TABLE 30
Stability of Manifest CylinderConsecutive Cohort[a]

Magnitude of Change in Non-vector Cylinder Distributions	Between 1 and 3 Months (N=328 Eyes) n %	Between 3 and 6 Months (N=318 Eyes) n %	Between 6 and 9 Months (N=226 Eyes) n %	Between 9 and 12 Months (N=182 Eyes) n %
Eyes with ≤1.00 D Change	310, 94.5%	318, 100%	226, 100%	182, 100%
Eyes with ≤0.50 D Change	269, 82.0%	313, 98.4%	220, 97.3%	180, 98.9%
Mean Outcomes (D)				
Mean Change between Visits	0.28	0.03	-0.02	0.02
SD	0.47	0.23	0.24	0.20
95% CI	0.23, 0.33	0.01, 0.06	-0.05, 0.01	-0.01, 0.05
Mean Change Per Year	1.70	0.13	-0.08	0.09
Mean Change Per Month[b]	0.14	0.01	-0.01	0.01

Change defined as current visit value minus previous visit value.
[a]Includes only eyes with data at two consecutive visits.
[b]Refractive stability criterion: mean change of $\leq$ 0.4 D/month between visits.
Percentage is calculated from (n/N).x 100%.

TABLE 31
Stability of Manifest Cylinder
Consistent Cohort[a]

Magnitude of Change in Non-vector Cylinder Distributions	Between 1 and 3 Months (N=224 Eyes) n %	Between 3 and 6 Months (N=224 Eyes) n %	Between 6 and 9 Months (N=224 Eyes) n %
Eyes with ≤1.00 D Change	209, 93.3%	224, 100%	224, 100%
Eyes with ≤0.50 D Change	182, 81.3%	219, 97.8%	218, 97.3%
Mean Outcomes (D)			
Mean Change between Visits	0.29	0.03	-0.02
SD	0.49	0.25	0.24
95% CI	0.23, 0.36	0.00, 0.06	-0.05, 0.01
Mean Change Per Year	1.75	0.13	-0.07
Mean Change Per Month	0.15	0.01	-0.01

Change defined as current visit value minus previous visit value.
[a]Includes only eyes with data at 1, 3, 6, and 9 Months visits.
Percentage is calculated from (n/N).x 100%.

Additional Cylinder Correction Analyses

Table 32 presents the proportions of eyes with residual manifest cylinder magnitude at 6 months and the absolute shift in axis from preoperative. Vector analysis summary statistics at 6 months are presented in **Table 33**. The mean correction ratio (CR; ratio of surgically induced refractive change compared to the intended refractive change) of 0.96 demonstrates a slight undercorrection of cylinder.

TABLE 32
Residual Manifest Refractive Astigmatic Axis Error at 6 Months

Residual Cylinder Magnitude	Absolute Shift in Axis: 0 (N=117 Eyes) n % 95% CI	>0 to ≤5 (N=31 Eyes) n % 95% CI	>5 to ≤10 (N=34 Eyes) n % 95% CI	>10 to ≤15 (N=26 Eyes) n % 95% CI	>15 to ≤30 (N=53 Eyes) n % 95% CI	>30 (N=61 Eyes) n % 95% CI	Total (N=322 Eyes) n % 95% CI
0.0 D	90 76.9%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	90 28.0%
>0 to ≤0.5 D	24 20.5%	27 87.1%	26 76.5%	20 76.9%	51 96.2%	59 96.7%	207 64.3%
>0.5 to ≤1.0 D	2 1.7%	4 12.9%	7 20.6%	6 23.1%	2 3.8%	2 3.3%	23 7.1%
>1.0 to ≤2.0 D	1 0.9%	0 0.0%	1 2.9%	0 0.0%	0 0.0%	0 0.0%	2 0.6%
>2.0 to ≤3.0 D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Total	**117 100**	**31 100**	**34 100**	**26 100**	**53 100**	**61 100**	**322 100**

% Percentage is calculated by dividing the number of eyes in the cell (n) / by the total number of eyes per column (N).

TABLE 33
Vector Analysis Summary at 6 Months[a]

Pre-Operative Cylinder	n (%)	|IRC| (Mean +/- SD)	|SIRC| (Mean +/- SD)	|EV| (Mean +/- SD)	CR (Mean +/- SD)	ER (Mean +/- SD)
All Eyes (N)	324 (100%)	1.01 +/- 0.84	0.93 +/- 0.75	0.29 +/- 0.26	0.96 +/- 0.38	0.41 +/- 0.58
0.0 D	21 (6.5%)	0.00 +/- 0.00	0.29 +/- 0.28	0.29 +/- 0.28		
>0.0 D to ≤0.5 D	115 (35.5%)	0.39 +/- 0.12	0.42 +/- 0.20	0.23 +/- 0.23	1.10 +/- 0.54	0.69 +/- 0.83
>0.5 D to ≤1.0 D	90 (27.8%)	0.88 +/- 0.13	0.77 +/- 0.23	0.24 +/- 0.22	0.88 +/- 0.23	0.27 +/- 0.25
>1.0 D to ≤2.0 D	60 (18.5%)	1.56 +/- 0.29	1.36 +/- 0.43	0.38 +/- 0.31	0.87 +/- 0.23	0.26 +/- 0.24
>2.0 D to ≤3.0 D	27 (8.3%)	2.56 +/- 0.29	2.29 +/- 0.41	0.37 +/- 0.24	0.89 +/- 0.11	0.14 +/- 0.09
>3.0 D to ≤4.0 D	11 (3.4%)	3.50 +/- 0.30	3.12 +/- 0.41	0.48 +/- 0.21	0.89 +/- 0.09	0.14 +/- 0.06

IRC = intended refractive change
SIRC = surgically induced refractive change
EV = error vector (IRC-SIRC)
CR = correction ratio (SIRC/IRC)
ER = error ratio (EV/IRC)

[a] The analysis was based on 324 evaluable patients at the 6-month time-point at final database lock on August 24, 2018. This analysis was submitted in P930016/S057/A001.

g) *Refractive Retreatment*

There were no eyes (0%; 0/334) that underwent refractive retreatment during the study.

3. Subgroup Analyses

Key safety and effectiveness outcomes at the 6-month timepoint of stability were stratified by subgroup based on the following characteristics: age, gender, race, site, preoperative contact lens wear, preoperative iDesign spherical equivalent (IDSE), preoperative iDesign sphere (IDS), preoperative iDesign cylinder, wavefront capture diameter, iris registration (IR) status, and clinically significant protocol deviations. Although some outcomes varied with respect to eyes achieving MRSE within 1.00 D and 0.5 D of target among age, gender, site, preoperative iDesign refractive parameters (IDSE and IDS), IR status, and clinically relevant protocol deviation subgroups, all subgroups met key effectiveness outcome targets. The number of safety events did not exceed 2 cases within any of the subgroups. No specific association between safety events and any subgroup was observed, given the low occurrence of those events in the study (less than 1% for the overall study population). In conclusion, there is reasonable assurance of safety for all subgroups.

The key endpoints at the point of stability stratified by pre-operative IDSE, IDS, and IDC are presented in **Tables 21, 22 and 23** in **Subsection 2** and by age and gender are presented in **Tables 34 and 35 below**.

TABLE 34
Key Safety and Effectiveness Endpoints at 6 Months Stratified by Age Groups

	Age Group (Years)				
Safety/Effectiveness Endpoints	**≥18 to ≤21 (N=54 eyes)**	**>21 to ≤25 (N=108 eyes)**	**>25 to ≤30 (N=110 eyes)**	**>30 to ≤47 (N=50 eyes)**	**Total (N=322 eyes)**
MRSE +/- 0.50 D 95% CI	48 88.9% (77.4, 95.8)	81 75.0% (65.7, 82.8)	103 93.6% (87.3, 97.4)	43 86.0% (73.3, 94.2)	275 85.4% (81.1, 89.1)
MRSE +/- 1.00 D 95% CI	52 96.3% (87.3, 99.5)	99 91.7% (84.8, 96.1)	109 99.1% (95.0, 100)	50 100% (94.2, 100)	310 96.3% (93.6, 98.1)
UCVA 20/40 or Better 95% CI	54 100% (94.6, 100)	108 100% (97.3, 100)	110 100% (97.3, 100)	50 100% (94.2, 100)	322 100% (99.1, 100)
BSCVA Worse than 20/40 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	0 0.0% (0.0, 2.7)	0 0.0% (0.0, 5.8)	0 0.0% (0.0, 0.9)
Loss of >2 Lines BSCVA* 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	1 0.3% (0.0, 1.7)
Haze with Loss of >2 Lines BSCVA* 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	1 0.3% (0.0, 1.7)
Induced Astigmatism>2.00D 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	0 0.0% (0.0, 2.7)	0 0.0% (0.0, 5.8)	0 0.0% (0.0, 0.9)
Serious Device-related AE: Corneal Infiltration 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	1 0.3% (0.0, 1.7)
Serious Device-related AE: Corneal Erosion 95% CI	0 0.0% (0.0, 5.4)	1 0.9% (0.0, 5.1)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	2 0.6% (0.1, 2.2)
Serious Device-related AE: Corneal Haze 95% CI	0 0.0% (0.0, 5.4)	2 1.9% (0.2, 6.5)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	3 0.9% (0.2, 2.7)

Percentages calculated based on non-missing values = (n/N).x 100%..

*Defined as change in logMAR >0.24.

TABLE 35
Key Safety and Effectiveness Endpoints at 6 Months Stratified by Gender

	Gender		
Safety/Effectiveness Endpoints	**Male (N=222 eyes)**	**Female (N=100 eyes)**	**Total (N=322 eyes)**
MRSE +/- 0.50 95% CI	188 84.7% (79.3, 89.2)	87 87.0% (78.8, 92.9)	275 85.4% (81.1, 89.1)
MRSE +/- 1.00 95% CI	210 94.6% (90.7, 97.2)	100 100% (97.0, 100)	310 96.3% (93.6, 98.1)
UCVA 20/40 or Better 95% CI	222 100% (98.7, 100)	100 100% (97.0, 100)	322 100% (99.1, 100)
BSCVA Worse Than 20/40 95% CI	0 0.0% (0.0, 1.3)	0 0.0% (0.0, 3.0)	0 0.0% (0.0, 0.9)
Loss of >2 Lines BSCVA* 95% CI	1 0.5% (0.0, 2.5)	0 0.0% (0.0, 3.0)	1 0.3% (0.0, 1.7)
Haze with Loss of >2 Lines BSCVA* 95% CI	1 0.5% (0.0, 2.5)	0 0.0% (0.0, 3.0)	1 0.3% (0.0, 1.7)
Induced Astigmatism>2.00D 95% CI	0 0.0% (0.0, 1.3)	0 0.0% (0.0, 3.0)	0 0.0% (0.0, 0.9)
Serious Device-related AE: Corneal Infiltration 95% CI	1 0.5% (0.0, 2.5)	0 0.0% (0.0, 3.0)	1 0.3% (0.0, 1.7)
Serious Device-related AE: Corneal Erosion 95% CI	1 0.5% (0.0, 2.5)	1 1.0% (0.0, 5.4)	2 0.6% (0.1, 2.2)
Serious Device-related AE: Corneal Haze 95% CI	1 0.5% (0.0, 2.5)	2 2.0% (0.2, 7.0)	3 0.9% (0.2, 2.7)

Percentages calculated based on non-missing values (n/N).x 100%..
*Defined as change in logMAR >0.24.

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 22 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

STAR-115-MIPS SUBGROUP ANALYSIS – 18 TO 21 YEARS OLD

A total of 27 subjects (54 eyes) in the study (16.2%; 54/334) were 18-21 years old. Subjects had to be at least 18 years old to participate in the study and have a stable refractive error (≤1.00 D MRSE) at least 12 months prior to preoperative manifest refraction. Key safety and effectiveness results at 6 months were exceeded in this cohort of eyes. At 6 months, 88.9% (48/54) of eyes achieved MRSE within 0.50 D and 96.3% (52/54) of eyes achieved MRSE within 1.00 D. All eyes (100%; 54/54) in this subgroup achieved UCVA of 20/40 or better. No eye (0%; 0/54) had BSCVA worse than 20/40 and no eye (0%; 0/54) had a decrease in BSCVA of more than 2 lines. The mean rate of MRSE change per month was 0.00 D/month between 3 and 6 months and 0.04 D/month between 6 and 9 months, and the corresponding confidence intervals of the mean rate of change in MRSE include zero. No eye belonging to subjects in this age group experienced any serious adverse event. The 18-21-year age group met all postoperative effectiveness and safety endpoints. Therefore, it is deemed reasonable to include the 18-21-year age group in the ***iDESIGN***-based PRK indicated age range.

STAR-125-ARID

A prospective, single-center, monocular, measurement-only clinical study was conducted to evaluate if the modified ***iDESIGN***® settings proposed for ***iDESIGN*** Refractive Studio system software v2.1 (i.e., slower fogging prior to autorefraction) resulted in reducing instrument accommodation. For this study, the ***iDESIGN***® Refractive Studio with standard settings and modified settings to allow slower fogging speed were used. Inclusion criteria included: myopic refractive error with sphere and spherical equivalent (SE) up to -11.00 D, cylinder between 0.0 and -5.00 D, hyperopic refractive error with maximum SE of +6.00 D, and cylinder between 0.00 and 4.00 D, and mixed astigmatism where the magnitude of cylinder (up to 6.00 D) is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs; subject age between 18 and 55 years; monocular distance best spectacle corrected visual acuity (BSCVA) of 20/25 or better in the study eye; no soft contact lens wear for at least 12 hours and no rigid gas permeable contact lens wear for 1 month prior to the day of study measurements in the study eye; no prior ocular surgery or injury, and no concomitant use of systemic or ocular medications that may affect vision; no concurrent participation in any other clinical study; and no pregnant or lactating women.

Manifest refraction and ***iDESIGN***® measurements were captured in one visit. Of the 70 subjects that were enrolled 53 eyes were included for analysis – 49 with myopia, 3 with hyperopia and 1 with mixed astigmatism. Out of the 17 excluded subjects, one subject was not eligible because of participation in another clinical trial and16 subjects were excluded due to procedural protocol deviations.

The results showed that ***iDESIGN***® baseline and proposed slow fog settings were not significantly different from each other in terms of the mean paired difference with manifest refraction spherical equivalent, -0.36 D and -0.33 D, respectively. When accommodation

was stimulated by moving the fixation target vergence, the slow fogging resulted in a narrower range of paired differences (1.96 D) as compared to the range for baseline settings (3.67 D).

In conclusion, while the different ***iDESIGN***® settings showed no statistically significant differences based on mean outcomes, individual results indicated that some of the outliers may be eliminated by using a slower fog speed.

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

In the clinical investigation of wavefront-guided PRK correction of myopia with and without astigmatism with the ***iDESIGN*®** Refractive Studio and ***STAR S4 IR***® Excimer Laser System, effectiveness outcomes met study targets. Refractive stability was achieved at 6 months; at this time, the proportion of eyes with a UCVA of 20/40 or better (Target ≥85%; ***iDESIGN*®** 100%), and the proportions of eyes that achieve MRSE within 0.50 D (Target ≥50%; ***iDESIGN*®** 85.4%) and 1.00 D (Target ≥75%; ***iDESIGN*®** 96.3%) met the target values.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory studies as well as data collected in a clinical study conducted to support PMA approval as described above. In the clinical investigation of wavefront-guided PRK correction of myopia with and without astigmatism with the ***iDESIGN***® Refractive Studio System and ***STAR S4 IR***® Excimer Laser System, safety outcomes were found to be acceptable and met the safety targets. There were seven serious device-related adverse events (SADE): 2 cases of corneal infiltrate, 3 cases of corneal haze, and 2 cases of corneal erosion. All seven SADEs have resolved.

At 6 months, the proportion of eyes with >2 line loss of BSCVA (Target <5%; ***iDESIGN***® 0.3%), the proportion of eyes with haze and >2 line loss of BSCVA (Target <1%; ***iDESIGN***® 0.3%), the proportion of eyes with BSCVA worse than 20/40 (Target <1%; ***iDESIGN***® 0%), the proportion of eyes with induced manifest refractive astigmatism >2.00 D (Target <5%; ***iDESIGN***® 0.0%), and the rate of each

type of serious, device-related ocular adverse events (Target <1%; ***iDESIGN***® ≤0.9%; corneal infiltrate 0.6% [2/334], corneal erosion 0.6% [2/334], corneal haze 0.9% [3/334]) were within target values. The most common adverse events that occurred during the study were corneal edema at 1 month (rate of 3%; 10/334); all resolved by 3 months. The clinical study results indicate that there is reasonable assurance of the safety of wavefront-guided PRK correction of myopic refractive errors using the ***iDESIGN***® System and ***Star S4 IR***® Excimer Laser System.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above.

Patients have a reasonable chance of experiencing the following benefit: improved uncorrected visual acuity. Monocular UCVA of 20/20 or better was seen in 99.4% (320/322) of eyes at 6 months.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The rate of each type of serious, device-related adverse event was <1% (corneal infiltrate 0.6%, 2/334; corneal erosion 0.6%, 2/334; corneal haze 0.9%, 3/334), meeting the safety endpoint for serious, device-related adverse events of <1%. The most frequent adverse events were corneal edema at 1 month or later (3.0% cumulatively; 0.0% at 6 months) and corneal infiltrate or ulcer (0.9% cumulatively; 0.0% at 6 months).

1. Patient Perspectives
   Patient perspective information considered during the review included results from administration of the following: Ocular Surface Disease Index (OSDI), Patient Reported Visual Symptom Questionnaire (PRVSQ for PRK/LASIK), National Eye Institute Refractive Error Quality of Life - 42 (NEI RQL 42), and exploratory Satisfaction Questionnaire.

In conclusion, given the available information above, the data support that for wavefront-guided PRK correction of myopic refractive errors with the ***iDESIGN***® Refractive Studio System and ***STAR S4 IR***® Excimer Laser System, the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. All safety and effectiveness endpoint targets at the stability time point of 6 months were achieved.

XIV. CDRH DECISION

CDRH issued an approval order on September 9, 2019. 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.