SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Ophthalmic Excimer Laser System
Device Trade Name:	TECHNOLAS TENEO™ 317 (MODEL 2) Excimer Laser System
Device Procode:	LZS
Applicant's Name and Address:	Bausch + Lomb Incorporated 1400 North Goodman Street Rochester, New York 14609
Date of Panel Recommendation:	N/A
Premarket Approval (PMA) Application Number:	P990027/S021
Date of FDA Notice of Approval:	November 22, 2023
Priority Review:	N/A
Breakthrough Device:	N/A

The parent laser system, the TECHNOLAS 217A excimer laser system with Planoscan (PS) software (SW), PMA P990027, was approved on February 25, 2000 and was indicated for photorefractive keratectomy for the reduction or elimination of myopia ranging from -1.00 D to -7.00 D spherical myopia with our without 5 -3.00 astigmatism. The device then gained approval for expansion of the indication for laser in-situ keratomileusis (LASIK) treatments for the reduction or elimination of myopic astigmatism up to -12.0 D MRSE, with sphere between < -7.00D to -10.99 D and cylinder between 0.00 and <-3.00 Din P990027/S002. The SSED to support the indication is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to expand the indications for the TECHNOLAS TENEO 317 MODEL2 US excimer laser system (TENEO 317).

II. INDICATIONS FOR USE

The TECHNOLAS TENEO 317 MODEL2 US is indicated for laser-assisted in situ keratomileusis (LASIK) in:

- Patients for the reduction or elimination of myopic astigmatism up to -10.00 D MRSE, with sphere between -1.00 D to -10.0 D and cylinder between 0.00 and -3.00 D;
- Patients who are 22 years of age or older;
- Patients must have a stable refraction in the last 12 months, as documented by previous clinical recordings, i.e., the spherical and cylindrical portions of the manifest distance refraction have not progressed at a rate of more than 0.50 D per year prior to the baseline examination in the eye(s) to be treated.

III. CONTRAINDICATIONS

TECHNOLAS TENEO 317 MODEL2 US driven LASIK surgery is contraindicated in:

- Patients with any type of active connective tissue disease or autoimmune disease
- Patients with signs of keratoconus, abnormal corneal topography, and degenerations of the structure of the cornea (including but not limited to pellucid marginal degeneration)
- Patients with significant dry eyes (severe Dry Eye Syndrome).
    - If patients have severely dry eyes, LASIK 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 LASIK.
- Patients for whom the combination of their baseline corneal thickness and the planned operative parameters for the LASIK procedure would result in less than 250 μm of residual corneal thickness from corneal endothelium.
- Patients with uncontrolled diabetes
- Patients with uncontrolled glaucoma
- Patients with active eye infection or active inflammation
- Patients with recent herpes eye infection or problems resulting from past infection
- Patients with known sensitivity to medications used for standard LASIK surgery

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the TECHNOLAS TENEO 317 MODEL2 US excimer laser system labeling.

V. DEVICE DESCRIPTION

The TECHNOLAS TENEO 317 MODEL2 US Laser System is an Excimer Laser System operating at a wavelength of 193 nm with a repetition rate of 500 Hz.

The TECHNOLAS TENEO 317 MODEL2 US uses the interaction of pulsed laser beams of Ultraviolet light at 193nm wavelength with the human cornea. The spot size of the laser beam is controlled by an aperture and an optical device to shape the intensity profile of each spot into a truncated Gaussian beam shape. Each laser pulse will remove a small amount of tissue from the corneal or stromal surface.

A high-precision scanner system directs each pulse to the predefined location. The combination of many individual pulses allows creating very precise, preprogrammed ablation patterns to reshape the cornea of the human eye, designed to treat a refractive error of the eye and improve the vision of the treated subject.

Due to the high 500 Hz repetition rate of the TECHNOLAS TENEO 317 MODEL2 US the system can operate using a small spot size of 1mm while still performing the whole ablation in a sufficiently short timeframe.

The laser offers additional aiming beams in the visible light range which allow the user to position the eye in height and lateral position, as well as to precisely register the desired treatment location of the eye. The operative microscope also supports the positioning of the eye.

Furthermore, the TECHNOLAS TENEO 317 MODEL2 US implements a video based state-of-the art multidimensional eye tracking system with a tracking speed adapted to the laser repetition rate. Lateral and rotational eye movement during the treatment is actively compensated by re-adjusting the treatment pattern accordingly.

The parent laser system, the TECHNOLAS 217A excimer laser system for LASIK myopic indication with Planoscan (PS) software (SW), was originally approved by FDA via P990027 with the treatment range expanded via P990027/S002. Subsequently, FDA approved P990027/S018 for TECHNOLAS 217z Zyoptix with Advanced Planoscan (AdvPS) SW. Both the PS and AdvPS SW deliver a non-aspheric ablation profile.

The key SW difference between the approved TECHNOLAS 217A PS/AdvPS treatment SW and the TECHNOLAS TENEO 317 MODEL2 US treatment SW is that the TECHNOLAS TENEO 317 MODEL2 US SW is designed to impart an aspheric ablation profile.

Advanced features:

- Beam path flushed with N2
- Plume evacuation
- 360° swiveling surgical microscope
- Spot size approximately 1 mm
- Closed energy loop control (using three energy monitors)
- Multidimensional high-speed eye tracking (eye tracker 1740 frames per second (fps)):
  - Tracks and simultaneously adjusts the ablation pattern for the entire duration of the procedure
  - Movements in X/Y direction and rotational movement of the patient's eye

- Dynamic rotational tracking

PROSCAN treatment
PROSCAN is based on the subjective refractive error of the eye intended to be treated for myopia with and without astigmatism and the intended optical zone. PROSCAN is an aspheric, non-customized (using population mean K- and Q-value) ablation profile.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of myopia or myopic astigmatism:

- Glasses or Contact Lenses
- Standard Photo Refractive Keratectomy (PRK) or LASIK
- Wavefront-guided or corneal topography-assisted LASIK or PRK
- Refractive Lenticule Extraction (ReLEx)
- Implantable lens surgery (phakic Intraocular Lens)

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 TECHNOLAS TENEO 317 MODEL2 US excimer laser systems have been distributed in over 55 countries including Algeria, Argentina, Armenia, Austria, Azerbaijan, Belgium, Brazil, Canada, Chile, Czech Republic, Dominican Republic, Ecuador, Egypt, Finland, France, Georgia, Germany, Greece, Hong Kong, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Korea, Kuwait, Lithuania, Malaysia, Mexico, Morocco, North Macedonia, Palestine, Peru, Philippines, Poland, Portugal, Romania, Russia, Saudi Arabia, Senegal, Serbia, Singapore, Slovenia, Spain, Switzerland, Taiwan, Thailand, Tunisia, Turkey, Ukraine, United Kingdom, and Uzbekistan.

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[1]:

Intraoperative complications:

- Miscreated flap (lost, incomplete, too thin, misaligned, buttonhole, etc.)
- Subconjunctival hemorrhage or bleeding

Postoperative complications

- Wrinkles in flap (striae) that may require a flap lift
- Corneal erosion/abrasion, epithelial defect
- Elevated IOP (e.g., steroid induced)
- Debris or foreign body under flap

[1] Please note: The potential complication / side effects reported during use of the device are not related exclusively to the laser device itself. For example, subconjunctival hemorrhage are a common complication of LASIK, but is not related to the excimer device, but to the flap creating devices.

- Epithelial ingrowth under flap
- Debilitating visual symptoms, especially at night time (glare, halo, starburst, ghost and double or multiple images, distortion, hazy or blurred vision, difficulty with night driving)
- Decreased or fluctuating visual acuity (uncorrected and/or best corrected)
- Decreased ability to see in low-light conditions (e.g., reading a street sign at dusk)
- Light sensitivity (e.g. Transient light-sensitivity syndrome (TLSS))
- Dry Eye syndrome (surgically induced, or worsening of pre-existing signs and/or symptoms)
- Inadequate treatment result, including (but not limited to):
    - Over-correction or under-correction, induced or residual astigmatism, may require eyeglass or contact lens wear
    - Decentered ablation
    - Anisometropia (imbalance between the two eyes that may cause headaches, eye strain, double vision and/or difficulty judging distance or depth perception)
- Regression (reduction in the refractive correction over time)
- Corneal damage:
    - Corneal ectasia (bulging)
    - Corneal edema (swelling)
    - Corneal haze
    - Corneal changes like anterior basement membrane dystrophy
    - Corneal scarring
    - Corneal decompensation
    - Corneal ulceration or perforation
    - Corneal infection or inflammation
- Posterior Vitreous Detachment or Retinal Detachment (e.g. macular hole), floaters or vascular accidents
- Foreign body sensation (feeling of grittiness or something in eye) or pain initial postoperative days); also, potentially including chronic eye pain that is resistant to therapy referred to as neuropathic pain
- Infection/Inflammation (like corneal infiltrates, ulcer, DLK (Diffuse lamellar keratitis), SPK (Superficial punctate keratopathy), uveitis, lamellar keratitis, sterile inflammation, etc.)
- CTK (Central Toxic Keratopathy)
- Medication intolerance (increased intraocular pressure, allergically reaction, etc.)
- Ptosis (drooping eyelid, may require surgical intervention)
- Cataract
- Ocular penetration
- Potential risk of psychological harm

Difficulties in future ophthalmic assessments:

- After refractive surgery, there may be difficulties in future ophthalmic assessments, such as selecting an appropriate intraocular lens (IOL) for implantation during cataract surgery and assessing intraocular pressure (IOP).
    - *It is recommended that physicians consider whether it may be useful to provide the patient their pre-operative values.*
- Patients around 40 years of age or older may need eyeglasses for close work such as

reading due to presbyopia

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

A. Laboratory Studies

N/A

B. Animal Studies

N/A

C. Additional Studies

A brief summary of nonclinical tests for the TENEO 317 (Model 2) laser is provided below:

Test	Purpose	Conclusion	Results
Repetition rate stability	Determination of stability of laser head repetition rate	These data demonstrate that the TECHNOLAS TENEO 317 (Model 2) delivers laser pulses at a frequency of 500 Hz.	PASS
Energy Density (Fluence) at the Eye	Evaluation of treatment energy within 2-hour laser calibration interval	It is concluded that the TECHNOLAS TENEO 317 (Model 2) maintains a steady energy of 1.6 mJ (representing an energy density of 200 mJ/cm2) throughout the recommended energy calibration interval.	PASS
Laser Pulse Duration	Evaluation of pulse length measurements	The results demonstrate that the pulse duration for TECHNOLAS TENEO 317 remains within specifications.	PASS
Accuracy of ablation profiles (spot positioning)	Evaluation of treatment pattern on porcine eyes	It was concluded that the differences between the intended versus achieved profile are within the acceptance criteria of 0.25 D, and therefore the TECHNOLAS TENEO 317 (Model 2) achieves intended ablation profiles with an accuracy of 0.25 D or better.	PASS
Thermal effect control	Evaluation of corneal temperature rise of myopic ablation on porcine corneas	It was concluded that ablations with the TECHNOLAS TENEO 317 (Model 2) laser system do not pose a substantial risk to the cornea in terms of temperature increase.	PASS
Hardware Validation	Employ a wide range of benchtop testing to ensure the safe and effective device function	Testing demonstrated validation of device housing modifications, eye tracker function, spot positioning accuracy, verification of the excimer laser source, verification of all aspects of the optical beam path, verification of the extremal energy monitor, verification of microscope operation, verification of the operational field illumination, verification if the component requirements of the scanner module, verification of the excimer computer unit, verification results of the Monitor Column, verification of the foot switch, plume suction, and rotating patient bed, and radiation safety.	PASS
Software Validation	Evaluate the consistency, completeness, and correctness of the software and its supporting	The TECHNOLAS TENEO 317 (Model 2) laser system software has been designed, implemented, verified, and validated according with FDA recommendations. Additionally, the ablation algorithm has been reviewed and validated. Software validation has been provided in accordance with FDA guidance "Guidance for the Content	PASS

Test	Purpose	Conclusion	Results
	documentation, confirm that the software development output meets its input requirements, review software architecture, software detailed design, and traceability analyses	of Premarket Submissions for Software Contained in Medical Devices".	
Cybersecurity Validation	Ensures safeguards against unauthorized device access, software modification, misuse, denial of use, and unauthorized use of information that is stored, accessed, or transferred	The TECHNOLAS TENEO 317 (Model 2) laser system software and hardware environment employ sufficient security safeguards against cyber and physical security attacks. Cybersecurity validation has been provided in accordance with FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"	PASS
Electromagnetic safety and Compatibility	Ensure continuous device function in a noisy electromagnetic field environment	The results demonstrate that the TECHNOLAS TENEO 317 remains functional within specifications in the presence of a range of electromagnetic frequency signals and when subjected to electrostatic discharges. Testing has been performed in accordance with IEC 60601-1:2005 +AMD1:2012 + AMD2:2020; IEC 60601-1-2:2014 + AMD1:2020; and IEC 60601-2-22:2019.	PASS

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X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the PROSCAN treatment algorithm with TECHNOLAS TENEO 317 MODEL2 US for the reduction or elimination of myopia and myopic astigmatism, up to -11.50 D manifest refraction spherical equivalent (MRSE) with sphere between -1.00 D to -10.0 D and cylinder between 0.00 and <-3.00 D, at sites in the US under IDE # G180286. Data from this clinical study are the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between July 30, 2019 and December 4, 2020. The database for this Panel Track Supplement reflected data collected through August 6, 2021 and included 333 eyes of 168 patients. There were 10 investigational sites.
The study was a multicenter, prospective, open-label, nonrandomized, single-arm study evaluating the safety and effectiveness of the TENEO 317 (Model 2) when used in LASIK surgery to treat myopia or myopic astigmatism by comparing postoperative refraction and visual acuity to standard guidelines, as well as assessment of adverse events ant visual symptoms.
The study design allowed for 6 follow-up visits over 9 months to allow subjects' vision to achieve refractive stability postoperatively. All study eye treatments were targeted for emmetropia. The Statistical Analysis Plan was written with due consideration of the recommendations outlined in the most recent International Conference on Harmonisation (ICH) E3 Guideline (July 1996), entitled Guidance for Industry: Structure and Content of Clinical Study Reports.

General Analysis Methods
Summaries for continuous and ordinal variables included the number of observations (n), arithmetic mean, standard deviation, median, minimum, and maximum. Minima and maxima were reported with the same precision as the raw values; means and medians were presented to 1 additional decimal place than reported in the raw values. Standard deviations were presented to 2 additional decimal places than reported in the raw values. Summaries for discrete variables included counts and percentages. All percentages were rounded to 1 decimal place (ie, XX.X%). All statistical tests were one-sided with a significance level of 0.025 ($\alpha = 0.025$) unless otherwise specified. Confidence intervals (CIs) around single estimated proportions were two-sided at 95% confidence. All p-values were rounded to 4 decimal places. Eyes were treated as independent sampling units.

Determination of Sample Size
Prior clinical experience with the TENEO 317 (Model 2) in Europe showed that 94.5% of eyes were within 0.50 D and 99% of eyes were within 1.00 D of targeted MRSE 1 month after surgery. In addition, 100% of eyes achieved UCDVA of 20/40 or better at 1 month.

- Percentage of Eyes That Achieve Predictability of MRSE Within ± 0.50 D at the Time of Refractive Stability:
  A one group χ^2 test with a 2.5% one-sided significance level had > 99.99% power to detect the difference between the null hypothesis proportion, π_0, of 0.80 and the alternative proportion, π_1, of 0.945 when the sample size was 300.
- Percentage of Eyes That Achieve Predictability of MRSE Within ± 1.00 D at the Time of Refractive Stability:

A one group χ^2 test with a 2.5% one-sided significance level had > 99.99% power to detect the difference between the null hypothesis proportion, π_0, of 0.90 and the alternative proportion, π_1, of 0.99 when the sample size was 300.

- Percentage of Eyes Targeted for Emmetropia That Achieve uncorrected distance visual acuity (UCDVA) of 20/40 or Better at the Time of Refractive Stability:
  A one group χ^2 test with a 2.5% one-sided significance level had > 99.99% power to detect the difference between the null hypothesis proportion, π_0, of 0.88 and the alternative proportion, π_1, of 0.99 when the sample size was 300.

1. Clinical Inclusion and Exclusion Criteria

There was one treatment group in this study. All subjects who met eligibility criteria were consecutively offered enrollment into the trial. Both eyes of a subject could be enrolled if they met eligibility requirements, but if an intraoperative complication or adverse event (AE) occurred in the first eye, treatment was to be abandoned in the second eye.

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

- Are 22 years of age or older.
- Have read, understood, and signed an ICF (Informed Consent Form).
- Have demonstrated stable refraction (ie, a change of ≤ 0.5 D in sphere and cylinder) for a minimum of 12 months prior to surgery, verified by consecutive refractions and/or medical records or prescription history.
- Have myopic refractive error with or without astigmatism; sphere between -1.0 D and -10.00 D, cylinder between 0.0 D and -3.0 D; with a manifest refraction spherical equivalent (MRSE) between -1.0 D and -11.50 D.
- Have UCDVA of 20/40 or worse.
- Have manifest best spectacle-corrected distance visual acuity (BSCVA) of 20/25 (logMAR 0.1) or better in an operative eye.
- Have less than or equal to 0.50 D spherical equivalent (SE) difference between cycloplegic and manifest refractions at Visit 1 (Preoperative).
- Have normal corneal topography as determined by the Investigator.
- Have discontinued use of contact lenses for at least 2 weeks (for hard or toric lenses) or 3 days (for soft contact lenses) prior to the preoperative examination, and through the day of surgery.
- All contact lens wearers must demonstrate a stable refraction (within ± 0.5 D), as determined by MRSE, on 2 consecutive examinations at least 1 week apart, in an eye to be treated and the axis of cylinder should not differ by more than 15 degrees.
- Have the ability to lie flat without difficulty.
- Are willing and able to comply with the schedule for all post-surgery follow-up visits.

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

- Subjects for whom the combination of their baseline corneal thickness and the planned operative parameters for the LASIK procedure would result in treatment depth less than 250 µm from corneal endothelium.
- Eyes for which the baseline manifest subjective refraction exhibits a difference greater than 0.50 D in sphere power, or a difference greater than 0.50 D in cylinder power, or a difference in cylinder axis of more than 15 degrees compared to the baseline cycloplegic

subjective refraction. For manifest cylinder of less than 0.50 D, the difference in cylinder axis will not be taken into consideration.

- Subjects for whom the preoperative assessment of the cornea indicates that one or both eyes are not suitable candidates for treatment based upon the Investigator's medical judgment.
- Have evidence of retinal vascular disease.
- Have a history of or have active corneal disease or infection (e.g., recurrent corneal erosion syndrome, herpes simplex or herpes zoster keratitis, etc.) in an eye.
- Have a known sensitivity to any study medication.
- Have central corneal scars affecting visual acuity or unstable keratometry with irregular mires in an eye considered for eligibility.
- Have keratoconus, subclinical or forme fruste keratoconus, corneal dystrophy, or other corneal irregularity (e.g., irregular astigmatism).
- Have visually significant or progressive cataract in an eye considered for eligibility.
- Had previous intraocular or corneal surgery in an eye considered for eligibility that might confound the outcome of the study or increase the risk to the subject.
- Use chronic medications by any administration route that may increase risk to the subject or may confound the outcome of the study, including those known to affect wound healing (e.g., corticosteroids, antimetabolites, etc.).
- Are known to have acute or chronic disease or illness (e.g., dry eye, cataract, glaucoma, immuno-compromised, rheumatoid arthritis, clinically significant atopic disease, acne rosacea, etc.) that would increase operative risk or may confound the results of the study.
- Are taking medications contraindicated for LASIK such as isotretinoin (Accutane) or amiodarone hydrochloride (Cordarone).
- Are known to be pregnant, lactating, or who plan to become pregnant during the course of the study.
- Have known sensitivity to medications used for standard LASIK.
- Have the presence of systemic disease likely to affect wound healing, e.g., autoimmune disease, systemic connective tissue disease, diabetes, or severe atopic disease.
- Are participating in any other ophthalmic clinical trial within 30 days of screening or during this clinical trial.
- Have an ocular muscle disorder including a strabismus or nystagmus, or other disorder affecting fixation.
- Have a history of or evidence of glaucoma or are a glaucoma suspect.
- Have eyes with mesopic pupil size > 7.0 mm.
- Have a Schirmer's preoperative test without anesthesia < 4 mm/5 minutes

2. Follow-up Schedule

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

Visit 1	Pre-Op	(Day-60 to Day -1)
Visit 2	Operative Visit	(Day 0)
Visit 3	Day 1	
Visit 4	Week 1	(Day 5-9)
Visit 5	Month 1	(Week 3-5)
Visit 6	Month 3	(Week 10-14)
Visit 7	Month 6	(Week 21-26)
Visit 8	Month 9	(Week 35-43)

The preoperative and postoperative objective parameters measured during the study are shown in Table 1.

Table 1: preoperative and postoperative objective parameters of the study

PROCEDURE/ ASSESSMENTS	Visit 1	Visit 2	Visit 3[1]	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8
Informed consent/HIPAA	X							
Eligibility	X	X						
PROWL questionnaires[2]	X					X	X	X
Adverse events	X	X	X	X	X	X	X	X
Complications		X	X	X	X	X	X	X
Subject demographics	X							
Medical/Ocular history	X							
Concomitant medications	X	X	X	X	X	X	X	X
Schirmer's test[3]	X						X	
LASIK surgery,		X						
Manifest refraction	X			X	X	X	X	X
Keratometry[5]	X							
ECD[6]	X						X	
Corneal topography	X				X	X	X	X
Pupil size[7]	X					X	X	X
UCVNA[9]	X		X	X	X	X	X	X
UCDVA[8]	X		X	X	X	X	X	X
Distance BSCVA[9]	X			X[9]	X[10]	X[10,11]	X[10,11]	X[10,11]
Contrast sensitivity	X						X	
Slit lamp examination[11]	X		X	X	X	X	X	X
Pachymetry[12]	X							
Cycloplegic refraction	X							
IOP[13]	X				X	X	X	X
Dilated fundus exam	X					X[14]	X[14]	X[14]

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity; ECD endothelial cell density; HIPAA = Health Insurance Portability and Accountability Act; IOP = intraocular pressure; LASIK = laser in situ keratomileusis; OD = right eye; OS = left eye; PROWL = Patient-Reported Outcomes With LASIK; UCDVA = uncorrected distance visual acuity; UCNVA = uncorrected near visual acuity.

1.The same parameters are to be measured at each examination performed until re-epithelialization occurs (when applicable).

2.The PROWL questionnaires 34, 35 should be completed by the study subject in a secluded area, free of directions from clinical staff. at Visit 6, 7, and 8.

3. The Schirmer's test must not be conducted with anesthesia.

4. LASIK surgery is to be conducted by a refractive surgeon adequately trained by B+L or TPV technical representatives for use of the TENEO 317 (Model 2) and supervised by a technical representative for at least the first 4 LASIK surgeries completed by the refractive surgeon.
5. Keratometry should be assessed only at the preoperative study visit and as needed at a postoperative study visit to assess anomalous results in the postoperative period. Pachymetry should take place after manifest refraction has been done to avoid disturbing the cornea.
6. Preoperative and 6 Months ECD measurements will be done at three or four clinical sites by specular microscopy.
7. Pupil size should be assessed under mesopic conditions at the preoperative study visit and at months 3, 6 and 9 as well as Unscheduled Visits
8. UCNVA, UCDVA and BSCVA measurements are to be taken under photopic conditions (approximately 85 cd/m2) for each eye monocularly.
9. If the visual acuity with spectacle correction is ≥ 2 lines (10 letters) below that obtained at Visit 1, a rigid contact lens over refraction should be performed to estimate the best possible corrected visual acuity.
10. BSCVA to be completed OD and OS.
11. The slit lamp examination should include a complete survey of the anterior segment and grading of findings as detailed in Appendix B.
12. Pachymetry should be assessed only at the preoperative study visit and as needed at postoperative study Visit 7 to assess anomalous results in the postoperative period. Pachymetry should take place after manifest refraction has been done in order to avoid disturbing the cornea.
13. IOP should preferably be obtained using Goldmann applanation tonometry.
14. Dilated fundus examination (only required if loss of BSCVA occurs compared to preoperative BSCVA).

Adverse events and complications were recorded at all visits from V2 onwards.

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

3. Clinical Endpoints

With regard to safety, no clinical endpoint with regard to safety was defined for the study, but safety assessments were included. The following safety summaries were provided for primary safety analysis with descriptive statistics by visit for all treated eyes, eyes treated for spherical myopia, and eyes treated for astigmatic myopia unless otherwise specified:

- Eyes with BSCVA worse than 20/40 among eyes that had a BSCVA of 20/20 or better before surgery at each postoperative study visit
- Loss of BSCVA of 1, 2, ≥ 2, and > 2 lines compared to preoperative BSCVA, with 95% CIs around the proportions
- Percentage of eyes that had an increase of manifest refractive astigmatism > 2.00 D compared to the preoperative refraction, stratified by preoperative MRSE, and severity of preoperative myopia. A 95% CI around the percentage of all eyes that had an increase of > 2.00 D was displayed
- Incidence of Adverse Events (AEs) by event type
- Incidence of Complications
- Endothelial cell density changes (subgroup analysis)
- Contrast sensitivity changes under mesopic conditions
- Subject symptoms and results of prespecified question domains from PROWL questionnaires

With regard to effectiveness, the primary effectiveness endpoints at the time of refractive stability were provided as follows:

- The percentage of eyes that achieved predictability of MRSE within ± 0.50 D
- The percentage of eyes that achieved predictability of MRSE within ± 1.00 D

- The percentage of eyes targeted for emmetropia that achieved a UCDVA of 20/40 or better (logMAR of 0.3 or better)

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.

With regard to success/failure criteria, the individual patient success included demonstration of:

- Reduction of manifest spherical equivalent
- Improvement of uncorrected visual acuity

The study was defined as statistically successful if all primary effectiveness endpoints described above were analyzed successfully using data collected at the visit when refractive stability was achieved. Achievement of refractive stability for the study cohort required a minimum of 95% of treated eyes to have a change of ≤ 1.00 D of manifest refraction spherical equivalent between two refractions performed at least 3 months apart.

The hypotheses for the endpoints (i.e., protocol-defined effectiveness success criteria) were:

- **Percentage of eyes that achieve predictability of MRSE within ± 0.50 D** at the time of refractive stability

  The null hypothesis (H0) is that the proportion of eyes that achieve predictability within ± 0.50 D (π) is less than or equal to 0.80 (80%) at the time of refractive stability. The alternative hypothesis (H1) is that the proportion is **greater than 0.80 (80%).**

  $$H_0: \pi \leq 0.80$$
  $$H_1: \pi > 0.80$$

- **Percentage of eyes that achieve predictability of MRSE within ± 1.00 D** at the time of refractive stability

  The null hypothesis (H_0) is that the proportion of eyes that achieve predictability within ± 1.00 D (π) is less than or equal to 0.90 (90%) at the time of refractive stability. The alternative hypothesis (H_1) is that the proportion is **greater than 0.90 (90%).**

  $$H_0: \pi \leq 0.90$$
  $$H_1: \pi > 0.90$$

- **Percentage of eyes targeted for emmetropia that achieve UDVA of 20/40 or better** at the time of refractive stability

  The null hypothesis (H_0) is that the proportion of eyes targeted for emmetropia and that achieve UDVA of 20/40 or better at the time of refractive stability (π), is less than or equal to 0.88 (88%). The alternative hypothesis (H_1) is that the **proportion is greater than 0.88 (88%).**

  $$H_0: \pi \leq 0.88$$
  $$H_1: \pi > 0.88$$

B. Accountability of PMA Cohort

At the time of database lock, of 333 eyes of 168 patients enrolled in the PMA study, 94.9% (316/333) eyes are available for analysis at the completion of the study, the 9 month post-operative visit.
Table 2 presents the subject accountability:

Table 2: Subject Accountability

	Preoperative n/N (%)	Operative n/N (%)	Day 1 n/N (%)	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
All treated eyes,								
Available for analysis	333/333 (100.0%)	333/333 (100.0%)	333/333 (100.0%)	333/333 (100.0%)	325/333 (97.6%)	315/333 (94.6%)	313/333 (94.0%)	316/333 (94.9%)
Ongoing	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)
Discontinued[a]	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	2/333 (0.6%)	12/333 (3.6%)	17/333 (5.1%)
Lost to follow-up[a]	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	2/333 (0.6%)	10/333 (3.0%)	12/333 (3.6%)
Missed visit	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	8/333 (2.4%)	16/333 (4.8%)	8/333 (2.4%)	0/333 (0.0%)
% Accountability[b]	333/333 (100.0%)	333/333 (100.0%)	333/333 (100.0%)	333/333 (100.0%)	325/333 (97.6 %)	313/331 (95.2%)	313/321 (97.5%)	316/316 (100.0%)
Eyes treated for spherical myopia,								
Available for analysis	51/51 (100.0%)	51/51 (100.0%)	51/51 (100.0%)	51/51 (100.0%)	49/51 (96.1%)	49/51 (96.1%)	51/51 (100.0%)	51/51 (100.0%)
Ongoing	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)
Discontinued[a]	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)
Lost to follow-up[a]	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)
Missed visit	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	0/51 (0.0%)	2/51 (3.9%)	2/51 (3.9%)	0/51 (0.0%)	0/51 (0.0%)
% Accountability[b]	51/51 (100.0%)	51/51 (100.0%)	51/51 (100.0%)	51/51 (100.0%)	49/51 (96.1%)	49/51 (96.1%)	51/51 (100.0%)	51/51 (100.0%)
Eyes treated for astigmatic myopia,								
Available for analysis	282/282 (100.0%)	282/282 (100.0%)	282/282 (100.0%)	282/282 (100.0%)	276/282 (97.9%)	266/282 (94.3%)	262/282 (92.9%)	265/282 (94.0%)
Ongoing	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)
Discontinued[a]	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	2/282 (0.7%)	12/282 (4.3%)	17/282 (6.0%)
Lost to follow-up[a]	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	2/282 (0.7%)	10/282 (3.5%)	12/282 (4.3%)
Missed visit	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	0/282 (0.0%)	6/282 (2.1%)	14/282 (5.0%)	8/282 (2.8)	0/282 (0.0%)
% Accountability[b]	282/282 (100.0%)	282/282 (100.0%)	282/282 (100.0%)	282/282 (100.0%)	276/282 (97.9%)	266/280 (95.0%)	262/270 (97.0%)	265/265 (100.0%)

Note: N is the number of eyes in the respective population, which is used as a denominator in the percentage calculations other than % accountability.
a Cumulative totals are presented. For example, if an eye is discontinued at a visit, that eye is counted as discontinued at all subsequent visits.
b % Accountability = [(# Available for Analysis)/(N – # Discontinued – # Ongoing]*100.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a refractive study performed in the US. Overall, the mean age of subjects was 32.5 years, and a majority of subjects were white (83.3%; 140/168) and female (60.1%; 101/168;Table 3). All but 3 subjects had both eyes treated in the study.

Table 3 presents the demographics of the study population:

Table 3: Demographics

	All Treated Subjects (N=168)
Age, years	
n	168
Mean (SD)	32.5 (6.63)
Median	31.5
Min, Max	22, 50
Sex, n/N (%)	
Male	67/168 (39.9%)
Female	101/168 (60.1%)
Childbearing potential[a]	93/101 (92.1%)
Ethnicity, n/N (%)	
Hispanic or Latino	19/168 (11.3%)
Not Hispanic or Latino	149/168 (88.7%)
Race, n/N (%)	
American Indian or Alaska Native	1/168 (0.6%)
Asian	18/168 (10.7%)
Black/African American	3/168 (1.8%)
Native Hawaiian or Other Pacific Islander	0/168 (0.0%)
White	140/168 (83.3%)
Other	0/168 (0.0%)
Multi-racial	3/168 (1.8%)
Unknown	3/168 (1.8%)
Study eye, n/N (%)	
Right	1/168 (0.6%)
Left	2/168 (1.2%)
Both	165/168 (98.2%)

Abbreviations: Max = maximum, Min = minimum, SD = standard deviation.
Note: N is the number of subjects in the respective population, which is used as a denominator in the percentage calculation.
[a] Percentage is based on female subjects.

Among all treated eyes, preoperative sphere was distributed similarly across all dioptric bins (Table 4). The same was similar for the 2 subgroups, although 43% (22/51) of eyes treated for spherical myopia had sphere between -3.00 D and -5.00 D. Of the eyes treated for astigmatic myopia, nearly two-thirds (65.2%; 184/282) had preoperative cylinder between -0.25 D and -1.00 D.

Table 4: Preoperative Manifest Refraction Parameters (All Treated Eyes)

	All Treated Eyes (N=333) n/N (%)	Eyes Treated for Spherical Myopia (N=51) n/N (%)	Eyes Treated for Astigmatic Myopia (N=282) n/N (%)
Sphere			
-1.00 to -2.00 D	49/333 (14.7%)	5/51 (9.8%)	44/282 (15.6%)
-2.01 to -3.00 D	34/333 (10.2%)	2/51 (3.9%)	32/282 (11.3%)
-3.01 to -4.00 D	40/333 (12.0%)	11/51 (21.6%)	29/282 (10.3%)
-4.01 to -5.00 D	43/333 (12.9%)	11/51 (21.6%)	32/282 (11.3%)
-5.01 to -6.00 D	35/333 (10.5%)	3/51 (5.9%)	32/282 (11.3%)
-6.01 to -7.00 D	39/333 (11.7%)	6/51 (11.8%)	33/282 (11.7%)
-7.01 to -8.00 D	43/333 (12.9%)	7/51 (13.7%)	36/282 (12.8%)
-8.01 to -9.00 D	26/333 (7.8%)	3/51 (5.9%)	23/282 (8.2%)
-9.01 to -10.00 D	24/333 (7.2%)	3/51 (5.9%)	21/282 (7.4%)
Cylinder (in minus notation)			
0 D	51/333 (15.3%)	51/51 (100.0%)	0/282 (0.0%)
-0.25 to -0.50 D	107/333 (32.1%)	0/51 (0.0%)	107/282 (37.9%)
-0.51 to -1.00 D	77/333 (23.1%)	0/51 (0.0%)	77/282 (27.3%)
-1.01 to -2.00 D	74/333 (22.2%)	0/51 (0.0%)	74/282 (26.2%)
-2.01 to -3.00 D	24/333 (7.2%)	0/51 (0.0%)	24/282 (8.5%)

Abbreviation: D = diopter.
Note: N is the number of eyes in the respective population, which is used as a denominator in the percentage calculation.

D. Safety and Effectiveness Results

As refractive stability was achieved at 3 months, and confirmed at 6 months, the key safety and effectiveness study endpoints were evaluated at 3 months.

1. Safety Results

The analysis of safety was based on the total cohort of 333 eyes of 168 patients available up to the 9 month post-operative visit evaluation.

The safety summaries for this study are presented below in Table 5 to Table 11 and further in Table 14 to Table 16. Adverse effects and complications are reported in Table 12 to Table 13.

a. Eyes with best spectacle corrected visual acuity (BSCVA) worse than 20/40 (among eyes that had BSCVA 20/20 or better before surgery), at each postoperative study visit

Among all treated eyes with baseline BSCVA of 20/20 or better, none had BSCVA worse than 20/40 at the Month 3 Visit (Table 5). The same is true when all treated eyes with baseline BSCVA of 20/20 or better are divided into eyes treated for spherical myopia (Table 6) and eyes treated for astigmatic myopia (Table 7).

Table 5: Percentage of Eyes With BSCVA Worse Than 20/40 by Visit (All Treated Eyes With Baseline BSCVA of 20/20 or Better)

BSCVA	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Worse than 20/40	0/301 (0.0%)	0/283 (0.0%)	0/275 (0.0%)	0/269 (0.0%)	0/284 (0.0%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity;.
Note: N is the number of eyes with preoperative BSCVA of 20/20 or better and non-missing postoperative BSCVA in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Table 6: Percentage of Eyes With BSCVA Worse Than 20/40 by Visit (Eyes Treated for Spherical Myopia With Baseline BSCVA of 20/20 or Better)

BSCVA	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Worse than 20/40	0/43 (0.0%)	0/40 (0.0%)	0/42 (0.0%)	0/41 (0.0%)	0/43 (0.0%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity;
Note: N is the number of eyes with preoperative BSCVA of 20/20 or better and non-missing postoperative BSCVA in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Table 7: Percentage of Eyes With BSCVA Worse Than 20/40 by Visit (Eyes Treated for Astigmatic Myopia With Baseline BSCVA of 20/20 or Better)

BSCVA	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Worse than 20/40	0/258 (0.0%)	0/243 (0.0%)	0/233 (0.0%)	0/228 (0.0%)	0/241 (0.0%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity;
Note: N is the number of eyes with preoperative BSCVA of 20/20 or better and non-missing postoperative BSCVA in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

b. Loss of BSCVA of 1, 2, ≥ 2, and > 2 lines, compared to preoperative BSCVA

Among all treated eyes at the Month 3 Visit, none lost 2 or more lines of BSCVA from baseline, 5 eyes (1.6%; 5/305) lost 1 line from baseline. A total of 189 eyes (62.0%; 189/305) had no change in BSCVA from baseline at the Month 3 Visit (Table 8).

Table 8: Changes in Lines of BSCVA From Baseline to Each Postoperative Visit (All Treated Eyes)

BSCVA Change	Week 1	Month 1	Month 3	Month 6	Month 9
Loss of ≥ 2 lines					
Eyes, n/N (%)	4/333 (1.2%)	0/313 (0.0%)	0/305 (0.0%)	0/299 (0.0%)	0/316 (0.0%)
95% CI	(0.0, 2.4)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)
Loss of > 2 lines					
Eyes, n/N (%)	0/333 (0.0%)	0/313 (0.0%)	0/305 (0.0%)	0/299 (0.0%)	0/316 (0.0%)
95% CI	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)
Loss of 2 lines					
Eyes, n/N (%)	4/333 (1.2%)	0/313 (0.0%)	0/305 (0.0%)	0/299 (0.0%)	0/316 (0.0%)
95% CI	(0.0, 2.4)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)
Loss of 1 line					
Eyes, n/N (%)	20/333 (6.0%)	10/313 (3.2%)	5/305 (1.6%)	2/299 (0.7%)	4/316 (1.3%)
95% CI	(3.5, 8.6)	(1.2, 5.1)	(0.2, 3.1)	(0.0, 1.6)	(0.0, 2.5)
No change					
Eyes, n/N (%)	245/333 (73.6%)	210/313 (67.1%)	189/305 (62.0%)	198/299 (66.2%)	202/316 (63.9%)
95% CI	(68.8, 78.3)	(61.9, 72.3)	(56.5, 67.4)	(60.9, 71.6)	(58.6, 69.2)
Gain of 1 line					
Eyes, n/N (%)	54/333 (16.2%)	83/313 (26.5%)	101/305 (33.1%)	88/299 (29.4%)	96/316 (30.4%)
95% CI	(12.3, 20.2)	(21.6, 31.4)	(27.8, 38.4)	(24.3, 34.6)	(25.3, 35.5)
Gain of ≥ 2 lines					
Eyes, n/N (%)	10/333 (3.0%)	10/313 (3.2%)	10/305 (3.3%)	11/299 (3.7%)	14/316 (4.4%)
95% CI	(1.2, 4.8)	(1.2, 5.1)	(1.3, 5.3)	(1.5, 5.8)	(2.2, 6.7)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity; CI = confidence interval.
Note: Change is calculated as the difference between postoperative BSCVA result minus preoperative BSCVA result. N is the number of eyes with non-missing preoperative and postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

c. Percentage of eyes that had an increase of manifest refractive astigmatism > 2.00 D compared to the preoperative refraction

Among all treated eyes, none had an increase of manifest refractive astigmatism greater than 2.00D at the Month 3 Visit (Table 9). The same is true when all treated eyes are divided into eyes treated for spherical myopia (Table 10) and eyes treated for astigmatic myopia (Table 11).

Table 9: Percentage of Eyes With Increase of Manifest Refractive Astigmatism by Visit (All Treated Eyes)

≤ -2 D change from baseline in cylinder	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Eyes, n/N (%)	0/333 (0.0%)	0/313 (0.0%)	0/305 (0.0%)	0/299 (0.0%)	0/316 (0.0%)
95% CI	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)

Abbreviations: CI = confidence interval; D = diopter.
Note: N is the number of eyes with non-missing preoperative and postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Table 10: Percentage of Eyes With Increase of Manifest Refractive Astigmatism by Visit (Eyes Treated for Spherical Myopia)

≤ -2 D change from baseline in cylinder	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Eyes, n (%)	0/51 (0.0%)	0/47 (0.0%)	0/48 (0.0%)	0/49 (0.0%)	0/51 (0.0%)
95% CI	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)

Abbreviations: CI = confidence interval; D = diopter.
Note: N is the number of eyes with non-missing preoperative and postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Table 11: Percentage of Eyes With Increase of Manifest Refractive Astigmatism by Visit (Eyes Treated for Astigmatic Myopia)

≤ -2 D change from baseline in cylinder	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Eyes, n (%)	0/282 (0.0%)	0/266 (0.0%)	0/257 (0.0%)	0/250 (0.0%)	0/265 (0.0%)
95% CI	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)

Abbreviations: CI = confidence interval; D = diopter.
Note: N is the number of eyes with non-missing preoperative and postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

d. <u>Adverse Events and Complications that occurred in the PMA clinical study</u>:

Adverse Events:

- The most frequently reported AE throughout the study was **BSCVA worse than 20/25**, if 20/20 or better preoperatively, occurring in 5 eyes (1.5%; 5/333); Table 12). None of these events were serious or led to treatment discontinuation (all 5 resolved within 90 days; 3 resolved within 3 weeks).
- Two eyes experienced **loss of > 2 lines BSCVA** at 1 week (1 resolved by 1 month and 1 resolved by 3 months).
- One eye was reported at 1 week to have BSCVA worse than 20/25, if 20/20 or better preoperatively, associated with corneal edema (visual acuity improved by 1 month, the **corneal edema** (at 1 month or later) resolved by 6 months).
- One eye experienced a **miscreated flap** and was converted to PRK (reported as both a device deficiency and a protocol deviation).
- At the Month 3 Visit, 2 AEs were reported in the same eye: 1 **corneal edema at 1 month**

or later and 1 **BSCVA worse than 20/25** (in an eye that had preoperative BSCVA 20/20 or better). Both AEs were due to trauma not related to the study device or the study procedure. The corneal edema resolved within 4 days and the BSCVA worse than 20/25 resolved by the Month 6 visit.

- Two eyes of 1 subject were noted to have **corneal pigmentation** (i.e., Krukenberg spindles) at the 1 day visit. This was considered unrelated to the device or the procedure.
- One eye developed a **retinal vein occlusion** observed at the 1 week visit. This was considered unrelated to the device or the procedure.

Complications:

- The most frequently reported complication or potential AE throughout the study was SPK, occurring in 128 eyes (38.4% (128/333); Table 13).
- At the Month 3 Visit, complications or potential AEs reported were SPK (2.4%; 8/331), other: conjunctival hyperaemia (0.9%; 3/331), subconjunctival hemorrhage (0.6%; 2/331), trace microstriae (0.6%), debris in the interface (0.6%; 2/331), vitreous floaters (0.6%; 2/331), allergic conjunctivitis (0.6%; 2/331), corneal haze (0.6%; 2/331), double/ghost images in operative eye (0.3%; 1/331), iritis (0.3%; 1/331), other: face injury (0.3%; 1/331), and peripheral corneal epithelial defect at 1 month or later (0.3%; 1/331).
- One eye underwent corneal flap lifting between 1 day to 1 month post-surgery for a wrinkled flap considered related to eye rubbing; this eye maintained 20/20 or better BSCVA throughout the course of the study.
- One eye had corneal haze starting at Month 3 that was ongoing at study completion. This eye was followed up with resolution of corneal haze at 21 months postoperative.

There were no deaths, serious adverse events (SAEs), or other significant AEs during the study.

Table 12: Incidence of Adverse Events by Visit (All Treated Eyes)

AEs	Operative n/N (%)	Day 1 n/N (%)	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)	Total n/N (%)
BSCVA worse than 20/25, if 20/20 or better preoperatively	0/333 (0.0%)	0/333 (0.0%)	4/333 (1.2%)	0/333 (0.0%)	1/331 (0.3%)	0/321 (0.0%)	0/316 (0.0%)	5/333 (1.5%)
Corneal edema at 1 month or later	0/333 (0.0%)	0/333 (0.0%)	1/333 (0.3%)	0/333 (0.0%)	1/331 (0.3%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Loss of > 2 lines (10 letters) BSCVA	0/333 (0.0%)	0/333 (0.0%)	2/333 (0.6%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Other ocular event: Corneal pigmentation	0/333 (0.0%)	2/333 (0.6%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Miscreated flap (lost, incomplete, too thin)	1/333 (0.3%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Other ocular event: Retinal vein occlusion	0/333 (0.0%)	0/333 (0.0%)	1/333 (0.3%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)

Abbreviations: AE = adverse events; BSCVA = best spectacle-corrected distance visual acuity.
Note: AEs reported in the table are predetermined and not coded. AEs that start on or after the visit and before the next visit are counted under the first visit. N is the number of eyes from subjects who are active in the trial at a given visit, which is used as a denominator in the percentage calculation. The N for the Total column is the total number of treated eyes. The counts under the Total column are the unique numbers of eyes having the event and therefore may not be equal to the sum of counts in the visit columns.

Table 13: Incidence of Complications/Possible Adverse Events by Visit (All Treated Eyes)

Complications	Operative n/N (%)	Day 1 n/N (%)	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)	Total n/N (%)
Superficial punctate keratopathy (SPK)	0/333 (0.0%)	63/333 (18.9%)	36/333 (10.8%)	29/333 (8.7%)	8/331 (2.4%)	9/321 (2.8%)	10/316 (3.2%)	128/333 (38.4%)
Subconjunctival hemorrhage	0/333 (0.0%)	66/333 (19.8%)	0/333 (0.0%)	0/333 (0.0%)	2/331 (0.6%)	1/321 (0.3%)	0/316 (0.0%)	68/333 (20.4%)
Trace microstriae	0/333 (0.0%)	11/333 (3.3%)	5/333 (1.5%)	6/333 (1.8%)	2/331 (0.6%)	0/321 (0.0%)	0/316 (0.0%)	24/333 (7.2%)
Diffuse lamellar keratitis (Grade 2 or less)	0/333 (0.0%)	16/333 (4.8%)	5/333 (1.5%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	20/333 (6.0%)
Debris in the interface	1/333 (0.3%)	9/333 (2.7%)	3/333 (0.9%)	2/333 (0.6%)	2/331 (0.6%)	2/321 (0.6%)	0/316 (0.0%)	18/333 (5.4%)
Corneal edema between 1 week to less than 1 month after procedure	0/333 (0.0%)	5/333 (1.5%)	5/333 (1.5%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	10/333 (3.0%)
Meibomian gland dysfunction	0/333 (0.0%)	0/333 (0.0%)	4/333 (1.2%)	1/333 (0.3%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	5/333 (1.5%)
Other: Conjunctival hyperaemia	0/333 (0.0%)	1/333 (0.3%)	1/333 (0.3%)	0/333 (0.0%)	3/331 (0.9%)	0/321 (0.0%)	0/316 (0.0%)	5/333 (1.5%)
Vitreous floaters	0/333 (0.0%)	1/333 (0.3%)	2/333 (0.6%)	0/333 (0.0%)	2/331 (0.6%)	0/321 (0.0%)	0/316 (0.0%)	5/333 (1.5%)

Table 13: Incidence of Complications/Possible Adverse Events by Visit (All Treated Eyes)

Complications	Operative n/N (%)	Day 1 n/N (%)	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)	Total n/N (%)
Allergic conjunctivitis	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	2/331 (0.6%)	0/321 (0.0%)	2/316 (0.6%)	4/333 (1.2%)
Corneal abrasion	0/333 (0.0%)	4/333 (1.2%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	4/333 (1.2%)
Corneal haze	0/333 (0.0%)	0/333 (0.0%)	2/333 (0.6%)	0/333 (0.0%)	2/331 (0.6%)	0/321 (0.0%)	0/316 (0.0%)	4/333 (1.2%)
Loose epithelium	1/333 (0.3%)	3/333 (0.9%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	4/333 (1.2%)
Epithelium in the interface	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	1/333 (0.3%)	0/331 (0.0%)	1/321 (0.3%)	1/316 (0.3%)	3/333 (0.9%)
Rough epithelium	0/333 (0.0%)	2/333 (0.6%)	1/333 (0.3%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	3/333 (0.9%)
Conjunctivitis	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	2/321 (0.6%)	0/316 (0.0%)	2/333 (0.6%)
Corneal flap lifting between 1 day to 1 month post-surgery for wrinkled flap	0/333 (0.0%)	1/333 (0.3%)	1/333 (0.3%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Dry eye	0/333 (0.0%)	0/333 (0.0%)	2/333 (0.6%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Epithelium at the flap edge	0/333 (0.0%)	1/333 (0.3%)	0/333 (0.0%)	1/333 (0.3%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Other: Conjunctivitis viral	0/333 (0.0%)	0/333 (0.0%)	2/333 (0.6%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Other: Corneal oedema	0/333 (0.0%)	1/333 (0.3%)	1/333 (0.3%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Other: Hordeolum	0/333 (0.0%)	1/333 (0.3%)	0/333 (0.0%)	1/333 (0.3%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Steroid-induced IOP increase	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	2/333 (0.6%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	2/333 (0.6%)
Blepharitis	0/333 (0.0%)	0/333 (0.0%)	1/333 (0.3%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Double/ghost images in operative eye	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	1/331 (0.3%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Iritis	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	1/331 (0.3%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Mucus under edge of flap	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	1/333 (0.3%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Other: Corneal disorder	0/333 (0.0%)	1/333 (0.3%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Other: Corneal epithelium defect	0/333 (0.0%)	1/333 (0.3%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Other: Corneal erosion	0/333 (0.0%)	1/333 (0.3%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Other: Eye injury	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/331 (0.0%)	1/321 (0.3%)	0/316 (0.0%)	1/333 (0.3%)
Other: Face injury	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	1/331 (0.3%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)
Peripheral corneal epithelial defect at 1 month or later	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	0/333 (0.0%)	1/331 (0.3%)	0/321 (0.0%)	0/316 (0.0%)	1/333 (0.3%)

Abbreviations: AE = adverse events; IOP = intraocular pressure.

Note: Complications reported in the table are predetermined and not coded. Complications that start on or after a visit and before the next visit are counted under the first visit. m is the number of eyes from subjects who are active in the trial at a given visit, which is used as a denominator in the percentage calculation. The N for the Total column is the total number of treated eyes. The counts under Total column are the unique number of eyes having the complication and therefore may not be equal to the sum of counts in the visit columns.

e. Endothelial cell density (ECD) changes (substudy of 124 eyes)

Among all treated eyes within the ECD substudy, mean endothelial density was 2803.24 cells/mm^2 preoperatively and 2811.76 cells/mm^2 at the Month 6 Visit (Table 14). Only 1 eye at the Month 6 Visit had endothelial cell loss ≥ 10%.

Table 14: Endothelial Cell Density (cells/mm^2) by Visit

Visit Value Statistic	All Treated Eyes	Eyes Treated for Spherical Myopia	Eyes Treated for Astigmatic Myopia
Preoperative			
Actual value			
n	124	10	114
Mean (SD)	2803.24 (315.569)	2891.71 (254.174)	2795.48 (320.153)
Median	2813.00	2784.85	2817.50
Minimum, maximum	1867.5, 3455.2	2615.8, 3436.2	1867.5, 3455.2
Month 6			
Actual value			
n	111	11	100
Mean (SD)	2811.76 (297.642)	2820.45 (251.615)	2810.81 (303.364)
Median	2833.00	2819.70	2833.15
Minimum, maximum	1926.0, 3382.8	2420.0, 3297.5	1926.0, 3382.8
Change from baseline			
n	109	10	99
Mean (SD)	8.68 (134.452)	-58.44 (133.986)	15.46 (133.294)
Median	10.00	-2.65	11.80
Minimum, maximum	-353.4, 636.1	-353.4, 109.5	-265.7, 636.1
Categorical percent loss in ECD, n/N (%)			
0	57/109 (52.3%)	5/10 (50.0%)	52/99 (52.5%)
-10 to ≤ 0	51/109 (46.8%)	4/10 (40.0%)	47/99 (47.5%)
-20 to ≤ -10	1/109 (0.9%)	1/10 (10.0%)	0/99 (0.0%)
-30 to ≤ -20	0/109 (0.0%)	0/10 (0.0%)	0/99 (0.0%)
-40 to ≤ -30	0/109 (0.0%)	0/10 (0.0%)	0/99 (0.0%)
-50 to ≤ -40	0/109 (0.0%)	0/10 (0.0%)	0/99 (0.0%)
≤ -50	0/109 (0.0%)	0/10 (0.0%)	0/99 (0.0%)

Abbreviations: ECD = endothelial cell density; SD = standard deviation.
Note: Baseline is defined as the last measurement prior to LASIK surgery. Change from baseline is calculated as postoperative result minus baseline result. N is the number of eyes with non-missing preoperative and postoperative results, which is used as a denominator in the percentage calculation. Percent loss in ECD is calculated as: (Postoperative Result – Baseline Result)*100 / Baseline Result.

f. Contrast sensitivity changes under mesopic conditions

The change from baseline to the Month 6 Visit in contrast sensitivity among subjects participating in the contrast sensitivity substudy is presented in Table 15. Under glare conditions, the mean (SD) change in contrast sensitivity from baseline to 6 months at 1.5, 3, 6, and 12 cpd ranged from 0.06 (0.184) to 0.10 (0.198) logCS, respectively. Without glare, the mean (SD) change in contrast sensitivity from baseline to 6 months at 1.5, 3, 6, and 12 cpd ranged from 0.03 (0.159) to 0.15 (0.216) logCS, respectively.

Table 15: Contrast Sensitivity by Visit (All Treated Subjects)

Contrast sensitivity, logCS	Preoperative	Month 6
Mean contrast sensitivity with glare at 1.5 cpd		
Actual value		
n	47	41
Mean (SD)	1.98 (0.237)	2.03 (0.198)
Median	2.02	2.05
Min, Max	1.2, 2.3	1.6, 2.4
Change from baseline		
n		38
Mean (SD)		0.06 (0.184)
Median		0.05
Min, Max		-0.4, 0.7
Mean contrast sensitivity with glare at 3 cpd		
Actual value		
n	47	41
Mean (SD)	2.05 (0.234)	2.12 (0.190)
Median	2.10	2.15
Min, Max	1.4, 2.4	1.6, 2.4
Change from baseline		
n		38
Mean (SD)		0.08 (0.208)
Median		0.05
Min, Max		-0.5, 0.8
Mean contrast sensitivity with glare at 6 cpd		
Actual value		
n	47	41
Mean (SD)	1.70 (0.245)	1.83 (0.241)
Median	1.75	1.83
Min, Max	1.0, 2.2	1.1, 2.3
Change from baseline		
n		38
Mean (SD)		0.10 (0.202)
Median		0.09
Min, Max		-0.2, 0.7
Mean contrast sensitivity with glare at 12 cpd		
Actual value		

Table 15: Contrast Sensitivity by Visit (All Treated Subjects)

Contrast sensitivity, logCS	Preoperative	Month 6
n	47	41
Mean (SD)	1.13 (0.290)	1.26 (0.331)
Median	1.14	1.27
Min, Max	0.6, 2.0	0.5, 2.3
Change from baseline		
n		38
Mean (SD)		0.10 (0.198)
Median		0.14
Min, Max		-0.4, 0.5
Mean contrast sensitivity without glare at 1.5 cpd		
Actual value		
n	47	41
Mean (SD)	2.12 (0.188)	2.14 (0.165)
Median	2.15	2.18
Min, Max	1.4, 2.4	1.7, 2.4
Change from baseline		
n		38
Mean (SD)		0.03 (0.159)
Median		0.03
Min, Max		-0.3, 0.6
Mean contrast sensitivity without glare at 3 cpd		
Actual value		
n	47	41
Mean (SD)	2.17 (0.199)	2.20 (0.173)
Median	2.25	2.25
Min, Max	1.5, 2.4	1.7, 2.4
Change from baseline		
n		38
Mean (SD)		0.05 (0.163)
Median		0.06
Min, Max		-0.3, 0.5
Mean contrast sensitivity without glare at 6 cpd		
Actual value		
n	47	41
Mean (SD)	1.81 (0.275)	1.91 (0.259)
Median	1.80	1.90
Min, Max	1.2, 2.4	1.2, 2.4
Change from baseline		
n		38
Mean (SD)		0.11 (0.221)
Median		0.10
Min, Max		-0.3, 0.7
Mean contrast sensitivity without glare at 12 cpd		
Actual value		

Table 15: Contrast Sensitivity by Visit (All Treated Subjects)

Contrast sensitivity, logCS	Preoperative	Month 6
n	47	41
Mean (SD)	1.18 (0.355)	1.34 (0.356)
Median	1.14	1.30
Min, Max	0.6, 2.3	0.6, 2.3
Change from baseline		
n		38
Mean (SD)		0.15 (0.216)
Median		0.13
Min, Max		-0.3, 0.7

Abbreviations: cpd = cycles per degree; LASIK = laser in situ keratomileusis; Max = maximum, Min = minimum, SD = standard deviation.
Note: Baseline is defined as the last measurement prior to LASIK surgery. Change from baseline is calculated as postoperative result minus baseline result.

g. Patient-Reported Outcomes with LASIK (PROWL) questionnaire - Subject Symptoms and results for prespecified question domains :

Among all treated subjects at the Month 3 Visit, all PROWL questionnaire (Patient-Reported Outcomes with LASIK) domains showed score improvements from baseline, with change score mean (SD) values, ranging from 1.3 (8.28) units for eye dryness, to 42.1 (34.12) units for vision satisfaction (Table 16) Mean (SD) value for satisfaction with LASIK surgery was 96.6 (6.53) units.

Table 16: Patient-Reported Outcomes With LASIK Questionnaires by Visit (All Treated Subjects)

	Preoperative	Month 3	Month 6	Month 9
Far vision				
Actual value				
n	168	153	151	159
Mean (SD)	85.1 (15.62)	95.1 (8.02)	95.7 (7.21)	95.9 (7.26)
Median	90.0	100.0	100.0	100.0
Min, Max	10, 100	53, 100	57, 100	60, 100
Change from baseline				
n		153	151	159
Mean (SD)		9.2 (14.37)	9.9 (14.43)	10.2 (14.41)
Median		5.0	6.7	6.7
Min, Max		-25, 58	-37, 63	-30, 63
Near vision				
Actual value				
n	168	153	151	159
Mean (SD)	89.9 (12.77)	97.1 (6.97)	97.7 (5.27)	97.5 (6.86)
Median	93.3	100.0	100.0	100.0
Min, Max	27, 100	53, 100	78, 100	53, 100
Change from baseline				
N		153	151	159

Table 16: Patient-Reported Outcomes With LASIK Questionnaires by Visit (All Treated Subjects)

	Preoperative	Month 3	Month 6	Month 9
Mean (SD)		6.6 (13.15)	6.8 (12.48)	7.1 (13.13)
Median		5.0	0.0	5.0
Min, Max		-35, 53	-22, 53	-47, 53
Eye dryness				
Actual value				
n	168	153	151	159
Mean (SD)	92.2 (7.70)	93.5 (6.64)	94.3 (5.80)	94.9 (6.41)
Median	93.8	93.8	96.9	96.9
Min, Max	71, 100	68, 100	75, 100	68, 100
Change from baseline				
n		153	151	159
Mean (SD)		1.3 (8.28)	2.0 (7.87)	2.6 (8.08)
Median		0.0	0.0	1.0
Min, Max		-23, 23	-19, 26	-22, 29
Symptoms – Double images				
Actual value				
n	168	153	151	159
Mean (SD)	87.7 (14.71)	97.7 (9.29)	97.6 (8.84)	98.7 (5.03)
Median	92.5	100.0	100.0	100.0
Min, Max	29, 100	31, 100	42, 100	67, 100
Change from baseline				
n		153	151	159
Mean (SD)		9.8 (16.07)	9.3 (16.80)	10.6 (14.52)
Median		7.5	7.5	7.5
Min, Max		-47, 60	-50, 71	-33, 71
Symptoms – Glare				
Actual value				
n	168	153	151	159
Mean (SD)	82.0 (19.54)	94.0 (13.17)	95.4 (11.05)	95.9 (9.72)
Median	89.8	100.0	100.0	100.0
Min, Max	22, 100	13, 100	35, 100	48, 100
Change from baseline				
n		153	151	159
Mean (SD)		12.0 (18.97)	13.5 (21.39)	13.2 (20.08)
Median		7.5	8.3	7.5
Min, Max		-40, 78	-48, 78	-52, 78
Symptoms – Halo				
Actual value				
n	168	153	151	159
Mean (SD)	79.1 (20.59)	88.9 (16.65)	92.2 (13.69)	93.7 (12.66)
Median	88.0	100.0	100.0	100.0
Min, Max	18, 100	19, 100	35, 100	31, 100

Table 16: Patient-Reported Outcomes With LASIK Questionnaires by Visit (All Treated Subjects)

	Preoperative	Month 3	Month 6	Month 9
Change from baseline				
n		153	151	159
Mean (SD)		9.8 (21.55)	12.7 (22.66)	13.6 (22.64)
Median		7.5	10.4	10.0
Min, Max		-38, 65	-49, 74	-58, 74
Symptoms – Starbursts				
Actual value				
n	168	153	151	159
Mean (SD)	73.1 (23.16)	85.7 (18.37)	89.5 (15.52)	89.1 (14.72)
Median	78.4	95.0	100.0	100.0
Min, Max	5, 100	19, 100	23, 100	38, 100
Change from baseline				
n		153	151	159
Mean (SD)		12.8 (26.33)	16.7 (25.38)	15.2 (25.90)
Median		9.6	15.3	10.6
Min, Max		-46, 95	-65, 95	-63, 95
Driving				
Actual value				
n	168	153	151	159
Mean (SD)	87.1 (14.04)	95.6 (7.36)	96.2 (7.06)	96.3 (7.27)
Median	87.5	100.0	100.0	100.0
Min, Max	19, 100	60, 100	56, 100	50, 100
Change from baseline				
n		153	151	159
Mean (SD)		7.8 (13.65)	8.1 (13.22)	8.4 (13.02)
Median		6.3	6.3	6.3
Min, Max		-38, 54	-44, 60	-31, 60
Vision clarity[1]				
Actual value				
n	168	153	150	159
Mean (SD)	85.3 (26.58)	87.2 (23.63)	91.1 (21.02)	93.7 (17.16)
Median	100.0	100.0	100.0	100.0
Min, Max	17, 100	20, 100	0, 100	21, 100
Change from baseline				
n		153	150	159
Mean (SD)		1.5 (33.57)	5.6 (29.97)	7.9 (29.24)
Median		0.0	0.0	0.0
Min, Max		-80, 83	-100, 83	-79, 83
Vision satisfaction				
Actual value				
n	168	153	151	159
Mean (SD)	49.2 (28.02)	91.8 (16.15)	92.2 (17.28)	94.2 (12.40)

Table 16: Patient-Reported Outcomes With LASIK Questionnaires by Visit (All Treated Subjects)

	Preoperative	Month 3	Month 6	Month 9
Median	50.0	100.0	100.0	100.0
Min, Max	0, 100	0, 100	0, 100	0, 100
Change from baseline				
n		153	151	159
Mean (SD)		42.1 (34.12)	41.9 (32.77)	45.0 (30.69)
Median		40.0	40.0	40.0
Min, Max		-100, 100	-80, 100	-40, 100
Vision clarity[2]				
Actual value				
n	168	153	151	159
Mean (SD)	73.4 (21.44)	88.0 (17.78)	89.4 (17.37)	90.8 (16.31)
Median	66.7	100.0	100.0	100.0
Min, Max	0, 100	0, 100	33, 100	0, 100
Change from baseline				
n		153	151	159
Mean (SD)		14.4 (26.43)	14.8 (23.92)	16.1 (23.68)
Median		0.0	0.0	33.3
Min, Max		-100, 67	-33, 67	-67, 67
Satisfaction with LASIK surgery				
Actual value				
n		153	151	159
Mean (SD)		96.6 (6.53)	96.6 (6.99)	96.8 (5.99)
Median		100.0	100.0	100.0
Min, Max		70, 100	64, 100	61, 100

Abbreviations: LASIK = laser in situ keratomileusis; Max = maximum, Min = minimum, SD = standard deviation Note: Baseline is defined as the last measurement prior to surgery. Change from baseline is calculated as postoperative result minus baseline result.

[1]Vision clarity domain includes PROWL-PRQ questions 34, 34a, 35, 35a, 36, 36a and PROWL-POQ questions 28, 28a, 29, 29a, 30, 30a.

[2]Vision clarity domain includes PROWL-PRQ question 5 and PROWL-POQ question 5.

2. Effectiveness Results

The analysis of effectiveness was based on 316 eyes up to the 9 month time point. Key effectiveness outcomes are presented in Table 17 to Table 22. Additional effectiveness variables are presented in Table 23 to Table 46.

a. Primary Effectiveness Endpoints: Percentage of Eyes With Predictability of MRSE within ± 0.50 D and MRSE within ± 1.00 D of intended MRSE

Among all treated eyes at the Month 3 Visit, 94.0% (313.02/333) had MRSE within ± 0.50 D of predicted MRSE and 99.1% (330.00/333) had MRSE within ± 1.00 D of predicted MRSE (Table 17).
Similar results at the Month 3 Visit were observed in the 2 subsets, treated for spherical myopia and for myopic astigmatism. Sensitivity analyses using all treated eyes with observed case data were similar to the primary Analysis.

The first primary endpoint, percentage of eyes with MRSE within ± 0.50 D of predicted MRSE, showed that 94.0% (313.02/333) of all treated eyes had predictable MRSE within ± 0.50 D. Because the lower confidence limit of 91.3% is greater than the 80% threshold for the percentage of eyes with predictable MRSE within ± 0.50 D, the pre-specified performance standard was exceeded.

Similarly, the second primary endpoint, percentage of eyes with MRSE within ± 1.00 D of predicted MRSE, showed that 99.1% (330.00/333) of all treated eyes had predictable MRSE within ± 1.00 D. Because the lower confidence limit of 98.1% is greater than the 90% threshold for the percentage of eyes with predictable MRSE within ± 1.00 D, the pre-specified performance standard was exceeded.

Table 17: Percentage of Eyes With Predictability of MRSE (All Treated Eyes With Multiple Imputations)

Predictability of MRSE, %	Week 1	Month 1	Month 3	Month 6	Month 9
± 0.50 D					
Percentage of eyes % (n/N)	95.5% (318.02/333)	93.6% (311.69/333)	94.0% (313.02/333)	91.8% (305.69/333)	92.5% 308.03/333)
p-value	<0.0001*	<0.0001	<0.0001	<0.0001	<0.0001
95% CI	93.3, 97.7*	90.9, 96.3	91.3, 96.7	88.6, 94.9	89.5, 95.4
± 1.00 D					
Percentage of eyes % (n/N)	98.8% (329.00/333)	98.7% (328.67/333)	99.1% (330.00/333)	98.5% (328.01/333)	99.1% (330.00/333)
p-value	<0.0001*	<0.0001	<0.0001*	<0.0001*	<0.0001
95% CI	97.6, 100.0*	97.5, 100.0	98.1, 100.0*	97.2, 99.8*	98.1, 100.0

Abbreviations: CI = confidence interval; D = diopter; MRSE = manifest refraction spherical equivalent, n = numerator; N = denominator; % = percentage (n/N)
Note: Predictability of MRSE is calculated as the absolute difference between postoperative MRSE and targeted MRSE. If targeted MRSE is emmetropic, then it is equal to postoperative MRSE. 95% CIs and p-values are based on normal approximation for binomial proportion. Numerators (n) are calculated as the product of the percentage and the denominator rounded to the nearest 0.01.
CIs and p -values are calculated from a single imputation when there is zero variance among multiple imputations.

Table 18: Percentage of Eyes With Predictability of MRSE (Eyes Treated for Spherical Myopia With Multiple Imputations)

Predictability of MRSE, %	Week 1	Month 1	Month 3	Month 6	Month 9
± 0.50 D					
Percentage of eyes% (n/N)	98.0% (49.98/51)	92.8% (47.33/51)	94.0% (47.94/51)	93.8% (47.84/51)	96.1% (49.01/51)
95% CI	94.2, 100.0*	85.2, 100.0	87.5, 100.0	87.1, 100.0	90.8, 100.0*
± 1.00 D					
Percentage of eyes %(n/N)	100.0% (51/51)	100.0% (51/51)	100.0% (51/51)	98.0% (49.98/51)	100.0% (51/51)
95% CI	100.0, 100.0*	100.0, 100.0*	100.0, 100.0*	94.2, 100.0*	100.0, 100.0*

Abbreviations: CI = confidence interval; D = diopter; MRSE = manifest refraction spherical equivalent; ; n = numerator; N = denominator; % = percentage (n/N).
Note: Predictability of MRSE is calculated as the absolute difference between postoperative MRSE and targeted MRSE. If targeted MRSE is emmetropic, then it is equal to postoperative MRSE. 95% CI is based on normal approximation for binomial proportion. Numerators (n) are calculated as the product of the percentage and the denominator rounded to the nearest 0.01.
*CIs are calculated from a single imputation when there is zero variance among multiple imputations.

Table 19: Percentage of Eyes With Predictability of MRSE (Eyes Treated for Astigmatic Myopia With Multiple Imputations)

Predictability of MRSE, %	Week 1	Month 1	Month 3	Month 6	Month 9
± 0.50 D					
Percentage of eyes % (n/N)	95.0% (267.90/282)	93.7% (264.23/282)	94.0% (265.08/282)	91.4% (257.75/282)	91.8% (258.88/282)
95% CI	92.5, 97.6*	90.8, 96.7	91.0, 96.9	87.9, 94.9	88.4, 95.2
± 1.00 D					
Percentage of eyes % (n/N)	98.6% (278.05/282)	98.5% (277.77/282)	98.9% (278.33/282)	98.6% (278.05/282)	98.9% (278.90/282)
95% CI	97.2, 100.0*	97.1, 100.0	97.7, 100.0*	97.2, 100.0*	97.7, 100.0

Abbreviations: CI = confidence interval; D = diopter; MRSE = manifest refraction spherical equivalent; n = numerator; N = denominator; % = percentage (n/N)
Note: Predictability of MRSE is calculated as the absolute difference between postoperative MRSE and targeted MRSE. If targeted MRSE is emmetropic, then it is equal to postoperative MRSE. 95% CI is based on normal approximation for binomial proportion. Numerators (n) are calculated as the product of the percentage and the denominator rounded to the nearest 0.01.
*CIs are calculated from a single imputation when there is zero variance among multiple imputations.

b. Primary Effectiveness Endpoint: Percentage of Eyes Targeted for Emmetropia With UCDVA of 20/40 or Better

Among all treated eyes targeted for emmetropia, 99.7% (332/333) had UCDVA of 20/40 or better at the Month 3 Visit (Table 20). Because the lower confidence limit of 99.1% is greater than the 88% threshold for the percentage of eyes with UCDVA 20/40 or better, the performance standard was exceeded. Similar results at the Month 3 Visit were observed in the 2 subsets; 100.0% (51/51) of eyes treated for spherical myopia (Table 21) and 99.6% (280.87/282) of eyes treated for astigmatic myopia (Table 22) had UCDVA of 20/40 or better at the Month 3 Visit.

Sensitivity analyses using all treated eyes with observed case data were similar.

Table 20: Percentage of Eyes Targeted for Emmetropia With UCDVA of 20/40 or Better (All Treated Eyes With Multiple Imputations)

UCDVA, %	Week 1	Month 1	Month 3	Month 6	Month 9
20/40 or better					
Percentage of eyes %	99.7%	99.7%	99.7%	99.4%	99.7%
(n/N)	(332/333)	(332/333)	(332/333)	(331/333)	(332/333)
p-value	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
95% CI	99.1, 100.0*	99.1, 100.0*	99.1, 100.0*	98.6, 100.0*	99.1, 100.0*

Abbreviations: CI = confidence interval; logMAR = logarithm of the minimum angle of resolution; SAP = Statistical Analysis Plan; UCDVA uncorrected distance visual acuity ; n = numerator; N = denominator; % percentage (n/N .
Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. 95% CIs and p-values are based on normal approximation for binomial proportion. Numerators (n) are calculated as the product of the percentage and the denominator rounded to the nearest 0.01.
CIs and p -values are calculated from a single imputation when there is zero variance among multiple imputations.

Table 21: Percentage of Eyes Targeted for Emmetropia With UCDVA of 20/40 or Better (Eyes Treated for Spherical Myopia With Multiple Imputations)

UCDVA, %	Week 1	Month 1	Month 3	Month 6	Month 9
20/40 or better					
Percentage of eyes %	100.0%	100.0%	100.0%	100.0%	100.0%
(n/N)	(51/51)	(51/51)	(51/51)	(51/51)	(51/51)
p-value	NE	NE	NE	NE	NE
95% CI	100.0, 100.0*	100.0, 100.0*	100.0, 100.0*	100.0, 100.0*	100.0, 100.0*

Abbreviations: CI = confidence interval; logMAR = logarithm of the minimum angle of resolution; SAP = Statistical Analysis Plan; UCDVA uncorrected distance visual acuity, NE=not evaluable ; n = numerator; N denominator; % = percentage (n/N).
Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. 95% CI is based on normal approximation for binomial proportion. Numerators (n) are calculated as the product of the percentage and the denominator rounded to the nearest 0.01.
*CIs are calculated from a single imputation when there is zero variance among multiple imputations.

Table 22: Percentage of Eyes Targeted for Emmetropia With UCDVA of 20/40 or Better (Eyes Treated for Astigmatic Myopia With Multiple Imputations)

UCDVA, %	Week 1	Month 1	Month 3	Month 6	Month 9
20/40 or better					
Percentage of eyes %	99.6%	99.6%	99.6%	99.3%	99.6%
(n/N)	(280.87/282)	(280.87/282)	(280.87/282)	(280.03/282)	(280.87/282)
p-value	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
95% CI	99.0, 100.0*	99.0, 100.0*	99.0, 100.0*	98.3, 100.0*	99.0, 100.0*

Abbreviations: CI = confidence interval; logMAR = logarithm of the minimum angle of resolution; SAP = Statistical Analysis Plan; UCDVA uncorrected distance visual acuity;; n numerator; N = denominator; % percentage (n/N . Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. 95% CIs and p-values are based on normal approximation for binomial proportion. Numerators (n) are calculated as the product of the percentage and the denominator rounded to the nearest 0.01.
CIs and p -values are calculated from a single imputation when there is zero variance among multiple imputations.

c. <u>Additional Effectiveness Variable: Mean MRSE Across Visits</u>

At the Preoperative Visit, all treated eyes had a mean (SD) MRSE of -5.666 (2.5249) D (Table 23). At the Week 1 Visit, mean (SD) MRSE had improved to 0.035 (0.3051) D, and it ranged from -0.011 (0.3066) D to -0.041 (0.3212) D at the remaining postoperative visits.

At the Preoperative Visit, all eyes treated for spherical myopia had a mean (SD) MRSE of -5.216 (2.2338) D (Table 24). At the Week 1 Visit, mean (SD) MRSE had improved to 0.059 (0.2043) D, and it ranged from -0.034 (0.2341) D to -0.091 (0.2845) D at the remaining postoperative visits.

At the Preoperative Visit, all eyes treated for astigmatic myopia had a mean (SD) MRSE of -5.748 (2.5692) D (Table 25). At the Week 1 Visit, mean (SD) MRSE had improved to 0.030 (0.3200) D, and it ranged from -0.007 (0.3179) D to -0.031 (0.3274) at the remaining postoperative visits.

Table 23: Mean MRSE by Visit (All Treated Eyes)

MRSE, D	Preoperative	Week 1	Month 1	Month 3	Month 6	Month 9
n	333	333	313	305	299	316
Mean (SD)	-5.666 (2.5249)	0.035 (0.3051)	-0.011 (0.3066)	-0.026 (0.3139)	-0.056 (0.3290)	-0.041 (0.3212)
Median	-5.630	0.000	0.000	0.000	0.000	0.000
Min, Max	-10.88, -1.25	-0.63, 1.75	-1.00, 1.63	-1.38, 1.50	-1.50, 1.25	-1.13, 1.63

Abbreviations: D = diopter; Max = maximum; Min = minimum; MRSE = manifest refraction spherical equivalent; SD = standard deviation.

Table 24: Mean MRSE by Visit (Eyes Treated for Spherical Myopia)

MRSE, D	Preoperative	Week 1	Month 1	Month 3	Month 6	Month 9
n	51	51	47	48	49	51
Mean (SD)	-5.216 (2.2338)	0.059 (0.2043)	-0.034 (0.2341)	-0.068 (0.2884)	-0.071 (0.3131)	-0.091 (0.2845)
Median	-5.000	0.000	0.000	0.000	0.000	0.000
Min, Max	-9.50, -1.25	-0.50, 0.88	-0.75, 0.63	-0.75, 0.63	-1.25, 0.50	-1.00, 0.38

Abbreviations: D = diopter; Max = maximum; Min = minimum; MRSE = manifest refraction spherical equivalent; SD = standard deviation.

Table 25: Mean MRSE by Visit (Eyes Treated for Astigmatic Myopia)

MRSE, D	Preoperative	Week 1	Month 1	Month 3	Month 6	Month 9
n	282	282	266	257	250	265
Mean (SD)	-5.748 (2.5692)	0.030 (0.3200)	-0.007 (0.3179)	-0.018 (0.3184)	-0.053 (0.3326)	-0.031 (0.3274)
Median	-5.880	0.000	0.000	0.000	0.000	0.000
Min, Max	-10.88, -1.25	-0.63, 1.75	-1.00, 1.63	-1.38, 1.50	-1.50, 1.25	-1.13, 1.63

Abbreviations: D = diopter; Max = maximum; Min = minimum; MRSE = manifest refraction spherical equivalent; SD = standard deviation.

d. Additional Effectiveness Variable: Changes in MRSE Between Subsequent Visits (Stability of MRSE)

When comparing MRSE of all treated eyes at the Month 3 and Month 6 Visits, 95.3% (266/279) of eyes had a change in MRSE within ± 0.50 D, 99.3% (277/279) had a change in MRSE within ± 1.00 D, and 100.0% (279/279) had a change in MRSE within ± 2.00 D (Table 26). Nearly identical results were observed between the Month 3 and Month 6 Visits in the consistent cohort, with 95.3% (262/275), 99.3% (273/275), and 100.0% (275/275) of eyes with a change in MRSE within ± 0.50 D, ± 1.00 D, and ± 2.00 D, respectively (Table 27).
For all treated eyes at the Month 3 and Month 6 Visits, the change in mean (SD) MRSE was -0.028 (0.2671) D overall, and -0.008 (0.1059) D per month (Table 28). Refractive stability was achieved at 3 months and confirmed at 6 months.

Table 26: Percentage of Eyes With Changes in MRSE Between Subsequent Visits (All Treated Eyes)

Change in MRSE	Month 1 vs Month 3 n/N (%)	Month 3 vs Month 6 n/N (%)	Month 6 vs Month 9 n/N (%)
± 0.50 D	278/289 (96.2%)	266/279 (95.3%)	276/294 (93.9%)
± 1.00 D	287/289 (99.3%)	277/279 (99.3%)	292/294 (99.3%)
± 2.00 D	289/289 (100.0%)	279/279 (100.0%)	294/294 (100.0%)

Abbreviations: D = diopter; MRSE = manifest refraction spherical equivalent.
Note: N is the number of eyes with non-missing MRSE results at both visits being compared, which is used as a denominator in the percentage calculation.

Table 27: Percentage of Eyes With Changes in MRSE Between Subsequent Visits (Consistent Cohort)

Change in MRSE	Month 1 vs Month 3 n/N (%)	Month 3 vs Month 6 n/N (%)	Month 6 vs Month 9 n/N (%)
± 0.50 D	278/289 (96.2%)	262/275 (95.3%)	260/276 (94.2%)
± 1.00 D	287/289 (99.3%)	273/275 (99.3%)	274/276 (99.3%)
± 2.00 D	289/289 (100.0%)	275/275 (100.0%)	276/276 (100.0%)

Abbreviations: D = diopter; MRSE = manifest refraction spherical equivalent.
Note: N is the number of eyes with non-missing MRSE results at both visits being compared, which is used as a denominator in the percentage calculation.

Table 28: Mean Change in MRSE Between Subsequent Visits (All Treated Eyes)

MRSE, D	Month 1 vs Month 3	Month 3 vs Month 6	Month 6 vs Month 9
Overall change			
n	289	279	294
Mean (SD)	-0.021 (0.2639)	-0.028 (0.2671)	0.016 (0.2858)
Median	0.000	0.000	0.000
Min, Max	-1.51, 0.75	-1.01, 1.13	-0.76, 1.50
95% CI	(-0.052, 0.010)	(-0.060, 0.003)	(-0.017, 0.049)
Change per month			
n	289	279	294
Mean (SD)	-0.013 (0.1500)	-0.008 (0.1059)	0.009 (0.1528)
Median	0.000	0.000	0.000
Min, Max	-0.96, 0.39	-0.34, 0.43	-0.29, 2.16
95% CI	(-0.031, 0.004)	(-0.020, 0.005)	(-0.008, 0.027)

Abbreviations: CI, confidence interval; D = diopter; Max = maximum; Min minimum; MRSE = manifest refraction spherical equivalent; SD = standard deviation.
Note: Change per month is calculated as: Change/(Duration in Months), where month = 30 days. 95% CIs are calculated using t-distribution.

e. Additional Effectiveness Variable: Predictability of MRSE

When examining the predictability of MRSE of all treated eyes at the Month 3 Visit, 94.1% (287/305) had MRSE within ± 0.50 D of predicted MRSE, 99.0% (302/305) had MRSE within ± 1.00 D of predicted MRSE, and 100.0% (305/305) had MRSE within ± 2.00 D of predicted MRSE (Table 29). Among those eyes with low-to-moderate preoperative myopia, predictability was 95.3% (183/192), 99.5% (191/192), and 100.0% (192/192) for MRSE within ± 0.50 D, ± 1.00 D, and ± 2.00 D thresholds, respectively. Among those eyes with high preoperative myopia, predictability was 92.0% (104/113), 98.2% (111/113), and 100.0% (113/113) for MRSE within ± 0.50 D, ± 1.00 D, and ± 2.00 D thresholds, respectively.

When examining the predictability of MRSE of eyes treated for spherical myopia at the Month 3 Visit, 93.8% (45/48) had MRSE within ± 0.50 D of predicted MRSE and 100.0% (48/48) had MRSE within ± 1.00 D and ± 2.00 D of predicted MRSE (Table 30). Among those eyes with low-to-moderate preoperative spherical myopia, predictability was 94.1% (32/34), 100.0% (34/34), and 100.0% (34/34) for MRSE within ± 0.50 D, ± 1.00 D, and ± 2.00 D thresholds, respectively. Among those eyes with high preoperative spherical myopia, predictability was 92.9% (13/14), 100.0% (14/14), and 100.0% (14/14) for MRSE within ± 0.50 D, ± 1.00 D, and ± 2.00 D thresholds, respectively.

When examining the predictability of MRSE of eyes treated for astigmatic myopia at the Month 3 Visit, 94.2% (242/257) had MRSE within ± 0.50 D of predicted MRSE, 98.8% (254/257) had MRSE within ± 1.00 D of predicted MRSE, and 100.0% (257/257) had MRSE within ± 2.00 D of predicted MRSE (Table 31). Among those eyes with low-to-moderate preoperative astigmatic myopia, predictability was 95.6% (151/158), 99.4% (157/158), and 100.0% (158/158) for MRSE within ± 0.50 D, ± 1.00 D, and ± 2.00 D thresholds, respectively. Among those eyes with high preoperative astigmatic myopia, predictability was 91.9% (91/99), 98.0% (97/99), and 100.0% (99/99) for MRSE within ± 0.50 D, ± 1.00 D, and ± 2.00 D thresholds, respectively.

Stratification by preoperative sphere, assessed during ad hoc analysis, did not reveal any trends in predictability of MRSE.

Table 29: Percentage of Eyes With Predictability of MRSE Stratified by Preoperative MRSE and Severity of Myopia (All Treated Eyes)

MRSE Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
± 0.50 D	295/313 (94.2%)	287/305 (94.1%)	275/299 (92.0%)	293/316 (92.7%)
± 1.00 D	309/313 (98.7%)	302/305 (99.0%)	294/299 (98.3%)	313/316 (99.1%)
± 2.00 D	313/313 (100.0%)	305/305 (100.0%)	299/299 (100.0%)	316/316 (100.0%)
Preoperative MRSE				
-1.00 to -2.00 D				
± 0.50 D	27/29 (93.1%)	29/29 (100.0%)	26/26 (100.0%)	28/28 (100.0%)
± 1.00 D	29/29 (100.0%)	29/29 (100.0%)	26/26 (100.0%)	28/28 (100.0%)
± 2.00 D	29/29 (100.0%)	29/29 (100.0%)	26/26 (100.0%)	28/28 (100.0%)
-2.01 to -3.00 D				
± 0.50 D	34/34 (100.0%)	31/32 (96.9%)	27/27 (100.0%)	28/29 (96.6%)
± 1.00 D	34/34 (100.0%)	32/32 (100.0%)	27/27 (100.0%)	29/29 (100.0%)
± 2.00 D	34/34 (100.0%)	32/32 (100.0%)	27/27 (100.0%)	29/29 (100.0%)
-3.01 to -4.00 D				
± 0.50 D	40/41 (97.6%)	35/37 (94.6%)	35/38 (92.1%)	37/39 (94.9%)
± 1.00 D	41/41 (100.0%)	36/37 (97.3%)	37/38 (97.4%)	39/39 (100.0%)
± 2.00 D	41/41 (100.0%)	37/37 (100.0%)	38/38 (100.0%)	39/39 (100.0%)
-4.01 to –5.00 D				
± 0.50 D	33/36 (91.7%)	25/26 (96.2%)	30/31 (96.8%)	34/35 (97.1%)
± 1.00 D	36/36 (100.0%)	26/26 (100.0%)	30/31 (96.8%)	35/35 (100.0%)
± 2.00 D	36/36 (100.0%)	26/26 (100.0%)	31/31 (100.0%)	35/35 (100.0%)
-5.01 to 6.00 D				
± 0.50 D	32/32 (100.0%)	33/36 (91.7%)	29/32 (90.6%)	33/34 (97.1%)
± 1.00 D	32/32 (100.0%)	36/36 (100.0%)	32/32 (100.0%)	34/34 (100.0%)
± 2.00 D	32/32 (100.0%)	36/36 (100.0%)	32/32 (100.0%)	34/34 (100.0%)
-6.01 to -7.00 D				
± 0.50 D	33/34 (97.1%)	34/38 (89.5%)	33/36 (91.7%)	36/36 (100.0%)
± 1.00 D	34/34 (100.0%)	38/38 (100.0%)	36/36 (100.0%)	36/36 (100.0%)
± 2.00 D	34/34 (100.0%)	38/38 (100.0%)	36/36 (100.0%)	36/36 (100.0%)
-7.01 to -8.00 D				
± 0.50 D	32/36 (88.9%)	37/38 (97.4%)	29/35 (82.9%)	33/39 (84.6%)
± 1.00 D	35/36 (97.2%)	38/38 (100.0%)	34/35 (97.1%)	39/39 (100.0%)
± 2.00 D	36/36 (100.0%)	38/38 (100.0%)	35/35 (100.0%)	39/39 (100.0%)
-8.01 to -9.00 D				
± 0.50 D	39/43 (90.7%)	35/40 (87.5%)	37/44 (84.1%)	36/46 (78.3%)
± 1.00 D	42/43 (97.7%)	38/40 (95.0%)	42/44 (95.5%)	43/46 (93.5%)
± 2.00 D	43/43 (100.0%)	40/40 (100.0%)	44/44 (100.0%)	46/46 (100.0%)
-9.01 to -10.00 D				

Table 29: Percentage of Eyes With Predictability of MRSE Stratified by Preoperative MRSE and Severity of Myopia (All Treated Eyes)

MRSE Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
± 0.50 D	19/21 (90.5%)	21/22 (95.5%)	22/23 (95.7%)	22/23 (95.7%)
± 1.00 D	20/21 (95.2%)	22/22 (100.0%)	23/23 (100.0%)	23/23 (100.0%)
± 2.00 D	21/21 (100.0%)	22/22 (100.0%)	23/23 (100.0%)	23/23 (100.0%)
-10.01 to -11.00 D				
± 0.50 D	6/7 (85.7%)	7/7 (100.0%)	7/7 (100.0%)	6/7 (85.7%)
± 1.00 D	6/7 (85.7%)	7/7 (100.0%)	7/7 (100.0%)	7/7 (100.0%)
± 2.00 D	7/7 (100.0%)	7/7 (100.0%)	7/7 (100.0%)	7/7 (100.0%)
-11.01 to -12.00 D				
± 0.50 D	0/0 (NE)	0/0 (NE)	0/0 (NE)	0/0 (NE)
± 1.00 D	0/0 (NE)	0/0 (NE)	0/0 (NE)	0/0 (NE)
± 2.00 D	0/0 (NE)	0/0 (NE)	0/0 (NE)	0/0 (NE)
Severity of preoperative myopia				
> -7 D (low to moderate)				
± 0.50 D	194/200 (97.0%)	183/192 (95.3%)	174/184 (94.6%)	190/195 (97.4%)
± 1.00 D	200/200 (100.0%)	191/192 (99.5%)	182/184 (98.9%)	195/195 (100.0%)
± 2.00 D	200/200 (100.0%)	192/192 (100.0%)	184/184 (100.0%)	195/195 (100.0%)
≤ -7 D (high)				
± 0.50 D	101/113 (89.4%)	104/113 (92.0%)	101/115 (87.8%)	103/121 (85.1%)
± 1.00 D	109/113 (96.5%)	111/113 (98.2%)	112/115 (97.4%)	118/121 (97.5%)
± 2.00 D	113/113 (100.0%)	113/113 (100.0%)	115/115 (100.0%)	121/121 (100.0%)

Abbreviations: D = diopter; MRSE = manifest refraction spherical equivalent, NE = not evaluable.
Note: Predictability of MRSE is calculated as the absolute difference between MRSE at a given visit minus targeted MRSE collected at Preoperative Visit. N is the number of eyes with non-missing preoperative and postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.
Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

Table 30: Percentage of Eyes With Predictability of MRSE Stratified by Preoperative MRSE and Severity of Myopia (Eyes Treated for Spherical Myopia)

MRSE Category	Month 3 n/N (%)
Total	
± 0.50 D	45/48 (93.8%)
± 1.00 D	48/48 (100.0%)
± 2.00 D	48/48 (100.0%)
Preoperative MRSE	
-1.00 to -2.00 D	
± 0.50 D	5/5 (100.0%)
± 1.00 D	5/5 (100.0%)
± 2.00 D	5/5 (100.0%)
-2.01 to -3.00 D	
± 0.50 D	2/2 (100.0%)
± 1.00 D	2/2 (100.0%)
± 2.00 D	2/2 (100.0%)
-3.01 to -4.00 D	
± 0.50 D	9/9 (100.0%)
± 1.00 D	9/9 (100.0%)
± 2.00 D	9/9 (100.0%)
-4.01 to -5.00 D	
± 0.50 D	10/10 (100.0%)
± 1.00 D	10/10 (100.0%)
± 2.00 D	10/10 (100.0%)
-5.01 to -6.00 D	
± 0.50 D	2/3 (66.7%)
± 1.00 D	3/3 (100.0%)
± 2.00 D	3/3 (100.0%)
-6.01 to -7.00 D	
± 0.50 D	5/6 (83.3%)
± 1.00 D	6/6 (100.0%)
± 2.00 D	6/6 (100.0%)
-7.01 to -8.00 D	
± 0.50 D	6/7 (85.7%)
± 1.00 D	7/7 (100.0%)
± 2.00 D	7/7 (100.0%)
-8.01 to -9.00 D	
± 0.50 D	3/3 (100.0%)
± 1.00 D	3/3 (100.0%)
± 2.00 D	3/3 (100.0%)
-9.01 to -10.00 D	
± 0.50 D	3/3 (100.0%)
± 1.00 D	3/3 (100.0%)
± 2.00 D	3/3 (100.0%)

Table 30: Percentage of Eyes With Predictability of MRSE Stratified by Preoperative MRSE and Severity of Myopia (Eyes Treated for Spherical Myopia)

MRSE Category	Month 3 n/N (%)
-10.01 to -11.00 D	
± 0.50 D	0/0 (NE)
± 1.00 D	0/0 (NE)
± 2.00 D	0/0 (NE)
-11.01 to -12.00 D	
± 0.50 D	0/0 (NE)
± 1.00 D	0/0 (NE)
± 2.00 D	0/0 (NE)
Severity of preoperative myopia	
>-7 D (low to moderate)	
± 0.50 D	32/34 (94.1%)
± 1.00 D	34/34 (100.0%)
± 2.00 D	34/34 (100.0%)
≤ -7 D (high)	
± 0.50 D	13/14 (92.9%)
± 1.00 D	14/14 (100.0%)
± 2.00 D	14/14 (100.0%)

Abbreviations: D = diopter; MRSE = manifest refraction spherical equivalent. Note: Predictability of MRSE is calculated as the absolute difference between MRSE at a given visit minus targeted MRSE collected at Preoperative Visit, NE= not evaluable. N is the number of eyes with non-missing preoperative and postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

Table 31: Percentage of Eyes With Predictability of MRSE Stratified by Preoperative MRSE and Severity of Myopia (Eyes Treated for Astigmatic Myopia)

MRSE Category	Month 3 n/N (%)
Total	
± 0.50 D	242/257 (94.2%)
± 1.00 D	254/257 (98.8%)
± 2.00 D	257/257 (100.0%)
Preoperative MRSE	
-1.01 to -2.00 D	
± 0.50 D	24/24 (100.0%)
± 1.00 D	24/24 (100.0%)
± 2.00 D	24/24 (100.0%)
-2.01 to -3.00 D	
± 0.50 D	29/30 (96.7%)
± 1.00 D	30/30 (100.0%)
± 2.00 D	30/30 (100.0%)
-3.01 to -4.00 D	
± 0.50 D	26/28 (92.9%)
± 1.00 D	27/28 (96.4%)
± 2.00 D	28/28 (100.0%)
-4.01 to -5.00 D	
± 0.50 D	15/16 (93.8%)
± 1.00 D	16/16 (100.0%)
± 2.00 D	16/16 (100.0%)
-5.01 to -6.00 D	
± 0.50 D	31/33 (93.9%)
± 1.00 D	33/33 (100.0%)
± 2.00 D	33/33 (100.0%)
-6.01 to -7.00 D	
± 0.50 D	29/32 (90.6%)
± 1.00 D	32/32 (100.0%)
± 2.00 D	32/32 (100.0%)
-7.01 to -8.00 D	
± 0.50 D	31/31 (100.0%)
± 1.00 D	31/31 (100.0%)
± 2.00 D	31/31 (100.0%)
-8.01 to -9.00 D	
± 0.50 D	32/37 (86.5%)
± 1.00 D	35/37 (94.6%)
± 2.00 D	37/37 (100.0%)
-9.01 to -10.00 D	
± 0.50 D	18/19 (94.7%)
± 1.00 D	19/19 (100.0%)
± 2.00 D	19/19 (100.0%)

Table 31: Percentage of Eyes With Predictability of MRSE Stratified by Preoperative MRSE and Severity of Myopia (Eyes Treated for Astigmatic Myopia)

MRSE Category	Month 3 n/N (%)
-10.01 to -11.00 D	
± 0.50 D	7/7 (100.0%)
± 1.00 D	7/7 (100.0%)
± 2.00 D	7/7 (100.0%)
-11.01 to -12.00 D	
± 0.50 D	0/0 (NE)
± 1.00 D	0/0 (NE)
± 2.00 D	0/0 (NE)
Severity of preoperative myopia	
> -7 D (low to moderate)	
± 0.50 D	151/158 (95.6%)
± 1.00 D	157/158 (99.4%)
± 2.00 D	158/158 (100.0%)
≤ -7 D (high)	
± 0.50 D	91/99 (91.9%)
± 1.00 D	97/99 (98.0%)
± 2.00 D	99/99 (100.0%)

Abbreviations: D = diopter; MRSE = manifest refraction spherical equivalent, NE = not evaluable. Note: Predictability of MRSE is calculated as the absolute difference between MRSE at a given visit minus targeted MRSE collected at Preoperative Visit. N is the number of eyes with non-missing preoperative and postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

f. Additional Effectiveness Variable: Residual Astigmatic Error

Among all eyes treated for astigmatic myopia, 89.5% (230/257) had residual cylinder within ± 0.50 D at the Month 3 Visit, 98.8% (254/257) had residual cylinder within ± 1.00 D, and 1.2% (3/257) had residual cylinder
> ± 1.00 D (Table 32).

- Of the 89.5% (230/257) of eyes with residual cylinder within ± 0.50 D, 53.7% (138/257) had no shift in axis and 16.0% (41/257) had >30 degrees shift in axis.
- Three eyes had residual cylinder > ± 1.00 D and an axis shift > 15 degrees at the Month 3 Visit or later (Table 32).
    - One eye at 3 month visit had -1.25 D residual cylinder and a 30-degree axis shift. Residual cylinder in this eye improved to -1.00 D at Month 6 and -0.50 D at Month 9, but axis shift worsened to 50 degrees at Month 6 and Month 9.. At Month 9, UCDVA for this eye measured 20/20.
    - One eye at 3 month visit had -1.25 D residual cylinder and a 30-degree axis shift. Residual cylinder in this eye stayed the same at Month 6 and Month 9, and axis shift improved slightly to 25 degrees at both time points. At Month 9, UCDVA for this eye measured 20/25.
    - Once eye at the Month 6 Visit, had -1.25 D residual cylinder and a 67-degree axis shift OD. Residual cylinder in this eye improved to -0.75 D at Month 9, but axis shift worsened slightly to 72 degrees at the same time point.. At Month 9, UCDVA for this eye measured 20/16.

- Among the eyes with -0.25 to -0.50 D preoperative cylinder, 94.8% (91/96) had residual cylinder within ± 0.50 D at the Month 3 Visit and 100.0% (96/96) had residual cylinder within ± 1.00 D (Table 33). Of the 94.8% (91/96) with residual cylinder within ± 0.50 D, 58.3% (56/96) had no shift in axis and 17.7% (17/96) had a > 30 degree shift in axis.
- Among the eyes with -0.51 to -1.00 D preoperative cylinder, 88.7% (63/71) had residual cylinder within ± 0.50 D at the Month 3 Visit and 100.0% (71/71) had residual cylinder within ± 1.00 D. Of the 88.7% (63/71) with residual cylinder within ± 0.50 D, 60.6% (43/71) had no shift in axis and 14.1% (10/71) had a >30 degree shift in axis.
- Among the eyes with -1.01 to -2.00 D preoperative cylinder, 88.4% (61/69) had residual cylinder within ± 0.50 D at the Month 3 Visit and 100.0% (69/69) had residual cylinder within ± 1.00 D. Of the 88.4% (61/69) with residual cylinder within ± 0.50 D, 47.8% (33/69) had no shift in axis and 14.5% (10/69) had a >30 degree shift in axis.
- Among the eyes with -2.01 to -3.00 D preoperative cylinder, 71.4% (15/21) had residual cylinder within ± 0.50 D at the Month 3 Visit, 85.7% (18/21) had residual cylinder within ± 1.00 D, and 14.3% (3/21) had residual cylinder > ± 1.00 D. Two of the eyes with residual cylinder > ± 1.00 D also had an axis shift > 15 degrees. These eyes are described above. Of the 71.4% (15/21)with residual cylinder ± 0.50 D, 28.6% (6/21) had no shift in axis and 19.0% (4/21) had a >30 degree shift in axis.

Table 32: Residual Astigmatic Error by Visit (Eyes Treated for Astigmatic Myopia)

	Absolute Shift in Axis (degrees)						
Visit Residual Cylinder Magnitude	**0 n/N (%)**	**>0 to ≤5 n/N (%)**	**>5 to ≤10 n/N (%)**	**>10 to ≤15 n/N (%)**	**>15 to ≤30 n/N (%)**	**>30 n/N (%)**	**Total n/N (%)**
Month 1							
± 0.50 D	160/266 (60.2%)	6/266 (2.3%)	8/266 (3.0%)	7/266 (2.6%)	17/266 (6.4%)	48/266 (18.0%)	246/266 (92.5%)
± 1.00 D	160/266 (60.2%)	8/266 (3.0%)	10/266 (3.8%)	7/266 (2.6%)	22/266 (8.3%)	57/266 (21.4%)	264/266 (99.2%)
± >1.00 D	0/266 (0.0%)	0/266 (0.0%)	1/266 (0.4%)	0/266 (0.0%)	1/266 (0.4%)	0/266 (0.0%)	2/266 (0.8%)
Month 3							
± 0.50 D	138/257 (53.7%)	11/257 (4.3%)	14/257 (5.4%)	8/257 (3.1%)	18/257 (7.0%)	41/257 (16.0%)	230/257 (89.5%)
± 1.00 D	139/257 (54.1%)	13/257 (5.1%)	17/257 (6.6%)	11/257 (4.3%)	22/257 (8.6%)	52/257 (20.2%)	254/257 (98.8%)
± >1.00 D	0/257 (0.0%)	0/257 (0.0%)	1/257 (0.4%)	0/257 (0.0%)	2/257 (0.8%)	0/257 (0.0%)	3/257 (1.2%)
Month 6							
± 0.50 D	132/250 (52.8%)	9/250 (3.6%)	9/250 (3.6%)	7/250 (2.8%)	22/250 (8.8%)	44/250 (17.6%)	223/250 (89.2%)
± 1.00 D	133/250 (53.2%)	14/250 (5.6%)	11/250 (4.4%)	9/250 (3.6%)	27/250 (10.8%)	53/250 (21.2%)	247/250 (98.8%)
± >1.00 D	0/250 (0.0%)	0/250 (0.0%)	1/250 (0.4%)	0/250 (0.0%)	1/250 (0.4%)	1/250 (0.4%)	3/250 (1.2%)
Month 9							
± 0.50 D	151/265 (57.0%)	8/265 (3.0%)	9/265 (3.4%)	15/265 (5.7%)	15/265 (5.7%)	46/265 (17.4%)	244/265 (92.1%)
± 1.00 D	151/265 (57.0%)	11/265 (4.2%)	11/265 (4.2%)	19/265 (7.2%)	20/265 (7.5%)	51/265 (19.2%)	263/265 (99.2%)
± >1.00 D	0/265 (0.0%)	0/265 (0.0%)	1/265 (0.4%)	0/265 (0.0%)	1/265 (0.4%)	0/265 (0.0%)	2/265 (0.8%)

Abbreviation: D = diopter.

Note: Shift in axis is calculated as follows: Shifts are defined to be zero if either of the axes is zero. If postoperative axis – preoperative axis > 90, then axis shift |postoperative axis – preoperative axis – 180|. In other cases, if postoperative axis – preoperative axis < -90, then axis shift = 180 + postoperative axis – preoperative axis. In other cases, axis shift |postoperative axis – preoperative axis|. Residual manifest cylinder magnitude is calculated as postoperative cylinder value – targeted cylinder value. N is the number of eyes with non-missing preoperative and postoperative cylinder and axis results, which is used as a denominator in the percentage calculation.

Table 33: Residual Astigmatic Error Stratified by Preoperative Cylinder at Month 3 Visit (Eyes Treated for Astigmatic Myopia)

	Absolute Shift in Axis (degrees)						
Preoperative Cylinder Residual Cylinder Magnitude	**0 n/N (%)**	**>0 to ≤5 n/N (%)**	**>5 to ≤10 n/N (%)**	**>10 to ≤15 n/N (%)**	**>15 to ≤30 n/N (%)**	**>30 n/N (%)**	**Total n/N (%)**
-0.25 to -0.50 D							
± 0.50 D	56/96 (58.3%)	4/96 (4.2%)	4/96 (4.2%)	3/96 (3.1%)	7/96 (7.3%)	17/96 (17.7%)	91/96 (94.8%)
± 1.00 D	56/96 (58.3%)	4/96 (4.2%)	5/96 (5.2%)	3/96 (3.1%)	9/96 (9.4%)	19/96 (19.8%)	96/96 (100.0%)
± >1.00 D	0/96 (0.0%)	0/96 (0.0%)	0/96 (0.0%)	0/96 (0.0%)	0/96 (0.0%)	0/96 (0.0%)	0/96 (0.0%)
-0.51 to -1.00 D							
± 0.50 D	43/71 (60.6%)	3/71 (4.2%)	3/71 (4.2%)	2/71 (2.8%)	2/71 (2.8%)	10/71 (14.1%)	63/71 (88.7%)
± 1.00 D	44/71 (62.0%)	4/71 (5.6%)	3/71 (4.2%)	3/71 (4.2%)	2/71 (2.8%)	15/71 (21.1%)	71/71 (100.0%)
± >1.00 D	0/71 (0.0%)	0/71 (0.0%)	0/71 (0.0%)	0/71 (0.0%)	0/71 (0.0%)	0/71 (0.0%)	0/71 (0.0%)
-1.01 to -2.00 D							
± 0.50 D	33/69 (47.8%)	3/69 (4.3%)	5/69 (7.2%)	2/69 (2.9%)	8/69 (11.6%)	10/69 (14.5%)	61/69 (88.4%)
± 1.00 D	33/69 (47.8%)	4/69 (5.8%)	6/69 (8.7%)	4/69 (5.8%)	10/69 (14.5%)	12/69 (17.4%)	69/69 (100.0%)
± >1.00 D	0/69 (0.0%)	0/69 (0.0%)	0/69 (0.0%)	0/69 (0.0%)	0/69 (0.0%)	0/69 (0.0%)	0/69 (0.0%)
-2.01 to -3.00 D							
± 0.50 D	6/21 (28.6%)	1/21 (4.8%)	2/21 (9.5%)	1/21 (4.8%)	1/21 (4.8%)	4/21 (19.0%)	15/21 (71.4%)
± 1.00 D	6/21 (28.6%)	1/21 (4.8%)	3/21 (14.3%)	1/21 (4.8%)	1/21 (4.8%)	6/21 (28.6%)	18/21 (85.7%)
± >1.00 D	0/21(0.0%)	0/21(0.0%)	1/21 (4.8%)	0/21(0.0%)	2/21 (9.5%)	0/21(0.0%)	3/21 (14.3%)

Abbreviation: D = diopter.

Note: Shift in axis is calculated as follows: Shifts are defined to be zero if either of the axes is zero. If postoperative axis – preoperative axis > 90, then axis shift = |postoperative axis – preoperative axis – 180|. In other cases, if postoperative axis – preoperative axis < -90, then axis shift = 180 + postoperative axis – preoperative axis. In other cases, axis shift = |postoperative axis – preoperative axis|. Residual manifest cylinder magnitude is calculated as postoperative cylinder value – targeted cylinder value. N is the number of eyes with non-missing preoperative and postoperative cylinder and axis results, which is used as a denominator in the percentage calculation.

g. Additional Effectiveness Variable: Cylinder Stability

When comparing cylinder stability of all treated eyes across the Month 3 and Month 6 Visits, 64.2% (179/279) had no change in cylinder, 33.3% (97/279) had a change in cylinder of ± 0.01 to 0.50 D, and 2.5% (7/279) had a change in cylinder ± 0.51 to 1.00 D (Table 34).

Among eyes treated for astigmatic myopia, at the Month 3 Visit, mean (SD) IRC (intended refractive correction) was 0.868 (0.5895) D, mean (SD) SIRC (surgically induced refractive correction.) was 0.842 (0.5831) D, and the mean (SD) SIRC/IRC ratio was 1.017 (0.4009) D (Table 35).

Eyes treated for astigmatic myopia were also analyzed for cylinder (non-vector) correction, stratified by preoperative cylinder. At the Month 3 Visit, mean (SD) percent reduction in absolute cylinder was -55.7% (65.24) for eyes with -0.25 to -0.50 D preoperative cylinder, -73.6% (38.42) for eyes with -0.51 to -1.00 D preoperative cylinder, -83.0% (20.95) for eyes with -1.01 to -2.00 D preoperative cylinder, and -82.7% (16.69) for eyes with -2.01 to -3.00 D preoperative cylinder (Table 36).

Table 34: Cylinder Stability Between Subsequent Visits (All Treated Eyes)

Change in Cylinder Magnitude	Month 1 vs Month 3 n/N (%)	Month 3 vs Month 6 n/N (%)	Month 6 vs Month 9 n/N (%)
0.00 D	184/289 (63.7%)	179/279 (64.2%)	195/294 (66.3%)
± 0.01 to 0.50 D	95/289 (32.9%)	93/279 (33.3%)	96/294 (32.7%)
± 0.51 to 1.00 D	10/289 (3.5%)	7/279 (2.5%)	3/294 (1.0%)
± 1.01 to 1.51 D	0/289 (0.0%)	0/279 (0.0%)	0/294 (0.0%)
± >1.51 D	0/289 (0.0%)	0/279 (0.0%)	0/294 (0.0%)

Abbreviation: D = diopter.
Note: N is the number of eyes with non-missing cylinder results at both visits being compared, which is used as a denominator in the percentage calculation.

Table 35: Vector Analysis Summary by Visit (Eyes Treated for Astigmatic Myopia)

D	Month 1	Month 3	Month 6	Month 9
IRC				
n	266	257	250	265
Mean (SD)	0.875 (0.5978)	0.868 (0.5895)	0.881 (0.6062)	0.865 (0.6068)
Median	0.655	0.650	0.655	0.650
Min, Max	0.20, 2.52	0.20, 2.52	0.20, 2.52	0.20, 2.52
SIRC				
n	266	257	250	265
Mean (SD)	0.856 (0.5904)	0.842 (0.5831)	0.854 (0.5980)	0.834 (0.5875)
Median	0.650	0.680	0.665	0.650
Min, Max	0.09, 2.58	0.02, 2.76	0.01, 2.77	0.04, 2.54
SIRC/IRC				
n	266	257	250	265
Mean (SD)	1.012 (0.3033)	1.017 (0.4009)	1.032 (0.4592)	1.013 (0.4171)
Median	1.000	1.000	1.000	1.000
Min, Max	0.28, 2.50	0.09, 3.37	0.03, 3.30	0.16, 3.46

Abbreviations: D = diopter; IRC = intended refractive correction; Max = maximum; Min minimum; MRSE = manifest refraction spherical

equivalent; SAP = Statistical Analysis Plan; SD = standard deviation; SIRC = surgically induced refractive correction.
Note: Refer to SAP for derivations.

Table 36: Cylinder Correction (Non-Vector) Stratified by Preoperative Cylinder (Eyes Treated for Astigmatic Myopia)

Preoperative Cylinder % Reduction of Absolute Cylinder	Month 1	Month 3	Month 6	Month 9
-0.25 to -0.50 D				
n	98	96	92	103
Mean (SD)	-67.3 (50.31)	-55.7 (65.24)	-57.1 (65.29)	-56.8 (64.19)
Median	-100.0	-100.0	-100.0	-100.0
Min, Max	-100, 100	-100, 200	-100, 100	-100, 100
-0.51 to -1.00 D				
n	76	71	69	70
Mean (SD)	-77.6 (33.78)	-73.6 (38.42)	-69.8 (38.43)	-74.6 (35.00)
Median	-100.0	-100.0	-100.0	-100.0
Min, Max	-100, 33	-100, 33	-100, 33	-100, 33
-1.01 to -2.00 D				
n	68	69	66	68
Mean (SD)	-85.2 (18.72)	-83.0 (20.95)	-80.9 (21.02)	-87.0 (16.12)
Median	-93.8	-87.5	-83.3	-100.0
Min, Max	-100, -20	-100, -20	-100, 0	-100, -40
-2.01 to -3.00 D				
n	24	21	23	24
Mean (SD)	-84.5 (15.88)	-82.7 (16.69)	-83.8 (15.46)	-83.8 (16.13)
Median	-85.0	-90.0	-83.3	-81.8
Min, Max	-100, -40	-100, -50	-100, -50	-100, -50

Abbreviations: D = diopter; Max = maximum; Min = minimum; SD = standard deviation.
Note: % Reduction of absolute cylinder is calculated as: (Postoperative Cylinder – Preoperative Cylinder)*100/ Preoperative Cylinder.

h. Additional Effectiveness Variable: UCDVA of 20/40 or Better

Among all treated eyes, 99.7% (304/305) had UCDVA of 20/40 or better at the Month 3 Visit (Table 37), as did 100.0% (315/315) of eyes treated for spherical myopia (Table 38) and 99.6% (256/257) of eyes treated for astigmatic myopia(Table 39). Only one eye of one subject demonstrated UCDVA worse than 20/40. This eye had UCDVA 20/50 at the Month 3 Visit and was reported to have diffuse lamellar keratitis (Grade 2 or less) in the early postoperative period and had trace microstriae as well as SPK at the time of the Month 3 Visit. This eye completed the study with UCDVA 20/20 at Month 9.

Stratification by preoperative sphere, assessed during ad hoc analysis, did not reveal any trends in percentage of eyes with UCDVA of 20/40 or better.

Table 37: Percentage of Eyes With UCDVA of 20/40 or Better Stratified by Preoperative MRSE and Severity of Myopia (All Treated Eyes)

UCDVA Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
20/40 or better	314/315 (99.7%)	304/305 (99.7%)	297/299 (99.3%)	315/316 (99.7%)
Preoperative MRSE				
-1.00 to -2.00 D				
20/40 or better	29/29 (100.0%)	29/29 (100.0%)	26/26 (100.0%)	28/28 (100.0%)
-2.01 to -3.00 D				
20/40 or better	34/34 (100.0%)	32/32 (100.0%)	27/27 (100.0%)	29/29 (100.0%)
-3.01 to -4.00 D				
20/40 or better	41/41 (100.0%)	37/37 (100.0%)	37/38 (97.4%)	38/39 (97.4%)
-4.01 to -5.00 D				
20/40 or better	36/36 (100.0%)	26/26 (100.0%)	30/31 (96.8%)	35/35 (100.0%)
-5.01 to -6.00 D				
20/40 or better	32/32 (100.0%)	36/36 (100.0%)	32/32 (100.0%)	34/34 (100.0%)
-6.01 to -7.00 D				
20/40 or better	36/36 (100.0%)	38/38 (100.0%)	36/36 (100.0%)	36/36 (100.0%)
-7.01 to -8.00 D				
20/40 or better	36/36 (100.0%)	38/38 (100.0%)	35/35 (100.0%)	39/39 (100.0%)
-8.01 to -9.00 D				
20/40 or better	42/43 (97.7%)	39/40 (97.5%)	44/44 (100.0%)	46/46 (100.0%)
-9.01 to -10.00 D				
20/40 or better	21/21 (100.0%)	22/22 (100.0%)	23/23 (100.0%)	23/23 (100.0%)
-10.01 to -11.00 D				
20/40 or better	7/7 (100.0%)	7/7 (100.0%)	7/7 (100.0%)	7/7 (100.0%)
-11.01 to -12.00 D				
20/40 or better	0/0 (NE)	0/0 (NE)	0/0 (NE)	0/0 (NE)
Severity of preoperative myopia				
> -7 D (low to moderate)				
20/40 or better	202/202 (100.0%)	192/192 (100.0%)	182/184 (98.9%)	194/195 (99.5%)
≤ -7 D (high)				
20/40 or better	112/113 (99.1%)	112/113 (99.1%)	115/115 (100.0%)	121/121 (100.0%)

Abbreviations: D = diopter; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity, NE = not evaluable.
Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. N is the number of eyes with non-missing postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.
Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

Table 38: Percentage of Eyes With UCDVA of 20/40 or Better Stratified by Preoperative MRSE and Severity of Myopia at Month 3 (Eyes Treated for Spherical Myopia)

UCDVA Category	Month 3 n/N (%)
Total	
20/40 or better	48/48 (100.0%)
Preoperative MRSE	
-1.00 to -2.00 D	
20/40 or better	5/5 (100.0%)
-2.01 to -3.00 D	
20/40 or better	2/2 (100.0%)
-3.01 to -4.00 D	
20/40 or better	9/9 (100.0%)
-4.01 to -5.00 D	
20/40 or better	10/10 (100.0%)
-5.01 to -6.00 D	
20/40 or better	3/3 (100.0%)
-6.01 to -7.00 D	
20/40 or better	6/6 (100.0%)
-7.01 to -8.00 D	
20/40 or better	7/7 (100.0%)
-8.01 to -9.00 D	
20/40 or better	3/3 (100.0%)
-9.01 to -10.00 D	
20/40 or better	3/3 (100.0%)
-10.01 to -11.00 D	
20/40 or better	0/0 (NE)
-11.01 to -12.00 D	
20/40 or better	0/0 (NE)
Severity of preoperative myopia	
> -7 D (low to moderate)	
20/40 or better	34/34 (100.0%)
≤ -7 D (high)	
20/40 or better	14/14 (100.0%)

Abbreviations: D = diopter; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity, NE = not evaluable.
Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – 0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. N is the number of eyes with non-missing postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.
Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

Table 39: Percentage of Eyes With UCDVA of 20/40 or Better Stratified by Preoperative MRSE and Severity of Myopia at Month 3 (Eyes Treated for Astigmatic Myopia)

UCDVA Category	Month 3 n/N (%)
Total	
20/40 or better	256/257 (99.6%)
Preoperative MRSE	
-1.00 to -2.00 D	
20/40 or better	24/24 (100.0%)
-2.01 to -3.00 D	
20/40 or better	30/30 (100.0%)
-3.01 to -4.00 D	
20/40 or better	28/28 (100.0%)
-4.01 to -5.00 D	
20/40 or better	16/16 (100.0%)
-5.01 to -6.00 D	
20/40 or better	33/33 (100.0%)
-6.01 to -7.00 D	
20/40 or better	32/32 (100.0%)
-7.01 to -8.00 D	
20/40 or better	31/31 (100.0%)
-8.01 to -9.00 D	
20/40 or better	36/37 (97.3%)
-9.01 to -10.00 D	
20/40 or better	19/19 (100.0%)
-10.01 to -11.00 D	
20/40 or better	7/7 (100.0%)
-11.01 to -12.00 D	
20/40 or better	0/0 (NE)
Severity of preoperative myopia	
>-7 D (low to moderate)	
20/40 or better	158/158 (100.0%)
≤ -7 D (high)	
20/40 or better	98/99 (99.0%)

Abbreviations: D = diopter; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; SAP = Statistical Analysis Plan; UCDVA uncorrected distance visual acuity NE = not evaluable.

Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. N is the number of eyes with non-missing postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

i. Additional Effectiveness Variable: UCDVA Equal to or Better Than Baseline BSCVA

Among all treated eyes, 80.7% (246/305) of eyes had UCDVA at the Month 3 visit that was equal to or better than baseline BSCVA (Table 40).

- Among those eyes with low-to-moderate preoperative myopia, 80.7% (155/192) had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA.
- Among those eyes with high preoperative myopia, 80.5% (91/113) had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA.

Among eyes treated for spherical myopia, 85.4% (41/48) of eyes had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA (Table 41).

- Among those eyes with low-to- moderate preoperative spherical myopia, 88.2% (30/34) had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA.
- Among those eyes with high preoperative spherical myopia, 78.6% had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA.

Among eyes treated for astigmatic myopia, 79.8% (205/257) of eyes had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA (Table 42).

- Among those eyes with low-to- moderate preoperative astigmatic myopia, 79.1% (125/158) had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA.
- Among those eyes with high preoperative astigmatic myopia, 80.8% (80/99)had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA.

- Among all eyes with baseline BSCVA of 20/20 or better, 99.6% (274/275) of eyes had UCDVA 20/40 or better at the Month 3 Visit (Table 43).Among those eyes with baseline BSCVA of 20/20 or better with low-to-moderate preoperative myopia, 100.0% (174/174) had UCDVA 20/40 or better at the Month 3 Visit.
- Among those eyes with baseline BSCVA of 20/20 or better with high preoperative myopia, 99.0% (100/101) had UCDVA 20/40 or better at the Month 3 Visit.

Among eyes treated for spherical myopia with BSCVA of 20/20 or better, 100.0% (42/42) of eyes had UCDVA 20/40 or better at the Month 3 Visit (Table 44).

Among eyes treated for astigmatic myopia with baseline BSCVA of 20/20 or better, 99.6% (232/233) of eyes had UCDVA 20/40 or better at the Month 3 Visit (Table 45).

- Among those eyes with baseline BSCVA of 20/20 or better with low-to-moderate preoperative astigmatic myopia, 100.0% (145/145) had UCDVA 20/40 or better at the Month 3 Visit.
- Among those eyes with baseline BSCVA of 20/20 or better with high preoperative astigmatic myopia, 98.9% (87/88) had UCDVA 20/40 or better at the Month 3 Visit.

Table 40: Percentage of Eyes With UCDVA Equal to or Better Than Baseline BSCVA Stratified by Severity of Preoperative Myopia (All Treated Eyes)

UCDVA Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
Improved	242/315 (76.8%)	246/305 (80.7%)	237/299 (79.3%)	262/316 (82.9%)
Severity of preoperative myopia				

>-7 D (low to moderate)				
Improved	156/202 (77.2%)	155/192 (80.7%)	147/184 (79.9%)	167/195 (85.6%)
≤ -7 D (high)				
Improved	86/113 (76.1%)	91/113 (80.5%)	90/115 (78.3%)	95/121 (78.5%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity; D = diopter; LASIK = laser in situ keratomileusis; logMAR = logarithm of the minimum angle of resolution; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity.

Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. Baseline BSCVA is the last measurement prior to LASIK surgery. N is the number of eyes with non-missing preoperative BSCVA and non-missing postoperative UCDVA results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation

Table 41: Percentage of Eyes With UCDVA Equal to or Better Than Baseline BSCVA Stratified by Severity of Preoperative Myopia (Eyes Treated for Spherical Myopia)

UCDVA Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
Improved	41/47 (87.2%)	41/48 (85.4%)	42/49 (85.7%)	45/51 (88.2%)
Severity of preoperative myopia				
>-7 D (low to moderate)				
Improved	33/36 (91.7%)	30/34 (88.2%)	31/35 (88.6%)	34/37 (91.9%)
≤ -7 D (high)				
Improved	8/11 (72.7%)	11/14 (78.6%)	11/14 (78.6%)	11/14 (78.6%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity; D = diopter; LASIK = laser in situ keratomileusis; logMAR = logarithm of the minimum angle of resolution; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity.

Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. Baseline BSCVA is the last measurement prior to LASIK surgery. N is the number of eyes with non-missing preoperative BSCVA and non-missing postoperative UCDVA results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Table 42: Percentage of Eyes With UCDVA Equal to or Better Than Baseline BSCVA Stratified by Severity of Preoperative Myopia (Eyes Treated for Astigmatic Myopia)

UCDVA Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
Improved	201/268 (75.0%)	205/257 (79.8%)	195/250 (78.0%)	217/265 (81.9%)
Severity of preoperative myopia				
>-7 D (low to moderate)				
Improved	123/166 (74.1%)	125/158 (79.1%)	116/149 (77.9%)	133/158 (84.2%)
≤ -7 D (high)				
Improved	78/102 (76.5%)	80/99 (80.8%)	79/101 (78.2%)	84/107 (78.5%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity; D = diopter; LASIK = laser in situ keratomileusis; logMAR = logarithm of the minimum angle of resolution; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity.

Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. Baseline BSCVA is the last measurement prior to LASIK surgery. N is the number of eyes with non-missing preoperative BSCVA and non-missing postoperative UCDVA results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Table 43: Percentage of Eyes With UCDVA of 20/40 or Better Stratified by Preoperative MRSE and Severity of Myopia (All Treated Eyes With Baseline BSCVA of 20/20 or Better)

UCDVA Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
20/40 or better	284/285 (99.6%)	274/275 (99.6%)	267/269 (99.3%)	283/284 (99.6%)
Preoperative MRSE				
-1.00 to -2.00 D				
20/40 or better	28/28 (100.0%)	28/28 (100.0%)	25/25 (100.0%)	27/27 (100.0%)
-2.01 to -3.00 D				
20/40 or better	33/33 (100.0%)	31/31 (100.0%)	26/26 (100.0%)	28/28 (100.0%)
-3.01 to -4.00 D				
20/40 or better	38/38 (100.0%)	36/36 (100.0%)	34/35 (97.1%)	35/36 (97.2%)
-4.01 to -5.00 D				
20/40 or better	33/33 (100.0%)	23/23 (100.0%)	28/29 (96.6%)	32/32 (100.0%)
-5.01 to -6.00 D				
20/40 or better	25/25 (100.0%)	28/28 (100.0%)	25/25 (100.0%)	26/26 (100.0%)
-6.01 to -7.00 D				
20/40 or better	33/33 (100.0%)	34/34 (100.0%)	32/32 (100.0%)	32/32 (100.0%)
-7.01 to -8.00 D				
20/40 or better	33/33 (100.0%)	35/35 (100.0%)	32/32 (100.0%)	36/36 (100.0%)
-8.01 to -9.00 D				
20/40 or better	39/40 (97.5%)	36/37 (97.3%)	41/41 (100.0%)	43/43 (100.0%)
-9.01 to -10.00 D				
20/40 or better	17/17 (100.0%)	18/18 (100.0%)	19/19 (100.0%)	19/19 (100.0%)
-10.01 to -11.00 D				
20/40 or better	5/5 (100.0%)	5/5 (100.0%)	5/5 (100.0%)	5/5 (100.0%)
-11.01 to -12.00 D				
20/40 or better	0/0 (NE)	0/0 (NE)	0/0 (NE)	0/0 (NE)
Severity of preoperative myopia				
>7 D (low to moderate)				
20/40 or better	184/184 (100.0%)	174/174 (100.0%)	164/166 (98.8%)	174/175 (99.4%)
≤ -7 D (high)				
20/40 or better	100/101 (99.0%)	100/101 (99.0%)	103/103 (100.0%)	109/109 (100.0%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity; D = diopter; LASIK = laser in situ keratomileusis; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity, NE = not evaluable

Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. Baseline BSCVA is the last measurement prior to LASIK surgery. N is the number of eyes with preoperative BSCVA of 20/20 or better and non-missing postoperative UCDVA results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

Table 44: Percentage of Eyes With UCDVA of 20/40 or Better Stratified by Preoperative MRSE and Severity of Myopia (Eyes Treated for Spherical Myopia With Baseline BSCVA of 20/20 or Better)

UCDVA Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
20/40 or better	40/40 (100.0%)	42/42 (100.0%)	41/41 (100.0%)	43/43 (100.0%)
Preoperative MRSE				
-1.00 to -2.00 D				
20/40 or better	5/5 (100.0%)	5/5 (100.0%)	4/4 (100.0%)	5/5 (100.0%)
-2.01 to -3.00 D				
20/40 or better	2/2 (100.0%)	2/2 (100.0%)	2/2 (100.0%)	2/2 (100.0%)
-3.01 to -4.00 D				
20/40 or better	8/8 (100.0%)	8/8 (100.0%)	7/7 (100.0%)	8/8 (100.0%)
-4.01 to -5.00 D				
20/40 or better	10/10 (100.0%)	9/9 (100.0%)	10/10 (100.0%)	10/10 (100.0%)
-5.01 to -6.00 D				
20/40 or better	3/3 (100.0%)	3/3 (100.0%)	3/3 (100.0%)	3/3 (100.0%)
-6.01 to -7.00 D				
20/40 or better	3/3 (100.0%)	3/3 (100.0%)	3/3 (100.0%)	3/3 (100.0%)
-7.01 to -8.00 D				
20/40 or better	7/7 (100.0%)	7/7 (100.0%)	7/7 (100.0%)	7/7 (100.0%)
-8.01 to -9.00 D				
20/40 or better	1/1 (100.0%)	3/3 (100.0%)	3/3 (100.0%)	3/3 (100.0%)
-9.01 to -10.00 D				
20/40 or better	1/1 (100.0%)	2/2 (100.0%)	2/2 (100.0%)	2/2 (100.0%)
-10.01 to -11.00 D				
20/40 or better	0/0 (NE)	0/0 (NE)	0/0 (NE)	0/0 (NE)
-11.01 to -12.00 D				
20/40 or better	0/0 (NE)	0/0 (NE)	0/0 (NE)	0/0 (NE)
Severity of preoperative myopia				
>-7 D (low to moderate)				
20/40 or better	30/30 (100.0%)	29/29 (100.0%)	28/28 (100.0%)	30/30 (100.0%)
≤ -7 D (high)				
20/40 or better	10/10 (100.0%)	13/13 (100.0%)	13/13 (100.0%)	13/13 (100.0%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity; D = diopter; LASIK = laser in situ keratomileusis; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity, NE not evaluable.

Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. Baseline BSCVA is the last measurement prior to LASIK surgery. N is the number of eyes with preoperative BSCVA of 20/20 or better and non-missing postoperative UCDVA results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

Table 45:Percentage of Eyes With UCDVA of 20/40 or Better Stratified by Preoperative MRSE and Severity of Myopia (Eyes Treated for Astigmatic Myopia With Baseline BSCVA of 20/20 or Better)

UCDVA Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
20/40 or better	244/245 (99.6%)	232/233 (99.6%)	226/228 (99.1%)	240/241 (99.6%)
Preoperative MRSE				
-1.00 to -2.00 D				
20/40 or better	23/23 (100.0%)	23/23 (100.0%)	21/21 (100.0%)	22/22 (100.0%)
-2.01 to -3.00 D				
20/40 or better	31/31 (100.0%)	29/29 (100.0%)	24/24 (100.0%)	26/26 (100.0%)
-3.01 to -4.00 D				
20/40 or better	30/30 (100.0%)	28/28 (100.0%)	27/28 (96.4%)	27/28 (96.4%)
-4.01 to -5.00 D				
20/40 or better	23/23 (100.0%)	14/14 (100.0%)	18/19 (94.7%)	22/22 (100.0%)
-5.01 to -6.00 D				
20/40 or better	22/22 (100.0%)	25/25 (100.0%)	22/22 (100.0%)	23/23 (100.0%)
-6.01 to -7.00 D				
20/40 or better	30/30 (100.0%)	31/31 (100.0%)	29/29 (100.0%)	29/29 (100.0%)
-7.01 to -8.00 D				
20/40 or better	26/26 (100.0%)	28/28 (100.0%)	25/25 (100.0%)	29/29 (100.0%)
-8.01 to -9.00 D				
20/40 or better	38/39 (97.4%)	33/34 (97.1%)	38/38 (100.0%)	40/40 (100.0%)
-9.01 to -10.00 D				
20/40 or better	16/16 (100.0%)	16/16 (100.0%)	17/17 (100.0%)	17/17 (100.0%)
-10.01 to -11.00 D				
20/40 or better	5/5 (100.0%)	5/5 (100.0%)	5/5 (100.0%)	5/5 (100.0%)
-11.01 to -12.00 D				
20/40 or better	0/0 (NE)	0/0 (NE)	0/0 (NE)	0/0 (NE)
Severity of preoperative myopia				
>-7 D (low to moderate)				
20/40 or better	154/154(100.0%)	145/145 (100.0%)	136/138 (98.6%)	144/145 (99.3%)
≤ -7 D (high)				
20/40 or better	90/91 (98.9%)	87/88 (98.9%)	90/90 (100.0%)	96/96 (100.0%)

Abbreviations: BSCVA = best spectacle-corrected distance visual acuity; D = diopter; LASIK = laser in situ keratomileusis; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity, NE not evaluable.

Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02*Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. Baseline BSCVA is the last measurement prior to LASIK surgery. N is the number of eyes with preoperative BSCVA of 20/20 or better and non-missing postoperative UCDVA results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

j. Additional Effectiveness Variable: Refraction Over-correction or Under-correction

Among all treated eyes at the Month 3 Visit, 1 eye (0.3%; 1/305) was overcorrected by > 1.00 D (but not > 2.00 D), and 2 eyes (0.7%; 2/305) were undercorrected by > 1.00 D (but not > 2.00 D; Table 46). The overcorrected eye and 1 of the undercorrected eyes had high preoperative myopia, and the other undercorrected eye had low-to-moderate preoperative myopia.

Table 46: Percentage of Eyes With Refraction Overcorrection or Undercorrection Stratified by Severity of Preoperative Myopia (All Treated Eyes)

MRSE Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
Total				
Overcorrection by > 1.00 D	4/313 (1.3%)	1/305 (0.3%)	1/299 (0.3%)	1/316 (0.3%)
Overcorrection by > 2.00 D	0/313 (0.0%)	0/305 (0.0%)	0/299 (0.0%)	0/316 (0.0%)
Undercorrection by > 1.00 D	0/313 (0.0%)	2/305 (0.7%)	4/299 (1.3%)	2/316 (0.6%)
Undercorrection by > 2.00 D	0/313 (0.0%)	0/305 (0.0%)	0/299 (0.0%)	0/316 (0.0%)
Severity of preoperative myopia				
> -7 D (low to moderate)				
Overcorrection by > 1.00 D	0/200 (0.0%)	0/192 (0.0%)	0/184 (0.0%)	0/195 (0.0%)
Overcorrection by > 2.00 D	0/200 (0.0%)	0/192 (0.0%)	0/184 (0.0%)	0/195 (0.0%)
Undercorrection by > 1.00 D	0/200 (0.0%)	1/192 (0.5%)	2/184 (1.1%)	0/195 (0.0%)
Undercorrection by > 2.00 D	0/200 (0.0%)	0/192 (0.0%)	0/184 (0.0%)	0/195 (0.0%)
≤ -7 D (high)				
Overcorrection by > 1.00 D	4/113 (3.5%)	1/113 (0.9%)	1/115 (0.9%)	1/121 (0.8%)
Overcorrection by > 2.00 D	0/113 (0.0%)	0/113 (0.0%)	0/115 (0.0%)	0/121(0.0%)
Undercorrection by > 1.00 D	0/113 (0.0%)	1/113 (0.9%)	2/115 (1.7%)	2/121 (1.7%)
Undercorrection by > 2.00 D	0/113 (0.0%)	0/113 (0.0%)	0/115 (0.0%)	0/121 (0.0%)

Abbreviations: D = diopter; MRSE = manifest refraction spherical equivalent.
Note: Refraction correction is calculated as the difference between postoperative MRSE result minus targeted MRSE collected at Preoperative Visit. N is the number of eyes with non-missing preoperative and postoperative results in each category/subcategory at a given visit, which is used as a denominator in the percentage calculation.

k. Additional Effectiveness Variable: Categorical UCDVA

Among all treated eyes at the Month 3 Visit, 89.8% (274/305) of eyes had UCDVA of 20/20 or better and 99.7% (397/305) had UCDVA of 20/40 or better (Table 47).

Table 47: Categorical UCDVA by Visit (All Treated Eyes)

UCDVA Category	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)
20/12.5 or better	49/315 (15.6%)	49/305 (16.1%)	48/299 (16.1%)	41/316 (13.0%)
20/16 or better	160/315 (50.8%)	171/305 (56.1%)	163/299 (54.5%)	179/316 (56.6%)
20/20 or better	272/315 (86.3%)	274/305 (89.8%)	256/299 (85.6%)	287/316 (90.8%)
20/25 or better	299/315 (94.9%)	297/305 (97.4%)	290/299 (97.0%)	309/316 (97.8%)
20/32 or better	312/315 (99.0%)	303/305 (99.3%)	297/299 (99.3%)	314/316 (99.4%)
20/40 or better	314/315 (99.7%)	304/305 (99.7%)	297/299 (99.3%)	315/316 (99.7%)
20/50 or better	315/315 (100.0%)	305/305 (100.0%)	299/299 (100.0%)	316/316 (100.0%)

Abbreviations: logMAR = logarithm of the minimum angle of resolution; SAP = Statistical Analysis Plan; UCDVA = uncorrected distance visual acuity.

Note: UCDVA is collected in letters and is converted to logMAR score as: [1.7 – (0.02 Letters Correct)] and then translated to Snellen score as per the chart given in the SAP. N is the number of eyes with non-missing postoperative results at a given visit, which is used as a denominator in the percentage calculation.

3. Subgroup Analyses

Several preoperative characteristics were evaluated for potential association with outcomes: sex/gender, race and ethnicity.

Percentage of Eyes With Predictability of MRSE by Subgroup

When examining the predictability of MRSE of all treated eyes at the Month 3 Visit by sex, 93.1% (175/188) of female subjects had MRSE within ± 0.50 D of predicted MRSE and 98.4% (185/188) had MRSE within ± 1.00 D of predicted MRSE; 95.7% (112/117) of male subjects had MRSE within ± 0.50 D of predicted MRSE and 100.0% (117/117) had MRSE within ± 1.00 D of predicted MRSE . No significant difference in predictability of MRSE between sexes was observed at the Month 3 Visit.

When examining the predictability of MRSE of all treated eyes at the Month 3 Visit by race, 93.7% (238/254) of white subjects had MRSE within ± 0.50 D of predicted MRSE and 98.8% (251/254) had MRSE within ± 1.00 D of predicted MRSE; 96.1% (49/51) of non-white subjects had MRSE within ± 0.50 D of predicted MRSE and 100.0% (51/51) had MRSE within ± 1.00 D of predicted MRSE . No significant difference in predictability of MRSE between races was observed at the Month 3 Visit.

When examining the predictability of MRSE of all treated eyes at the Month 3 Visit by ethnicity, 100.0% (36/36) of Hispanic or Latino subjects had MRSE within ± 0.50 D (and within ± 1.00 D) of predicted MRSE; 93.3% (251/269) of non−Hispanic or Latino subjects had MRSE within ± 0.50 D of predicted MRSE and 98.9% (266/269) had MRSE within ± 1.00 D of predicted MRSE . No significant difference in predictability of MRSE between ethnicities was observed at the Month 3 Visit.

Percentage of Eyes Targeted for Emmetropia With UCDVA of 20/40 or Better by Subgroup

When examining the percentage of eyes targeted for emmetropia with UCDVA of 20/40 or better at the Month 3 Visit by sex, 99.5% (187/188) of female subjects had UCDVA of 20/40 or better, and 100.0% (125/125) of male subjects had UCDVA of 20/40 or better, which was not a significant difference between sexes.

When examining the percentage of eyes targeted for emmetropia with UCDVA of 20/40 or better at the Month 3 Visit by race, 99.6% (253/254) of white subjects had UCDVA of 20/40 or better, and 100.0% (51/51) of non-white subjects had UCDVA of 20/40 or better, which was not a significant difference between races.

When examining the percentage of eyes targeted for emmetropia with UCDVA of 20/40 or better at the Month 3 Visit by ethnicity, 100.0% (36/36) of Hispanic or Latino subjects had UCDVA of 20/40 or better, and 99.6% (268/269) of non−Hispanic or Latino subjects had UCDVA of 20/40 or better, which was not a significant difference between ethnicities.

Incidence of Adverse Events by Subgroup

When examining the percentage of eyes with pre-determined AEs at the Month 3 Visit by sex, no female subjects had any of the pre-determined AEs, and 0.8% (1/131) of male subjects had BSCVA worse than 20/25 if 20/20 or better preoperatively and 0.8% (1/131) had corneal edema at 1 month or later, which were not significantly different between sexes. No significant differences were present overall for any of the pre-determined AEs.

When examining the percentage of eyes with pre-determined AEs at the Month 3 Visit by race, 0.4% (1/276) of white subjects had BSCVA worse than 20/25 if 20/20 or better preoperatively, and no non-white subjects had any of the pre-determined AEs, which were not significantly different between races. No significant differences were present overall for any of the pre-determined AEs.

When examining the percentage of eyes with pre-determined AEs at the Month 3 Visit by ethnicity, no Hispanic or Latino subjects had any of the pre-determined AEs, and 0.3% (1/293) of non−Hispanic or Latino subjects had BSCVA worse than 20/25 if 20/20 or better preoperatively and 0.3% (1/293) had corneal edema at 1 month or later, which were not significantly different between ethnicities. No significant differences were present overall for any of the pre-determined AEs.

Incidence of Complications/Possible Adverse Events

When examining the percentage of eyes with pre-determined complications/possible AEs at the Month 3 Visit by sex, no significant differences were reported between female and male subjects. No significant differences were present overall for any of the pre-determined complications/possible AEs.

When examining the percentage of eyes with pre-determined complications/possible AEs at the Month 3 Visit by race, no significant differences were reported between white and non-white subjects, except for vitreous floaters, which occurred at a nominally significantly greater incidence in non-white subjects compared with white subjects (3.6%; 2/55 vs 1.1%; 3/278, respectively). The term “nominal” significance is introduced here to describe comparisons with p-values less than 0.05 culled from over 1,000 exploratory subgroup comparisons that were made without adjustment for multiple comparisons. Three complications/possible AEs (steroid-induced IOP increase, SPK, and trace microstriae) had nominal significant differences overall between races. Steroid-induced IOP increase occurred at a nominally significantly greater incidence in non-white subjects compared with white subjects (3.6%; 2/55 vs 0%, 0/278, respectively; p=0.0269), SPK occurred at a nominally significantly greater incidence in non-white subjects compared with white subjects (52.7%; 29/55 vs 35.6%; 99/278, respectively; p=0.0171), and trace microstriae occurred at a nominally significantly greater incidence in white subjects compared with non-white subjects (8.6%; 24/278 vs 0%, 0/55 respectively; p=0.0195).

When examining the percentage of eyes with pre-determined complications/possible AEs at the Month 3 Visit by ethnicity, no significant differences were reported between Hispanic or Latino subjects and non−Hispanic or Latino subjects. Two complications/possible AEs (conjunctivitis viral and subconjunctival hemorrhage) had nominal significant differences overall between ethnicities. Conjunctivitis viral occurred at a nominally significantly greater incidence in Hispanic or Latino subjects compared with non−Hispanic or Latino subjects (5.3% ; 2/38 vs 0%, 0/295, respectively; p=0.0127), and subconjunctival hemorrhage occurred at a nominally significantly greater incidence in Hispanic or Latino subjects compared with non−Hispanic or Latino subjects (34.2%; 13/38 vs 18.6%; 55/295, respectively; p=0.0251).

Changes in Lines of BSCVA From Baseline by Subgroup

When examining the changes in lines of BSCVA from baseline at the Month 3 Visit by sex, no female subjects or male subjects lost 2 or more lines of BSCVA from baseline; therefore, calculation of a p-value comparing sexes was not possible.

When examining the changes in lines of BSCVA from baseline at the Month 3 Visit by race, no white subjects or non-white subjects lost 2 or more lines of BSCVA from baseline; therefore, calculation of a p-value comparing races was not possible.

When examining the changes in lines of BSCVA from baseline at the Month 3 Visit by ethnicity, no Hispanic or Latino subjects or non−Hispanic or Latino subjects lost 2 or more lines of BSCVA from baseline; therefore, calculation of a p-value comparing ethnicities was not possible.

BSCVA Worse Than 20/40 by Subgroup

When examining BSCVA worse than 20/40 at the Month 3 Visit by sex, no female subjects or male subjects had BSCVA worse than 20/40; therefore, calculation of a p-value comparing sexes was not possible.

When examining BSCVA worse than 20/40 at the Month 3 Visit by race, no white subjects or non-white subjects had BSCVA worse than 20/40; therefore, calculation of a p-value comparing races was not possible.

When examining BSCVA worse than 20/40 at the Month 3 Visit by ethnicity, no Hispanic or Latino subjects or non−Hispanic or Latino subjects had BSCVA worse than 20/40; therefore, calculation of a p-value comparing ethnicities was not possible.

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 10 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

N/A

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

All 3 primary effectiveness endpoints for this study, all measured at the Month 3 visit, were successfully met.

- Percentage of eyes with MRSE within ± 0.50 D of predicted MRSE: 94.0% (313.02/333) of all treated eyes had predictable MRSE within ± 0.50 D. Because the lower confidence limit of 91.3% is greater than the pre-specified 80% threshold for the percentage of eyes with predictable MRSE within ± 0.50 D, the performance standard was exceeded.
- Percentage of eyes with MRSE within ± 1.00 D of predicted MRSE: 99.1% (330/333) of all treated eyes had predictable MRSE within ± 1.00 D. Because the lower confidence limit of 98.1% is greater than the pre-specified 90% threshold for the percentage of eyes with predictable MRSE within ± 1.00 D, the performance standard was exceeded.
- Percentage of eyes targeted for emmetropia that achieved a UCDVA of 20/40 or better: 99.7% (332/333) of these eyes had UCDVA of 20/40 or better. Because the lower confidence limit of 99.1% is greater than the pre-specified 88% threshold for percentage of eyes targeted for emmetropia that achieved a UCDVA of 20/40 or better, the performance standard was exceeded.

Sensitivity analyses of all 3 of these endpoints using all treated eyes with observed case data at the Month 3 Visit were similar to the primary analyses.

Mean MRSE of all treated eyes improved from -5.666 D preoperatively to -0.026 D at 3 months postoperatively. When examining the stability of MRSE across the Month 3 and Month 6 Visits, 95.3% (266/279) had a change in MRSE within ± 0.50 D, 99.3% (277/279) had a change in MRSE within ± 1.00 D, and 100.0% (279/279) had a change in MRSE within ± 2.00 D.

Predictability of MRSE of all treated eyes at the Month 3 visit is demonstrated that 94.1% (287/305) had MRSE within ± 0.50 D, 99.0% (302/305) had MRSE within ± 1.00 D, and 100.0% (305/305)

had MRSE within ± 2.00 D. Similar results were observed whether stratified by type of myopia (spherical or astigmatic) or severity of myopia (low to moderate or high).

Among eyes with astigmatic myopia, 1.2% (3/257) had residual cylinder > ± 1.00 D. As preoperative cylinder increased, the proportion of eyes with residual cylinder within ± 0.50 D at the Month 3 Visit decreased; 94.8% (91/96) of eyes with -0.25
to -0.50 D preoperative cylinder had residual cylinder within ± 0.50 D at the Month 3 Visit, whereas 71.4% (15/21) of eyes with -2.01 to -3.00 D preoperative cylinder had residual cylinder within ± 0.50 D.

When examining cylinder stability of all treated eyes across the Month 3 and Month 6 Visits, 64.2% (179/279) had no change in cylinder, 33.3% (93/279) had a change in cylinder of ± 0.01 to 0.50 D, and 2.5% (7/279) had a change in cylinder ± 0.51 to 1.00 D. Among eyes treated for astigmatic myopia at the Month 3 Visit, mean surgically induced refractive correction/intended refractive correction ratio was 1.017 D.

Among all treated eyes, 80.7% (246/305) of eyes had UCDVA at the Month 3 Visit that was equal to or better than baseline BSCVA. This proportion was similar in eyes with low-to-moderate preoperative myopia (80.7%; 155/192) and high preoperative myopia (80.5%, 91/113), but it was higher in eyes with spherical myopia (85.4%, 41/48) than in eyes with astigmatic myopia (79.8%, 205/257).

Among all treated eyes at the Month 3 visit, 89.8% (274/305) of eyes had UCDVA of 20/20 or better and 99.7% (304/305) had UCDVA of 20/40 or better (Table 47).

Subgroup analyses by sex, race, and ethnicity of predictability of MRSE and of UCDVA of 20/40 or better in eyes targeted for emmetropia did not show any significant differences between any groups (female vs male subjects, white vs non-white subjects, and Hispanic or Latino vs non−Hispanic or Latino subjects) at the Month 3 Visit.

B. Safety Conclusions

The probable 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.

Among the 333 eyes enrolled in the clinical study, the most frequently reported AE throughout the study was BSCVA worse than 20/25 (in eyes with BSCVA 20/20 or better preoperatively), occurring in 5/333 eyes (1.5%); none of these events were serious or led to treatment discontinuation, and all resolved. Five other AEs were reported (corneal edema at 1 month or later, loss of > 2 lines BSCVA, corneal pigmentation [Krukenberg spindle], miscreated flap, and retinal vein occlusion), occurring at a frequency of 1 or 2 eyes each. There were no deaths, serious AEs, or other significant AEs during the study.

The most frequently reported complication or potential AE throughout the study was SPK, occurring in 38.4% (128/333) of eyes. At the Month 3 Visit, the only complication or potential AE reported with an incidence > 1% was SPK (2.4%; 8/331); the other complications or potential AEs were conjunctival
hyperaemia at an incidence of 0.9% (3/331); subconjunctival hemorrhage, trace microstriae, debris in the interface, vitreous floaters, allergic conjunctivitis, and corneal haze at an incidence of 0.6%

(2/331); and double/ghost images in operative eye, iritis, face injury, and peripheral corneal epithelial defect at 1 month or later at an incidence of 0.3% (1/331).

Three device deficiencies were reported: 1 due to a miscreated flap, 1 due to an error message occurring preoperatively for 3 subjects, and 1 due to a faulty eye tracker board. No subjects were injured as a result of these device deficiencies.

Among all treated eyes at the Month 3 Visit, none lost 2 or more lines of BSCVA from baseline, and none had an increase of manifest refractive astigmatism greater than 2.00 D. In addition, no treated eye was reported with corneal haze beyond 6 months with BCVA loss >2 lines.

Mean Endothelial Cell Density (ECD) was stable at the Month 6 Visit; 1/109 eye lost more than 10% ECD at 6 months.

Mean contrast sensitivity was also stable, showing a mean change from baseline to 6 months across cycles per degree (cpd) ranges of 0.06 to 0.10 logCS with glare and 0.03 to 0.15 logCS without glare.

Among all treated subjects at the Month 3 Visit, all 11 PROWL questionnaire parameters showed improvement from baseline in mean values, ranging from 1.3 units (eye dryness) to 42.1 units (vision satisfaction).

Subgroup analyses by sex, race, and ethnicity of several safety measures (pre-determined AEs, pre-determined complications/possible AEs, loss of 2 or more BSCVA lines from baseline, and BSCVA worse than 20/40) did not show any significant differences between any groups (female vs male subjects, white vs non-white subjects, and Hispanic or Latino vs non−Hispanic or Latino subjects) at the Month 3 Visit, except for the complication/possible AE of vitreous floaters, which occurred at a nominally significantly greater incidence in non-white subjects compared with white subjects p=0.0272). The term “nominal” significance is used to describe comparisons with p-values less than 0.05 culled from over 1,000 subgroup comparisons made without adjustment for multiplicity. Three complications/possible AEs had nominal significant differences overall between races, with steroid-induced IOP increase and SPK occurring at a nominally significantly greater incidence in non-white subjects compared with white subjects (p=0.0269 and p=0.0171, respectively) and trace microstriae occurring at a nominally significantly greater incidence in white subjects compared with non-white subjects (p=0.0195). Two complications/possible AEs had nominal significant differences overall between ethnicities, with conjunctivitis viral and subconjunctival hemorrhage occurring at a nominally significantly greater incidence in Hispanic or Latino subjects compared with non−Hispanic or Latino subjects (p=0.0127 and p=0.0251, respectively).

C. Benefit-Risk Determination

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

The main benefit of an aspheric LASIK procedure is the potential freedom from or reduced dependence on spectacles (glasses) and/or contact lenses for the correction of refractive error. This is achieved through:

- Reduction of manifest spherical equivalent (MRSE)
- Improvement of uncorrected visual acuity (UCDVA)

Patients have a reasonable chance of experiencing the benefit of improved uncorrected visual acuity. Among all treated eyes, 80.7% of eyes had UCDVA at Month 3 that was equal to or better than their baseline BSCVA. Among all treated eyes at the Month 3 visit, 89.8% (274/305) of eyes had UCDVA of 20/20 or better and 99.7% (304/305) had UCDVA of 20/40 or better (Table 47).

- Nearly all eyes (99.6%; 232/233) with baseline BSCVA of 20/20 or better had UCDVA 20/40 or better at 3 months postoperatively. Overall, three-quarters of eyes had UCDVA at 3 months postoperatively that was equal or better than their baseline BSCVA.
- At the Preoperative Visit, all treated eyes had a mean (SD) MRSE of -5.666 (2.5249) D, which improved to a mean (SD) MRSE of 0.035 (0.3051) D at week 1 visit, and ranged from -0.011 (0.3066) D to -0.041 (0.3212) D at the remaining postoperative visits.
- When examining the predictability of MRSE of all treated eyes at the Month 3 Visit, 94.1% (287/305)had MRSE within ± 0.50 D of predicted MRSE, 99.0% (302/305) had MRSE within ± 1.00 D of predicted MRSE, and 100.0% (305/305) had MRSE within ± 2.00 D of predicted MRSE.

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 risks of performing LASIK on sighted eyes include (but are not limited to) improper correction, decrease in BSCVA, visual problems/symptoms (new or worsening of pre-existing problems including glare, halo, and/or foreign body sensations), corneal scarring, corneal ulceration or perforation, intraocular infection, corneal decompensation, persistent corneal edema, hyphema, hypopyon, endophthalmitis, microbial keratitis, cataract, epithelium in the interface, lost/misplaced/misaligned flap, dry eye, and/or melting of the flap.

- Among all treated eyes at the Month 3 visit, none lost 2 or more lines of BSCVA from baseline, no eye had BSCVA worse than 20/40 (in treated eyes with baseline BSCVA 20/20 or better), and none had an increase of manifest refractive astigmatism greater than 2.00D.
- Adverse Events reported in the clinical study include BSCVA worse than 20/25 if 20/20 or better preop (5 eyes, 1.5%; 5/333), loss of >2 lines BSCVA at 1 week (2 eyes, 0.6%; 2/333), corneal edema at 1 month or later (2 eyes, 0.6%; 2/333), miscreated flap (1 eye, 0.3%; 1/333), corneal pigmentation [Krukenberg spindle] (2 eyes of 1 subject), and retinal vein occlusion (1 eye, 0.3%; 1/333). There were no deaths, serious AEs, or other

significant AEs during the study. No unexpected safety findings were reported.

- The most frequently reported complication or potential AE throughout the study was SPK, occurring in 38.4% (128/333) of eyes and was also the only complication or potential AE reported with an incidence > 1% from the 3 Month postoperative visit.

Patient Perspectives
Patient perspectives considered during the review included information on how a patient feels or functions as reported using the Patient-Reported Outcomes With LASIK (PROWL) questionnaire. Results of the PROWL are summarized above in Table 16. Among all treated subjects at the Month 3 Visit, all 11 PROWL questionnaire parameters showed improvement from baseline in mean values, ranging from 1.3 units (eye dryness) to 42.1 units (vision satisfaction). Mean (SD) value for satisfaction with LASIK surgery was 96.6 (6.53) units.

In conclusion, given the available information above, the data support that for the proposed intended use for LASIK correction of myopia and myopic astigmatism, 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 three primary effectiveness endpoints evaluated in this clinical study were met: predictability of MRSE ± 0.50 D, predictability of MRSE ± 1.00 D, and UCDVA 20/40 or better at 3 months postoperatively. No unexpected safety findings were observed.

In summary, data presented show the TECHNOLAS TENEO 317 MODEL2 US Excimer Laser is safe and effective for LASIK correction of myopia and myopic astigmatism.

XIV. CDRH DECISION

CDRH issued an approval order on [date of approval order].

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.