SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Excimer Laser

Device Trade Name: MEL90

Device Product Code: LZS

Applicant's Name and Address: Carl Zeiss Meditec, Inc.
5300 Central Parkway
Dublin, California 94568 USA

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P060004/S006

Date of Notice of Approval to Applicant: December 4, 2024

The original PMA (P060004) was approved on August 11, 2006. The MEL80 Excimer Laser is indicated for use in primary Laser Assisted *in situ* Keratomileusis (LASIK) treatments for the reduction or elimination of myopia of less than or equal to -7.0 D with or without refractive astigmatism of less than or equal to -3.0 D, with a maximum MRSE of -7.00 D, in patients who are 21 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by change in sphere and cylinder of ≤ 0.5 D. In S001 approved on 3/28/2011, the indications for use was expanded to include reduction or elimination of naturally-occurring hyperopia of less than or equal to +5.0 D with or without refractive astigmatism of > +0.50 D and ≤ +3.0 D, with a maximum MRSE of +5.0 D, in patients who are over 21 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change in sphere and cylinder of ≤ 0.5 D. 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 indication for the MEL90.

II. INDICATIONS FOR USE

The MEL90 is indicated for use in primary Laser-Assisted in situ Keratomileusis (LASIK) treatments for the reduction or elimination of:

- Myopia less in magnitude than -10.00 D sphere (in minus-cylinder notation), with and without cylinder up to -4.00 D, when MRSE is less in magnitude than -10.00 D;
- Hyperopia up to +4.00 D sphere (in plus-cylinder notation), with and without cylinder up to +3.00 D, when MRSE is up to +5.00 D; and
- Mixed astigmatism with cylinder from >1.00 D up to 4.00 D;

in patients who are 18 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change in MRSE within +/- 0.50 D.

III. CONTRAINDICATIONS

MEL90 LASIK procedure is contraindicated in patients with:

- a residual stromal bed thickness that is less than 250 microns from the corneal endothelium;
- abnormal corneal topographic findings, e.g. keratoconus, pellucid marginal degeneration;
- severe dry eye;
- active eye infection or inflammation;
- recent herpes eye infection or problems resulting from past infection;
- active autoimmune disease or connective tissue disease;
- uncontrolled diabetes;
- uncontrolled glaucoma;
- who are pregnant or nursing.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the MEL90 labeling.

V. DEVICE DESCRIPTION

The Carl Zeiss Meditec MEL90 Excimer Laser System (see Figure 1) is designed for refractive surgery based on the ablation of corneal tissue achieved with a short pulse excimer laser having a wavelength of 193 nanometers. The laser head emits 4 to 7 nanosecond pulses (FWHM nominal pulse duration) with a repetition rate of 500 Hz. The MEL90 Excimer Laser is a spot-scanning laser that utilizes a Gaussian beam with a 0.7 mm spot diameter.

Figure 1. MEL90 with patient supporting system LS Comfort 80 combi

The MEL90 Excimer Laser System also contains an ablation debris removal system called the Cone for Controlled Atmosphere (CCA+). The CCA+ is an airflow system that ensures constant ablation debris removal from the beam path.

The MEL90 is equipped with an active eye tracking system in order to be able to align the ablation spot to eye movements by determining the center of the pupil. To supply the eye tracker with illumination, the eye of the patient is illuminated by near-infrared (NIR) light which is not visible to patients. The system determines the pupil center from an infrared (NIR) image of the patient's eye, refreshed and processed at 1050 Hz.

A green laser (532 nm) light located inside the surgical microscope and centered on its optical axis serves as a fixation target for the patient. For ease of fixation, the laser is employed in a blinking mode at a frequency of 5Hz. The fixation light blinks during the entire surgery.

User control of the MEL90 Excimer Laser is implemented by a software application called the Operation Assistant (OPASS), which runs on the Main Control PC (operating system Windows 10) computer interface in order to provide the surgeon direct control over the preoperative data and an integrated application manual. The OPASS program allows the surgeon to import patient data and treatment plans, to input clinical data, and monitor the progress of the operation on a visual control panel. The Main Control PC transfers data to the Device Control (central control unit) of the excimer laser, which is fully independent and controls the operation of the excimer laser (note: the surgeon has no access to the Device Control).

The MEL90 is equipped with a patient supporting system (LS Comfort 80 combi) for supporting and positioning the patient. The LS Comfort 80 combi includes motorized adjustment of the patient supporting surface.

The MEL90 Excimer Laser System consists of the following major components:

Laser Arm	The Laser Arm contains the operating microscope, the debris removal system (called CCA+), the galvanometric scanners, the eye tracking camera, a portion of the optical system, the control panel and the laser arm interface.
Laser Unit	The excimer laser unit consists of the high voltage power supply, the solid state pulser circuit, the laser discharge trigger unit, and control interface board. The communication with the Device Control is done fiber-optically via the laser interface, which also optically controls the trigger unit. The laser head is provided with premix gas by the gas handling system.
Optics	The optics form the excimer raw beam and guide it to the treatment plane by means of a beam shaper, two lenses, and different mirrors, so that a well-defined beam of Gaussian shape emerges. A vacuum pump is used to evacuate air present in the beam path; this function is initiated automatically when the laser is started.
Device Control	The Device Control with laser control software (called POLO) provides the control of the whole laser system. It performs the following tasks: execution of the treatment (i.e. triggering of the laser head), monitoring and setting of the scanner position, control of the blower and the debris removal, communication with user interface software (called OPASS), execution of the gas management system functions, and energy control via high voltage setting and energy measuring.
Control Panel	The control panel provides control of the distance lasers (which are used for correct height adjustment of the patient's eye), the white light illumination, and the eyetracker parameters.
Eyetracker	A fast eyetracker unit ensures alignment of the laser beam to the eye of the patient in the working plane (2D eye tracking). It is comprised of a 1050 Hz infrared camera, an infrared LED illumination system (830 nm) and a separate control computer.
Operating Microscope	An operating stereomicroscope (OPMI) allows the surgeon to observe the patient's eye during the treatment.
Illumination System	An LED ring light consisting of 72 single visible light LEDs arranged in an annular pattern is mounted at the laser exit aperture for illumination of the operating area (maximum irradiance in treatment plane is 2.0 mW/cm^2). In addition, there is a satellite illumination system (two visible light LEDs) mounted on the CCA+ unit to allow grazing-angle illumination of the patient's eye (maximum irradiance in treatment plane is 1.2 mW/cm^2).
Gas Handling System	The gas handling system consists of a laser gas (premix) bottle, pipes, valves, pressure sensors, vacuum pump, filters (halogen), and pressure reducers. The central control unit performs an automatic gas change on user request. The bottles are placed inside the device.

CCA+ Debris Removal	A blower and suction unit called CCA+ debris removal provides a controlled environment at the patient's eye by removing the debris. It is mounted on a swivel arm (the entire component is referred to as the CCA+ unit), and also carries the infrared illumination. The CCA+ unit can be moved away when not in use.
Patient Supporting System	A motor-driven patient supporting system (LSC 80 combi) is movable in all 3 dimensions (X-, Y- and Z-directions). In addition, the patient headrest can be moved in the Z-direction and can be tilted in a dorsal and ventral direction. The bed can be swung out manually for easy exit of the patient.
Slit Lamp (optional)	The slit lamp produces an evenly illuminated field in front of a reflecting prism, the geometry and color of which can be varied by the use of apertures and filters. The slit lamp has a 6V (10W) halogen bulb, a slit width of 0.15 mm to 0.75 mm, and a slit height and illumination field size of 2 mm to 12 mm (continuous).

If the MEL90 is operated in conjunction with VISUMAX 600/800, the system uses the LS Comfort 80 combi as joint patient supporting system.

If the MEL90 is operated in conjunction with VisuMax, the MEL90 system also uses the patient supporting system of the VisuMax.

The MEL90 can be connected to the local clinic network and to the Zeiss FORUM patient image and data management system.

MEL90 Laser Specifications

Laser Type	Argon Fluoride Excimer Laser
Laser Wavelength	193 nm
Laser Spot Size (FWHM diameter)	0.7 mm ± 0.1 mm
Laser Pulse Duration (FWHM)	4 to 7 nanoseconds
Laser Head Repetition Rate	500 Hz
Fluence (at the treatment area)	> 150 mJ/cm² (peak)
Range of Ablation Diameter	Up to 9.2 mm (optical zone of 6.0 to 7.0 mm, diameter including a transition zone: up to 2.2 mm). The laser has a maximum ablation diameter of up to 10 mm.
Eye-tracker, tracking frequency	1050 Hz

Working distance	190 mm ± 0.1 mm
Installation Requirements	Please refer to the Instructions for Use for restrictions, tolerances or other requirements established regarding room air circulation, clearance between the laser room walls, and distance between the laser and other electronic or radiation-producing medical equipment.
The software versions in the laser system are as follows:	a. OPASS Software version 4.3.4 b. Main Control PC Operating System: Image Version 4, Windows 10 c. POLO Software version 4.1.1.65 d. Eyetracker Firmware version 1.0.0.135 e. Software Package Gate Control version 1.1.2.

This laser is locked out for treatments outside the set approved and the set accepted under flagged warning treatment parameters.

VI. ALTERNATIVE PRACTICES OR PROCEDURES

There are several other alternatives for the correction of myopia, myopic astigmatism, hyperopia and mixed astigmatism.

Alternatives to the LASIK procedure include:

- Spectacle correction (glasses)
- Contact lenses
- Photorefractive Keratectomy (PRK)
- Refractive lenticule extraction
- Phakic intraocular lenses

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 Zeiss MEL90 is commercially available in 98 countries including the following: European Union countries, China, Canada, Brazil, Australia, Argentina, India, Iraq, Republic or Korea, Japan, Malaysia, Mexico, Saudi Arabia, the United Kingdom, Taiwan, and Vietnam.

The Zeiss MEL90 has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

Intraoperative complications:

- Miscreated flap (perforated, lost, incomplete, too thin, misaligned, buttonhole, etc.)
- Treatment interruption, difficult flap lifting with tissue damage, ocular penetration
- Subconjunctival hemorrhage or bleeding

Postoperative complications:

- Wrinkles in flap (striae or microstriae) and/or debris or foreign body under flap and/or epithelial ingrowth under flap all of which may require a flap lift (i.e. additional surgery)
- Corneal changes such as epithelial defects, haze, scarring, edema (swelling), anterior basement membrane dystrophy
- Corneal ectasia (thinning)
- Infection/Inflammation (e.g. conjunctivitis, corneal infiltrates/ulcer, DLK (Diffuse lamellar keratitis), SPK (Superficial punctate keratopathy), uveitis, iritis, lamellar keratitis, sterile inflammation, CTK (Central Toxic Keratopathy), corneal decompensation etc.)
- Grittiness and/or ocular pain/soreness
- Dry eye syndrome
- Decreased or fluctuating visual acuity (uncorrected and/or best corrected visual acuity)
- Inadequate treatment result (over- or under-correction, induced or residual cylinder, decentered ablation)
- Worsening of visual symptoms such as glare, halos, starbursts, hazy or blurred vision, distortion, double or ghost images, fluctuation of vision, focusing difficulty, difficulty with depth perception, light sensitivity (e.g. Transient light-sensitivity syndrome (TLSS))
- Headache or eyestrain due to imbalance between the eyes
- Difficulty with night driving or other low light tasks
- Discomfort or pain, potentially including chronic eye pain that is resistant to therapy referred to as neuropathic corneal pain

- Retinal or posterior vitreous detachment and/or vascular accidents
- Ptosis
- Increase in IOP
- Medication intolerance (allergic reaction, etc.)
- 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 clinical study, please see Section X (Summary of Primary Clinical Study) below.

IX. SUMMARY OF NONCLINICAL STUDIES

A. Laboratory Studies

1. Ablation Profiles

To verify ablation profiles, a representative set of lenses was shot onto polymethylmethacrylate (PMMA) plates. The attempted refractive powers of the lenses were -0.0 to -10.0 D for myopia (spherical) and 0.0 to -4.0 D for myopic cylinder, 0.0 to +5.0 D for hyperopia (spherical) and 0.0 to +4.0 D for hyperopic cylinder, and +3.0 D sphere and -4.0 D cylinder for mixed astigmatism. Optical zones from 6 to 7 mm were used. Before creating each of the lenses, a fluence test was performed and a calibration lens was shot on a separate piece of PMMA to ensure correct energy setting of the laser. Each of the ablation profiles were then ablated on a PMMA plate. The PMMA plates were then measured for ablation depth, and the measurement data were exported for analysis. Profilometry curves were generated that included the actual measurement data as well as tolerance curves that represented lower and upper limits of acceptable depth values. The tolerance curves were derived from the desired curve by variation of the sphere and cylinder value by ± 10% for >3.5 D of absolute sphere and cylinder, and ± 0.35 D for <3.5 D. The results of the testing demonstrated that the profilometry met these specified requirements.

2. Beam Homogeneity Measurements

Beam homogeneity (profile) measurements for the MEL90 Laser System were performed by measuring the beam profile in the working plane and its variation along the optical axis, and

by measuring the fluence, beam profile, and energy for production units. The results of the testing confirmed that the beam profile meets the specified requirements of a full width at half maximum (FWHM) beam diameter in the working plane between 0.69 mm to 0.76 mm in x and 0.67 mm to 0.72 mm in y direction.

3. Pulse Width and Stability

The MEL90 specification for pulse width (duration) is 5.5 ± 1.5 ns and was verified by measurement testing.

Two separate tests were conducted with similar methods, whereby the laser source was triggered from a fiber-optic signal with a predefined repetition frequency with a targeted repetition rate of 500 Hz. The results of Test 1 demonstrated that the laser output frequency measured with a photodiode and an oscilloscope was equal to the predefined input frequency. All the results were within the acceptance criteria. Test 2 used a photodiode and an oscilloscope to register 100 input and output laser pulses to determine the temporal variation of registered laser pulses (jitter) and the delay. The test results demonstrated the jitter and the delay were below the defined test limits.

4. Tests of Fluence Control & Fail-safe Systems

The fluence of the excimer beam in the treatment plane is kept constant by controlling the energy during operation. The energy is changed by controlling the discharge high voltage value, while the spot diameter is fixed by design.

The absolute value of the laser source output energy was measured with a pyroelectric sensor at 500 Hz repetition rate at different Pulse Width Modulation (PWM) values. The output energy recorded was within the predefined test values. The standard deviation was below the acceptance criterion of 5%.

Several fail-safe systems are implemented in the MEL90, including those for energy, the laser scanners, the shutter, the gas system, the eye-tracker, the cone for controlled atmosphere (CCA+) debris removal system, and the laser head. The fail-safe systems were tested as part of product verification testing using MEL90 lasers that are planned for product release.

To ensure that the delivered laser energy remains within tolerance, the user initiates a fluence test prior to each treatment. In addition, the overlap of the aiming beam with the working excimer beam is also checked during the fluence test.

5. Eye Tracking System

To check the overall performance of the eye-tracker, verification tests were performed by ablating test lenses from PMMA plates that were overlayed on a tracking target. The PMMA plate and the tracking target were moved by means of a translation stage. The moving coordinates come from a pseudo-random trajectory. The refractive powers of the PMMA lenses attached to the tracking target were measured and compared to the specified limits as for the static case.

Verification tests were completed to ensure that the performance of the eye-tracking and laser position correction system meets the eye tracker subsystem and MEL90 system specifications. All specifications for eye tracking control signals, monitor signals, video and graphical display data signals and functions were also tested.

6. Environmental Testing

To ensure that the environmental conditions specified for the MEL90 do not adversely affect system performance or the operating environment for users and patients, testing was performed to verify system operation for transport and storage environmental requirements following the IEC 60601-1 standard for medical device safety and essential performance. Verification and bench testing was performed regarding potential gas hazards and the proper performance of the CCA+ plume removal system. The generation of ozone gas by the excimer laser and the leakage and/or exhaust of fluorine excimer gas from the gas containment system must fall below limits specified in the MEL90 system specifications. Verification testing was performed for the presence of both gases using appropriate gas detection apparatus. The ozone detection was performed during laser operation at a point closest to the laser aperture where ozone production is potentially the greatest. Fluorine gas was measured in the vicinity of the gas handling system and downstream of the fluorine gas-scrubbing filter during a typical excimer gas exchange procedure. The ozone measurements did not exceed the limit. The fluorine measurements showed no fluorine gas above the detection limit was present.

B. Animal Studies

Not applicable

C. Additional Studies

1. Electrical Safety, Electromagnetic Compatibility, Optical Radiation Safety Testing

The MEL90 was tested in-house and by accredited third-party laboratories to ensure compliance with the applicable international standards for electromagnetic compatibility, electrical safety, and laser safety.

The standards for electrical safety and electromagnetic compatibility include IEC 60601-1 (General Requirements for Basic Safety and Essential Performance), IEC 60601-1-2 (Electromagnetic Compatibility Requirements and Tests), IEC 60601-2-22 (Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment). The purpose of the testing was to ensure continuous device function in a noisy electromagnetic field environment. The results demonstrated the MEL90 remains functional within specifications in the presence of a range of electromagnetic frequency signals and when subjected to electrostatic dischargers.

Optical radiation safety of the excimer treatment laser and the auxiliary light sources was respectively evaluated as per the requirements of IEC 60825-1 (Safety of Laser Products, Part 1-Equipment Classification) and ANSI Z80.36 (American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments). The excimer treatment

laser was classified according to IEC 60825-1 as a Class 4 laser and the illumination system of the MEL90 was found to meet the requirements of ANSI Z80.36.

2. Software and Cybersecurity Validation Testing

Carl Zeiss Meditec procedures follow IEC 62304 standard, FDA software guidance "Content of Premarket Submissions for Device Software Functions " and FDA cybersecurity guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" and require the establishment and review of specifications, development of risk analysis, and adequate verifications and validation of software and hardware prior to release. The results of the overall software and cybersecurity validation testing demonstrate that the MEL90 meets the system specifications for performance and accuracy.

3. Human Factor Testing

The MEL90 excimer laser system were evaluated based on Human factor engineering expectations in accordance with the FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices” issued in February 2016. A use failure modes and effects analysis (uFMEA) summary for the MEL90 as well as comparative use-related risk analysis (cURRA) reports were created for MEL80 and MEL90. All critical user tasks were compared between the MEL80 and MEL90 to evaluate the effectiveness of the risk mitigations identified in the Risk Analysis report. The cURRA report confirmed that no new critical tasks or existing critical tasks were introduced or impacted in the MEL90 as compared to MEL80. Through this process, it was determined that all critical tasks were confirmed to be mitigated to an acceptable level of risk. The results of the overall human factor testing demonstrated that MEL90 is both safe and effective for intended users, uses, and use environments.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of LASIK with the MEL90 Excimer Laser System in treatments for the reduction or elimination of:

- Myopia less in magnitude than -10.00 D sphere (in minus-cylinder notation), with and without cylinder up to -4.00 D, when MRSE is less in magnitude than -10.00 D;
- Hyperopia up to +4.00 D sphere (in plus-cylinder notation), with and without cylinder up to +3.00 D, when MRSE is up to +5.00 D; and
- Mixed astigmatism with cylinder from >1.00 D up to 4.00 D;

in patients who are 18 years of age or older with documentation of stable manifest refraction. The study was conducted in the U.S. under IDE # G190113. Data from this clinical study was the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between October 3, 2019 and October 24, 2023. The database for this Panel Track Supplement, P060004/S006, reflected data collected through 24 April 2024, and included 358 treated patients with 714 treated eyes. There were 9 investigational sites.

The study was a prospective, multi-center, single-arm, unmasked clinical study. Subjects were enrolled and treated and were followed for 12 months postoperatively. Retreatments were not allowed during the study. No statistical hypothesis tests were used in key study analyses. Key study outcomes were based upon point estimates of the rates of occurrence of the key safety and effectiveness outcome parameters at the timepoint at which refractive stability was established, and upon cumulative adverse event rates for all treated eyes.

1. Clinical Inclusion and Exclusion Criteria

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

- Male or females must be at least 18 years of age.
- Myopia up to -10.00 D with and without cylinder up to -4.00 D, or hyperopia up to +5.00 D with and without cylinder up to +4.00 D, or mixed astigmatism up to 4.00 D in magnitude; with spherical equivalent from -11.00 D through +5.00 D.
- Intended treatment targeted for emmetropia in the eye(s) to be treated.
- Stable refraction (within ± 0.50 D), as determined by MRSE for a minimum of 12 months prior to surgery, verified by consecutive manifest refractions and/or medical records or glasses prescription history in the eye(s) to be treated.
- A difference between cycloplegic and manifest refractions of < 0.75 D spherical equivalent in the eye(s) to be treated.
- For myopes, an uncorrected distance visual acuity (UCDVA) of 0.3 logMAR or worse in the eye(s) to be treated; for hyperopes and mixed astigmatism, difficulty maintaining UCDVA of 0.3 logMAR, as evidenced by the need for constant contact lens wear or spectacle wear in the eye(s) to be treated.
- Best corrected distance visual acuity (BCDVA) of at least 0.0 logMAR in the eye(s) to be treated.
- Must be willing to discontinue use of contact lenses for at least 2 weeks (for hard lenses) or 3 days (for soft lenses) prior to the preoperative examination, and through the day of surgery in the eye(s) to be treated.
- Contact lens wearers must demonstrate a stable refraction (within ±0.5 D), as determined by MRSE, on two consecutive examinations at least 1 week apart, in the eye(s) to be treated after discontinuing contact lens use for at least 2 weeks (for hard lenses) or 3 days (for soft lenses) prior to baseline examination. Central corneal thickness of at least 480 microns in the eye(s) to be treated. Willing and able to return for scheduled follow-up examinations. Able to follow study instruction in English.

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

- Anticipated residual stromal bed thickness < 250 microns in the eye(s) to be treated.
- Fellow eye BCDVA worse than 0.3 logMAR.

- Abnormal corneal topographic findings, e.g. keratoconus, pellucid marginal degeneration in either eye.
- History of or current anterior or posterior segment pathology, including cataracts in the eye(s) to be treated.
- Planned treatment for monovision.
- History of any of the following medical conditions, or any other condition that could affect wound healing: collagen vascular disease, autoimmune disease, immunodeficiency diseases, endocrine disorders (including, but not limited to unstable thyroid disorders), lupus, rheumatoid arthritis, diabetes (regardless of type, duration, severity or control); active ophthalmic disease or abnormality (including, but not limited to, symptomatic blepharitis, recurrent corneal erosion, severe dry eye syndrome or symptoms, neovascularization > 1 mm from limbus), retinal detachment/repair, clinically/visually significant lens opacity, clinical evidence of trauma, corneal opacity within the central 9 mm and visible on topography, at risk for developing strabismus, or with ocular hypertension, intraocular pressure (IOP) >21 mmHg at screening or evidence of glaucoma or propensity for narrow angle glaucoma.
- Residual, recurrent, active ocular or uncontrolled eyelid disease, corneal scars or other corneal abnormality such as recurrent corneal erosion or severe basement membrane disease in the eye(s) to be treated.
- Ophthalmoscopic signs of progressive or unstable myopia or keratoconus suspect in either eye.
- Irregular or unstable (distorted/not clear) corneal mires on central keratometry images in either eye.
- History of ocular herpes zoster or herpes simplex keratitis in either eye.
- Difficulty following directions or unable to fixate.
- For hyperopes, clinically measurable strabismus or amblyopia in the eye(s) to be treated.
- For hyperopes, white-to-white less than or equal to 11.5 mm as measured by corneal topography in the eye(s) to be treated.
- For hyperopes, slit lamp examination demonstrating potentially occludable angle as judged by the investigator in the eye(s) to be treated.
- Previous intraocular or corneal surgery of any kind in the eye(s) to be treated, including any type of surgery for either refractive or therapeutic purposes.
- History of steroid-responsive rise in intraocular pressure, glaucoma, or preoperative IOP > 21 mmHg in either eye.
- Immunocompromised or requires chronic systemic corticosteroids or other immunosuppressive therapy that may affect wound healing.
- History of or has a current, clinically significant major psychiatric disorder (e.g., major depressive disorder, psychosis, schizophrenia).
- Subjects with known sensitivity to planned study concomitant medications.
- Enrollment in another drug or device clinical study within the prior 3 months.
- Subjects who are pregnant, lactating, or of child-bearing potential and not practicing a medically approved method of birth control.

Further, fellow (second) eyes of patients undergoing simultaneous, bilateral treatment were not enrolled in the study if they met any of the following exclusion criteria:

- Flap complications during the first eye's surgery such as a free cap, partial flap, thin flap, or irregular flap.
- Epithelial defect exceeding 2 mm x 2 mm in dimension.
- Severe blepharospasm in the first eye that may have prevented or impeded the completion of the keratectomy and/or the laser ablation procedure.
- Poor subject cooperation with instructions for the first eye's surgery and/or poor subject fixation on the laser fixation target.
- Aborted LASIK procedure in the first eye or PRK was performed in the first eye because LASIK was not possible.

2. Follow-up Schedule

All patients were to return for follow-up examinations per the following schedule:

Patient Screening for Eligibility	
Preoperative Evaluation:	Day -60 to Day -1
Operative Evaluation:	Day 0, day of surgery
Postoperative Day 1:	Day 1
Postoperative Week 1:	Days 5 to 9
Postoperative Month 1:	Days 21 to 35 (Weeks 3 to 5)
Postoperative Month 3:	Days 70 to 98 (Weeks 10 to 14)
Postoperative Month 6:	Days 147 to 182 (Weeks 21 to 26)
Postoperative Month 9:	Days 245 to 301 (Weeks 35 to 43)
Postoperative Month 12:	Days 330 to 420 (Months 11 to 14)

The parameters to be measured preoperatively and postoperatively during the study are summarized in **Table 1** below. Adverse events and complications were recorded at all visits.

Table 1. Study Visits and Clinical Parameters

Visits	Preop	Op Visit	1 Day	7 Days	1 Mo	3 Mos	6 Mos	9 Mos	12 Mos	Interim Visits[1]
UCDVA	x		x	x	x	x	x	x	x	x
UCNVA[2]	x					x[2]			x	
BCDVA[3]	x		x	x	x[3]	x[3]	x[3]	x[3]	x[3]	x[3]
Objective refraction[4]	x[4]									
Manifest refraction	x		x	x	x	x	x	x	x	x
Cycloplegic refraction	x								x	
Corneal topography	x									
Central keratometry	x									
Pupil size (mesopic)	x								x	
Intraocular pressure	x			x	x	x	x	x	x	
Slit lamp exam	x		x	x	x	x	x	x	x	x
Ocular surface grading	x		x	x	x	x	x	x	x	x[1]
Dilated fundus examination	x								x	
Pachymetry	x									
Intraoperative events		x								
Adverse events		x	x	x	x	x	x	x	x	x
Subject Questionnaire	x					x	x	x	x	

1 Clinical assessments performed at interim visits beyond those indicated are at the discretion of the investigator based on the patient's condition at presentation.
2 Only for eyes treated with hyperopia with or without astigmatism.
3 If the visual acuity with spectacle correction is ≥10 letters below that obtained preoperatively, a rigid contact lens over refraction should be performed to estimate the best possible corrected visual acuity beginning at 1-month postoperatively.
4 Preoperative if needed for confirmation of cylinder magnitude.

Patient reported outcomes in the IDE clinical study were obtained with the Patient Reported Outcomes with LASIK (PROWL) questionnaire with accompanying photographs, and 2 of the 3 domains of the Ocular Surface Disease Index (OSDI). The study protocol specified that the PRO instrument was to be administered at the preoperative visit and at Months 3, 6, 9, and 12 postoperatively.

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

3. Clinical Endpoints

With regards to safety, the primary outcomes for the study were:

Decrease in Best Corrected Distance Visual Acuity (BCDVA)

a) In eyes with preoperative BCDVA 0.0 logMAR or better, the percentage of eyes with BCDVA worse than 0.3 logMAR at the postoperative interval at which stability is established were calculated.

b) Percentage of eyes with BCDVA loss ≥ 10 letters from baseline at the point at which stability is established were calculated.

Induced Manifest Refractive Astigmatism

The percentage of eyes with induced manifest refractive cylinder of > 2.00 D of absolute cylinder at the postoperative interval at which stability is established were calculated.

Incidence of Adverse Events

The rate of each type of adverse event, by the proportion of subject and eyes, were summarized.

With regards to effectiveness, the primary outcomes for the study were:

Refractive Predictability

The percentage of eyes with MRSE and MRCYL within ± 1.00 D and ± 0.50 D of the intended refractive outcome at the point at which stability is established.

Uncorrected Distance Visual Acuity

The percentage of eyes with UCDVA of 0.3 logMAR or better at the point at which stability is established.

With regards to success/failure criteria, the following applied:

The protocol stated that refractive stability was considered to have been achieved at the latter of two postoperative refractions performed at least 3 months apart or at 3 months after surgery when compared with the 1-month interval if all the stability criteria were met. These criteria are as follows:

1. At least 95% of the treated eyes should have a change ≤ 1.00 D of MRSE, MRCYL, and vector cylinder at the latter of two postoperative refractions performed at least 3 months apart or at 3 months after surgery when compared with the 1-month interval;
2. The mean rate of change in MRSE, MRCYL, and vector cylinder, as determined by paired analysis, is ≤ 0.5 D per year (0.04 D/month) over the same time period;

3. The mean rate of change of MRSE, MRCYL, and vector cylinder decreases monotonically over time, with a projected asymptote of zero or a rate of change attributable to normal aging;
4. The 95% confidence interval for the mean rate of change includes zero or a rate of change attributable to normal aging; and
5. Stability will be confirmed at least 3 months after the stability time point by a statistically adequate subgroup.

Success criteria for safety are:

- < 5% of eyes with a loss of ≥ 10 letters of BCDVA at the time point at which stability is established.
- < 1% of eyes with a BCDVA of 0.0 logMAR or better preoperatively that have a BCDVA of worse than 0.3 logMAR at the time point at which stability is established.
- < 5% of eyes with induced manifest refractive astigmatism > 2.00 D of absolute cylinder at the time point at which stability is established.
- < 1% of eyes with each ocular serious adverse event type (non-flap related)

The MEL90 device will meet the acceptance criteria if the point estimates for all of the above meet or exceed the stated goal.

Success criteria for effectiveness are as follows:

- ≥ 85% of eyes with an uncorrected visual acuity (UCDVA) of 0.3 logMAR or better at the point at which stability is established.
- ≥ 50% of eyes with a manifest refractive spherical equivalent (MRSE) within 0.50 D of intended correction at the point at which stability is established.
- ≥ 75% of eyes with an MRSE within 1.00 D of intended correction at the point at which stability is established.
- ≥ 95% of eyes achieve refractive stability between 2 refractions, performed at 1 and 3 months postoperatively, or over a minimum 3-month period thereafter.

The MEL90 device will meet the acceptance criteria if the point estimates for all of the above meet or exceed the stated goal when evaluated by treatment cohort.

B. Accountability of PMA Cohort

At the time of database lock, of the 714 eyes (of 358 subjects) enrolled and treated in the PMA study, 95.8% (684 eye) are available at the 6 months post-operative visit (the timepoint of refractive stability, the timepoint for the key safety and effectiveness analyses), with confirmatory data available on 674 eyes at the completion of the study, the 12 months postoperative visit.

Of the 836 eyes of 418 subjects enrolled, 382 eyes of 195 subjects were assigned to the myopia cohort, 293 eyes of 154 subjects to the hyperopia cohort, and 157 eyes of 89 subjects to the mixed astigmatism cohort. Four eyes were not assigned: two (2) eyes of 1 subject and 2 fellow eyes of 2 subjects due to screen failure of the primary eye.

Of all enrolled eyes, 122 were not treated. Of those, 98 eyes of 49 subjects and 1 eye each of 2 subjects were excluded from the study based on failure to meet inclusion criteria or meeting exclusion criteria; 8 subjects (16 eyes) withdrew consent; and 3 subjects (6 eyes) were discontinued by the investigator.

As a result, 714 eyes of 358 subjects were treated, of which 358 eyes of 183 subjects received treatment for myopia, 221 eyes of 117 subjects for hyperopia, and 135 eyes of 77 subjects for mixed astigmatism.

Over the course of the postoperative follow-up, greater than 92% accountability was achieved at all scheduled visits through Month 12, except Months 3 and 6 (Table 2). At Month 6 visit, percent accountability for all available eyes within-window was 89.3% and percent accountability for all available eyes completing visits whether within-window or out-of-window was 96.6%. The exam cut-off for inclusion in analyses for this report was April 24, 2024; therefore, a few eyes were still active at the time. With 6 eyes active at Month 12, the percent accountability for all available eyes within-window was 96.0% and percent accountability for all available eyes completing visits whether within-window or out-of-window was 96.6%. It should be noted that analyses supported the poolability of out-of-window data with the within-window data.

Table 2. Postoperative Accountability for All Eyes

N=714 Eyes		**Day 1**	**Week 1**	**Month 1**	**Month 3**	**Month 6**	**Month 9**	**Month 12**
Available for analysis	In or Out of Window	712 (99.7%)	700 (98.0%)	686 (96.1%)	684 (95.8%)	684 (95.8%)	666 (93.3%)	674 (94.4%)
	In Window	712 (99.7%)	694 (97.2%)	654 (91.6%)	638 (89.4%)	632 (88.5%)	650 (91.0%)	670 (93.8%)
	Out of Window	0 (0.0%)	6 (0.8%)	32 (4.5%)	46 (6.4%)	52 (7.3%)	16 (2.2%)	4 (0.6%)
Active		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	6 (0.8%)
Discontinued		2 (0.3%)	2 (0.3%)	4 (0.6%)	4 (0.6%)	6 (0.8%)	8 (1.1%)	10 (1.4%)
Lost to follow-up		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	10 (1.4%)	16 (2.2%)
Missed visit	Missing	0 (0.0%)	12 (1.7%)	24 (3.4%)	26 (3.6%)	22 (3.1%)	28 (3.9%)	8 (1.1%)
	Missing or Out of Window	0 (0.0%)	18 (2.5%)	56 (7.8%)	72 (10.1%)	74 (10.4%)	44 (6.2%)	12 (1.7%)
% Accountability*	In or Out of Window	712 / 712 (100.0%)	700 / 712 (98.3%)	686 / 710 (96.6%)	684 / 710 (96.3%)	684 / 708 (96.6%)	666 / 704 (94.6%)	674 / 698 (96.6%)
	In Window	712 / 712 (100.0%)	694 / 712 (97.5%)	654 / 710 (92.1%)	638 / 710 (89.9%)	632 / 708 (89.3%)	650 / 704 (92.3%)	670 / 698 (96.0%)
	Out of Window	0 / 712 (0.0%)	6 / 712 (0.8%)	32 / 710 (4.5%)	46 / 710 (6.5%)	52 / 708 (7.3%)	16 / 704 (2.3%)	4 / 698 (0.6%)

* % Accountability = Available for Analysis / (Treated - [Discontinued + Active])

For the myopia cohort of 382 enrolled eyes, 358 were treated. Twenty-four of the eyes were not treated, 20 based on failure to meet inclusion criteria or meeting exclusion criteria; 4 eyes (2 subjects) withdrew consent.

For hyperopia cohort of 293 enrolled eyes, 221 were treated. Seventy-two (72) of the eyes were not treated, 62 eyes based on failure to meet inclusion criteria or meeting exclusion criteria; 6 eyes (3 subjects) withdrew consent; and 4 eyes (2 subjects) were discontinued by the investigator.

For the mixed astigmatism cohort of the 157 enrolled eyes,135 were treated. Twenty-four of the eyes were not treated, 20 due to not meeting Inclusion/Exclusion Criteria; 6 eyes (3subjects) due to the withdrawal of consent; and 2 eyes (1 subject) was discontinued by the investigator.

The accountability for each of the treatment cohorts is shown below in Tables 2.1 to 2.3. For all three cohorts, when considering eyes within-window, greater than 90% accountability was for all visits through Month 12, except Month 6 for the myopia cohort and Months 3 and 6 for the hyperopia cohort. Accountability for eyes whether within or out-of-window exceeded 95% for the myopia and mixed astigmatism cohorts. For the hyperopia cohort, accountability for eyes whether within or outside of window was at least 93% for all visits, except for Month 9 where accountability was 88.5% due to a higher number of missed visits at this exam. Each cohort had two (2) eyes still active at the Month 12 visit.

Table 2.1 - Postoperative Accountability for All Myopia Cohort Eyes

N=358 Eyes		**Day 1**	**Week 1**	**Month 1**	**Month 3**	**Month 6**	**Month 9**	**Month 12**
Available for analysis	In or Out of Window	356 (99.4%)	353 (98.6%)	340 (95.0%)	345 (96.4%)	342 (95.5%)	347 (96.9%)	348 (97.2%)
	In Window	356 (99.4%)	352 (98.3%)	329 (91.9%)	321 (89.7%)	307 (85.8%)	339 (94.7%)	345 (96.4%)
	Out of Window	0 (0.0%)	1 (0.3%)	11 (3.1%)	24 (6.7%)	35 (9.8%)	8 (2.2%)	3 (0.8%)
Active		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)
Discontinued		2 (0.6%)	2 (0.6%)	2 (0.6%)	2 (0.6%)	2 (0.6%)	2 (0.6%)	2 (0.6%)
Lost to follow-up		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.1%)	4 (1.1%)
Missed visit	Missing	0 (0.0%)	3 (0.8%)	16 (4.5%)	11 (3.1%)	14 (3.9%)	5 (1.4%)	2 (0.6%)
	Missing or Out of Window	0 (0.0%)	4 (1.1%)	27 (7.5%)	35 (9.8%)	49 (13.7%)	13 (3.6%)	5 (1.4%)
% Accountability*	In or Out of Window	356 / 356 (100.0%)	353 / 356 (99.2%)	340 / 356 (95.5%)	345 / 356 (96.9%)	342 / 356 (96.1%)	347 / 356 (97.5%)	348 / 354 (98.3%)
	In Window	356 / 356 (100.0%)	352 / 356 (98.9%)	329 / 356 (92.4%)	321 / 356 (90.2%)	307 / 356 (86.2%)	339 / 356 (95.2%)	345 / 354 (97.5%)
	Out of Window	0 / 356 (0.0%)	1 / 356 (0.3%)	11 / 356 (3.1%)	24 / 356 (6.7%)	35 / 356 (9.8%)	8 / 356 (2.2%)	3 / 354 (0.8%)

Subject (01-074) experienced a seizure prior to undergoing treatment with the MEL90. the procedure was not completed, the subject was discontinued due to the unrelated medical event.

* % Accountability = Available for Analysis / (Treated - [Discontinued + Active])

Table 2.2 - Postoperative Accountability for All Hyperopia Cohort Eyes

N=221 Eyes		Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
Available for analysis	In or Out of Window	221 (100.0%)	213 (96.4%)	219 (99.1%)	210 (95.0%)	210 (95.0%)	193 (87.3%)	199 (90.0%)
	In Window	221 (100.0%)	213 (96.4%)	205 (92.8%)	193 (87.3%)	202 (91.4%)	189 (85.5%)	199 (90.0%)
	Out of Window	0 (0.0%)	0 (0.0%)	14 (6.3%)	17 (7.7%)	8 (3.6%)	4 (1.8%)	0 (0.0%)
Active		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)
Discontinued		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	3 (1.4%)	5 (2.3%)
Lost to follow-up		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)	6 (2.7%)	11 (5.0%)
Missed visit	Missing	0 (0.0%)	8 (3.6%)	2 (0.9%)	11 (5.0%)	8 (3.6%)	19 (8.6%)	4 (1.8%)
	Missing or Out of Window	0 (0.0%)	8 (3.6%)	16 (7.2%)	28 (12.7%)	16 (7.2%)	23 (10.4%)	4 (1.8%)
% Accountability*	In or Out of Window	221 / 221 (100.0%)	213 / 221 (96.4%)	219 / 221 (99.1%)	210 / 221 (95.0%)	210 / 220 (95.5%)	193 / 218 (88.5%)	199 / 214 (93.0%)
	In Window	221 / 221 (100.0%)	213 / 221 (96.4%)	205 / 221 (92.8%)	193 / 221 (87.3%)	202 / 220 (91.8%)	189 / 218 (86.7%)	199 / 214 (93.0%)
	Out of Window	0 / 221 (0.0%)	0 / 221 (0.0%)	14 / 221 (6.3%)	17 / 221 (7.7%)	8 / 220 (3.6%)	4 / 218 (1.8%)	0 / 214 (0.0%)

* % Accountability = Available for Analysis / (Treated - [Discontinued + Active])

Table 2.3 - Postoperative Accountability for All Mixed Astigmatism Cohort Eyes

N=135 Eyes		Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
Available for analysis	In or Out of Window	135 (100.0%)	134 (99.3%)	127 (94.1%)	129 (95.6%)	132 (97.8%)	126 (93.3%)	127 (94.1%)
	In Window	135 (100.0%)	129 (95.6%)	120 (88.9%)	124 (91.9%)	123 (91.1%)	122 (90.4%)	126 (93.3%)
	Out of Window	0 (0.0%)	5 (3.7%)	7 (5.2%)	5 (3.7%)	9 (6.7%)	4 (3.0%)	1 (0.7%)
Active		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.5%)	2 (1.5%)
Discontinued		0 (0.0%)	0 (0.0%)	2 (1.5%)	2 (1.5%)	3 (2.2%)	3 (2.2%)	3 (2.2%)
Lost to follow-up		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
Missed visit	Missing	0 (0.0%)	1 (0.7%)	6 (4.4%)	4 (3.0%)	0 (0.0%)	4 (3.0%)	2 (1.5%)
	Missing or Out of Window	0 (0.0%)	6 (4.4%)	13 (9.6%)	9 (6.7%)	9 (6.7%)	8 (5.9%)	3 (2.2%)
% Accountability*	In or Out of Window	135 / 135 (100.0%)	134 / 135 (99.3%)	127 / 133 (95.5%)	129 / 133 (97.0%)	132 / 132 (100.0%)	126 / 130 (96.9%)	127 / 130 (97.7%)
	In Window	135 / 135 (100.0%)	129 / 135 (95.6%)	120 / 133 (90.2%)	124 / 133 (93.2%)	123 / 132 (93.2%)	122 / 130 (93.8%)	126 / 130 (96.9%)
	Out of Window	0 / 135 (0.0%)	5 / 135 (3.7%)	7 / 133 (5.3%)	5 / 133 (3.8%)	9 / 132 (6.8%)	4 / 130 (3.1%)	1 / 130 (0.8%)

* % Accountability = Available for Analysis / (Treated - [Discontinued + Active])

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a LASIK study performed in the US. A summary of demographic information for all treated subjects is provided in Table 3, with stratification by subjects treated for each cohort: myopia, hyperopia, and mixed astigmatism. The proportions enrolled are consistent with the sex, gender, age, racial and ethnic prevalence of patients who get LASIK surgery in the US.

Table 3. Demographics for All Treated Subjects by Treatment Cohort

		Myopia		Hyperopia		Mixed Astigmatism		Total	
		N (%)		N (%)		N (%)		n/N (%)	
Gender	Male	88/183	(48.1%)	52/117	(44.4%)	46/77	(59.7%)	177/358	(49.4%)
	Female	95/183	(51.9%)	65/117	(55.6%)	31/77	(40.3%)	181/358	(50.6%)
Race	White	167/183	(91.3%)	109/117	(93.2%)	71/77	(92.2%)	329/358	(91.9%)
	Black	4/183	(2.2%)	6/117	(5.1%)	1/77	(1.3%)	11/358	(3.1%)
	Asian	8/183	(4.4%)	0/117	(0.0%)	0/77	(0.0%)	8/358	(2.2%)
	Other	4/183	(2.2%)	2/117	(1.7%)	5/77	(6.5%)	10/358	(2.8%)
Ethnicity	Hispanic or Latino	13/183	(7.1%)	8/117	(6.8%)	10/77	(13.0%)	28/358	(7.8%)
	Not Hispanic or Latino	170/183	(92.9%)	109/117	(93.2%)	67/77	(87.0%)	330/358	(92.2%)
Age (years)	Mean (SD)	33.1 (7.5)		39.9 (11.5)		35.3 (9.1)		35.7 (9.6)	
	Median	32.0		42.0		35.0		34.0	
	Min, Max	19, 63		18, 62		20, 57		18, 63	
Age Category	Age 18 to < 22	9/183	(4.9%)	5/117	(4.3%)	6/77	(7.8%)	18/358	(5.0%)
	Age 22 and older	174/183	(95.1%)	112/117	(95.7%)	71/77	(92.2%)	340/358	(95.0%)

Abbreviations: SD=Standard Deviation.

Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated. 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.
Note that only treated subjects are summarized.

The preoperative manifest refractive sphere (MRSPH) and cylinder (MRCYL) are the key baseline parameters for clinically relevant variables important for understanding the safety and treatment effects. Tables 4.1 and 4.2 show the distribution of baseline MRSPH and MRCYL for all treated eyes, with stratification by subjects treated for each cohort: myopia, hyperopia, and mixed astigmatism. For these tables, the baseline refraction is represented in minus cylinder form for all cohorts. As a result, 11 eyes in the hyperopia cohort have a MRSPH greater than +5.00 D in minus cylinder form; however, these same eyes are within the treatment range of +5.00 D MRSPH when represented in plus cylinder form.

Table 4.1. Preoperative Manifest Refraction Sphere (MRSPH) for All Eyes

Cohort	Myopia Eyes		Hyperopia Eyes		Mixed Astigmatism Eyes		Total Eyes	
	N (%)		N (%)		N (%)		N (%)	
Manifest Refraction Sphere (D)								
-10.00 to -9.01 D	26/358	(7.3%)					26/714	(3.6%)
-9.00 to -8.01 D	28/358	(7.8%)					28/714	(3.9%)
-8.00 to -7.01 D	26/358	(7.3%)					26/714	(3.6%)
-7.00 to -6.01 D	29/358	(8.1%)					29/714	(4.1%)
-6.00 to -5.01 D	42/358	(11.7%)					42/714	(5.9%)
-5.00 to -4.01 D	38/358	(10.6%)					38/714	(5.3%)
-4.00 to -3.01 D	45/358	(12.6%)					45/714	(6.3%)
-3.00 to -2.01 D	47/358	(13.1%)					47/714	(6.6%)
-2.00 to -1.01 D	48/358	(13.4%)					48/714	(6.7%)
-1.00 to -0.01 D	25/358	(7.0%)					25/714	(3.5%)
0.00 D	4/358	(1.1%)	0/221	(0.0%)	0/135	(0.0%)	4/714	(0.6%)
+0.01 to +1.00 D			15/221	(6.8%)	77/135	(57.0%)	92/714	(12.9%)
+1.01 to +2.00 D			50/221	(22.6%)	26/135	(19.3%)	76/714	(10.6%)
+2.01 to +3.00 D			55/221	(24.9%)	23/135	(17.0%)	78/714	(10.9%)
+3.01 to +4.00 D			48/221	(21.7%)	9/135	(6.7%)	57/714	(8.0%)
+4.01 to +5.00 D			42/221	(19.0%)			42/714	(5.9%)
+5.01 to +6.00 D			10/221	(4.5%)			10/714	(1.4%)
+6.01 to +7.00 D			1/221	(0.5%)			1/714	(0.1%)
Manifest Refraction Sphere (D)								
N	358		221		135		714	
Mean (SD)	-4.64 (2.74)		+2.97 (1.31)		+1.26 (0.99)		-1.17 (4.12)	
Median	-4.50		3.00		+1.00		0.00	
Min, Max	-10.0, 0.00		+0.75, +6.25		+0.25, +3.50		-10.0, +6.25	

Abbreviations: SD=Standard Deviation.

*Shaded cells: Treatment of > +4.00 D sphere (in plus-cylinder notation) will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

Table 4.2. Preoperative Manifest Refraction Cylinder (MRCYL) for All Eyes

Cohort	Myopia Eyes		Hyperopia Eyes		Mixed Astigmatism Eyes		Total Eyes	
	N (%)		N (%)		N (%)		N (%)	
Manifest Refraction Cylinder (D)								
-3.01 to -4.00 D*	24/358	(6.7%)	12/221*	(5.4%)	51/135	(37.8%)	87/714	(12.2%)
-2.01 to -3.00 D	34/358	(9.5%)	26/221	(11.8%)	39/135	(28.9%)	99/714	(13.9%)
-1.01 to -2.00 D	65/358	(18.2%)	29/221	(13.1%)	30/135	(22.2%)	124/714	(17.4%)
-1.00 D**	25/358	(7.0%)	23/221	(10.4%)	13/135**	(9.6%)	61/714	(8.5%)
-0.75 D**	44/358	(12.3%)	29/221	(13.1%)	2/135**	(1.5%)	75/714	(10.5%)
-0.50 D***	37/358	(10.3%)	26/221	(11.8%)	0/135***	(0.0%)	63/714	(8.8%)
-0.25 D***	37/358	(10.3%)	18/221	(8.1%)	0/135***	(0.0%)	55/714	(7.7%)
0.00 D***	92/358	(25.7%)	58/221	(26.2%)	0/135***	(0.0%)	150/714	(21.0%)
Manifest Refraction Cylinder (D)								
N	358		221		135		714	
Mean (SD)	-1.002 (1.048)		-0.988 (1.040)		-2.602 (0.992)		-1.300 (1.210)	
Median	-0.75		-0.75		-2.75		-1.00	
Min, Max	-4.00, 0.00		-4.00, 0.00		-4.00, -0.75		-4.00, 0.00	

Abbreviations: SD=Standard Deviation.
Shaded cells:
* Treatments of hyperopia with cylinder magnitude > 3.00 D through 4.0 D will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.
** Treatments of mixed astigmatism with cylinder magnitude up to 0.50 D will be locked out.
*** Treatments of mixed astigmatism with cylinder magnitude > 0.50 D through 1.00 D will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based oneyes in the Safety Population, defined as "eyes with attempted LASIK (successful or aborted after initiation of flap)." The Safety Population includes all 714 eyes treated in the study available for the 6-month evaluation. This section presents key safety outcomes, BCDVA, adverse events and patient-reported outcomes. The key safety outcomes for this study are presented below in Table 5 to Table 6.1. Adverse effects are reported in Tables 7 to 7.3.

Key safety outcomes at the last available visit for each of the 714 eyes in the Safety Population are summarized in Table 5. No study subject presented with a loss of ≥ 2 lines BCDVA or with BCDVA worse than 0.3 logMAR at the last available visit. One subject **(Subject 08-001 OS)** presented with increased manifest refractive astigmatism > 2.00 D at the last available visit, this subject had a user transcription error which led to the wrong treatment axis.

Table 5. Key Safety Outcomes at Last Available Visit for All Eyes in Safety Population

Key Safety Outcome	Myopia n/N (%)	Hyperopia n/N (%)	Mixed Astigmatism n/N (%)	Total n/N (%)
Loss of ≥ 2 lines BCDVA	0/358 (0%)	0/221 (0%)	0/135 (0%)	0/714 (0%)
Loss of > 2 lines BCDVA	0/358 (0%)	0/221 (0%)	0/135 (0%)	0/714 (0%)
BCDVA worse than 0.3 logMAR	0/358 (0%)	0/221 (0%)	0/135 (0%)	0/714 (0%)
BCDVA worse than 0.3 logMAR if 0.0 logMAR or better preoperatively	0/358 (0%)	0/221 (0%)	0/135 (0%)	0/714 (0%)
Increased manifest refractive astigmatism > 2.00D	0/358 (0%)	0/221 (0%)	1/135 (0.7%)	1/714 (0.1%)

The primary safety outcomes for the study were defined in the protocol as:

- the percentage of eyes with preoperative BCDVA 0.0 logMAR or better with BCDVA worse than 0.3 logMAR at timepoint of refractive stability;
- the percentage of eyes with BCDVA loss ≥ 10 letters from baseline at the point of refractive stability;
- The percentage of eyes with induced manifest refractive cylinder of > 2.00 D of absolute cylinder at the timepoint of refractive stability;
- The rate of each type of adverse event, by the proportion of subject and eyes.

Stability was determined at the 6-month postoperative visit (see section "Stability of MRSE"). **Table 5.1** summarizes the results for the primary safety outcomes at 6 months for all eyes and for each treatment cohort separately. The results on adverse events are summarized further below (Table 6 and Tables 6.1 to 6.3).

At the timepoint of refractive stability, one eye, which had been treated for myopia, experienced a transient loss of BCDVA ≥2 lines. As described above, one eye presented with increased manifest refractive astigmatism > 2.00 D due to a treatment on the wrong axis. The eye was retreated before the 3-month visit (the last observation prior to retreatment was carried forward for this one eye); the 1 Month data showing induced astigmatism has been carried through to all visits for safety analysis.

Table 5.1. Primary Safety Outcomes at 6 months for All Eyes in Safety Population

Key Safety Outcome	Myopia n/N (%)	Hyperopia n/N (%)	Mixed Astigmatism n/N (%)	Total n/N (%)
Loss of ≥ 2 lines BCDVA	1/342 (0.3%)	0/210 (0%)	0/133 (0%)	1/685 (0.2%)
BCDVA worse than 0.3 logMAR if 0.0 logMAR or better preoperatively	1/342 (0.3%)	0/210 (0%)	0/133 (0%)	1/685 (0.2%)
Increased manifest refractive astigmatism > 2.00D	0/342 (0%)	0/210 (0%)	1/133 (0.8%)	1/685 (0.2%)

Data for subject 08-001 OS Month 1 was carried forward through all post-operative visits for safety analysis.

Best Corrected Distance Visual Acuity (BCDVA)

The gain and loss of BCDVA from baseline across visits for the full cohort is presented in Table 6. Regarding the key safety outcome of loss of 2 or more lines of BCDVA, five eyes experienced such loss temporarily at 1 month postoperatively or later. Three eyes are in the myopia cohort and two eyes in the hyperopia cohort; no eyes in the mixed astigmatism cohort had a loss of 2 or more lines of BCDVA.

Table 6. Change in Best Corrected Visual Acuity for All Eyes in Safety Population

	Day 1 n (%)		Week 1 n (%)		Month 1 n (%)		Month 3 n (%)		Month 6 n (%)		Month 9 n (%)		Month 12 n (%)		Unsched.[3] n (%)	
Lost > 2 lines (>10 letters)	19	(2.7%)	3	(0.4%)	2	(0.3%)	1	(0.2%)	1	(0.2%)	0	(0%)	0	(0%)	4	(8.3%)
Lost 2 lines (10 letters)	12	(1.7%)	1	(0.1%)	1	(0.2%)	0	(0%)	0	(0%)	0	(0%)	0	(0%)	0	(0%)
Lost 1 line (5-9 letters)	85	(11.9%)	74	(10.6%)	36	(5.3%)	24	(3.5%)	35	(5.1%)	19	(2.9%)	21	(3.1%)	2	(4.2%)
Unchanged (< 5 letters)	516	(72.5%)	518	(74.0%)	519	(75.7%)	526	(76.9%)	508	(74.2%)	504	(75.6%)	488	(72.3%)	39	(81.3%)
Gained 1 line (5-9 letters)	76	(10.7%)	102	(14.6%)	117	(17.1%)	118	(17.3%)	129	(18.8%)	125	(18.7%)	152	(22.5%)	3	(6.3%)
Gained 2 lines (10 letters)	4	(0.6%)	2	(0.3%)	9	(1.3%)	13	(1.9%)	5	(0.7%)	12	(1.8%)	10	(1.5%)	0	(0%)
Gained > 2 lines (>10 letters)	0	(0%)	0	(0%)	2	(0.3%)	2	(0.3%)	7	(1.0%)	7	(1.1%)	4	(0.6%)	0	(0%)
Not Reported	0		12		24		26		22		28		8			
Total with Data[1]	712		700		686		684		685		667		675		48	
On Study[2]	712		712		710		710		706		694		682			

Percentages are based on non-missing counts.

[1] Data for subject 08-001 OS Month 1 was carried forward through all post-operative visits

[2] On-study represents the number of eyes not discontinued, LTF, or active at that visit.

[3] Note that for eyes with more than one interim visit, the worst logMAR value was selected

Outlined rows represent results associated with safety.

The gain and loss of BCDVA at Month 6, stratified by treatment cohort, is presented in Table 6.1.

Table 6.1. Change in Best Corrected Visual Acuity at Month 6
Stratified by Treatment Cohort for All Eyes in Safety Population

	Myopia Cohort n (%)	Hyperopia Cohort n (%)	Mixed Astigmatism n (%)	Total n (%)
Lost > 2 lines (>10 letters)	1 (0.3%)	0 (0%)	0 (0%)	1 (0.2%)
Lost 2 lines (10 letters)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Lost 1 line (5-9 letters)	11 (3.2%)	19 (9.1%)	5 (3.8%)	35 (5.1%)
Unchanged (< 5 letters)	246 (71.9%)	162 (77.1%)	100 (75.2%)	508 (74.2%)
Gained 1 line (5-9 letters)	76 (22.2%)	27 (12.9%)	26 (19.6%)	129 (18.8%)
Gained 2 lines (10 letters)	3 (0.9%)	1 (0.5%)	1 (0.8%)	5 (0.7%)
Gained > 2 lines (>10 letters)	5 (1.5%)	1 (0.5%)	1 (0.8%)	7 (1.0%)
Not Reported	14	8	0	22
Total with Data	342	210	133	685
On Study[1,2]	356	218	132	706

[1] Data for subject 08-001 OS Month 1 was carried forward through all post-operative visits. Note: Month 3 through Month 12 data includes 1 additional eye "with data" than "on study" due to this additional data point.
[2] On-study represents the number of eyes not discontinued, LTF, or active at that visit.
Outlined rows represent results associated with safety.

Adverse effects that occurred in the PMA clinical study

Intraoperative and postoperative adverse events are reported in **Table 7** for all eyes, followed by **Tables 7.1 to 7.3** for each treatment cohort. One intraoperative event, interface debris, occurred at a rate above 1.0% (2.0%, 14/714). There were two (2) postoperative adverse events which occurred at a 1.0% incidence or greater, patient complaint of dry eye (2.8%, 20/714) and epithelium in the interface (1.1%, 8/714). There were three serious adverse events in the postoperative course for a retinal detachment, a flap melt, and hospitalization for a seizure event.

Three secondary surgical interventions were performed for epithelial ingrowth removal, for retreatment of an incorrect treatment axis, and for a scleral buckle procedure. No unanticipated adverse device effects (UADEs) were reported.

Table 7. Adverse Events for All Eyes

	Subjects with 1 or More AE		Eyes with 1 or More AE	Events	
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
One or More of Any Adverse Event	59/358	16.5%	84/714	11.8%	106
Intraoperative Adverse Events					
Interface debris	10/358	2.8%	14/714	2.0%	15
Flap is not of the size and shape as initially intended	1/358	0.3%	1/714	0.1%	1
Flap misaligned	1/358	0.3%	1/714	0.1%	1
Flap tear	1/358	0.3%	1/714	0.1%	1
Free cap	1/358	0.3%	1/714	0.1%	1
Hinge tissue ablated	1/358	0.3%	1/714	0.1%	1
Treatment was on wrong Axis	1/358	0.3%	1/714	0.1%	1
Procedure interruption due to seizure	1/358	0.3%	2/714	0.3%	2
Postoperative Adverse Events					
Clinical signs and subjective symptoms reported by the patient consistent with dry eye	13/358	3.6%	20/714	2.8%	23
Epithelium in the interface	6/358	1.7%	8/714	1.1%	9
Diffuse lamellar keratitis (Grade 2 or less)	6/358	1.7%	6/714	0.8%	6
Corneal edema between 1 week and 1 month after the procedure	2/358	0.6%	4/714	0.6%	4
Corneal striae	3/358	0.8%	4/714	0.6%	4
Conjunctivitis, allergic	2/358	0.6%	3/714	0.4%	3
Corneal abrasion	3/358	0.8%	3/714	0.4%	3
Conjunctivitis, viral	1/358	0.3%	2/714	0.3%	2
Epithelium in the interface with loss of 10 letters or more of BCDVA	1/358	0.3%	1/714	0.1%	2
MGD (Meibomian Gland Dysfunction)	1/358	0.3%	2/714	0.3%	2
Posterior Vitreous Detachment (PVD)	1/358	0.3%	2/714	0.3%	2
Transient light sensitivity syndrome (TLSS)	1/358	0.3%	2/714	0.3%	2
Vitreous syneresis	1/358	0.3%	2/714	0.3%	2
Anterior uveitis	1/358	0.3%	1/714	0.1%	1
Chemical splash in eye	1/358	0.3%	1/714	0.1%	1
Conjunctival laceration	1/358	0.3%	1/714	0.1%	1
Corneal dryness	1/358	0.3%	1/714	0.1%	1
Corneal edema at 1 month or later	1/358	0.3%	1/714	0.1%	1
Decrease in BCDVA ≥ 10 letters not due to irregular astigmatism at ≥ 3 months	1/358	0.3%	1/714	0.1%	1
Epithelial defect	1/358	0.3%	1/714	0.1%	1
Foreign body	1/358	0.3%	1/714	0.1%	1
Foreign body sensation	1/358	0.3%	1/714	0.1%	1
IOP increase of > 10 mmHg above baseline on 2 consec. exams or IOP > 30 mmHg on 2 consec. exams	1/358	0.3%	1/714	0.1%	1
Irregular flap margin	1/358	0.3%	1/714	0.1%	1
Loss of BCDVA	1/358	0.3%	1/714	0.1%	1
Metallic foreign body	1/358	0.3%	1/714	0.1%	1
Serious Adverse Events					
Melting of the flap	1/358	0.3%	1/714	0.1%	1
Retinal detachment	1/358	0.3%	1/714	0.1%	1
Seizure	1/358	0.3%	1/714	0.1%	1
Secondary Surgical Interventions					

	Subjects with 1 or More AE		Eyes with 1 or More AE	Events	
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
Epithelial ingrowth removal	1/358	0.3%	1/714	0.1%	1
Retreatment	1/358	0.3%	1/714	0.1%	1
Scleral buckle	1/358	0.3%	1/714	0.1%	1

AEs are sorted by descending frequency of events.
Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated, 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

Table 7.1. Adverse Events (AEs) for All Myopic Eyes

	Subjects with 1 or More AE		Eyes with 1 or More AE		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
One or More of Any Adverse Event	32/183	17.5%	46/358	12.8%	58
Intraoperative Adverse Events					
Interface debris	9/183	4.9%	13/358	3.6%	14
Procedure interruption due to seizure	1/183	0.5%	2/358	0.6%	2
Postoperative Adverse Events					
Diffuse lamellar keratitis (Grade 2 or less)	6/183	3.3%	6/358	1.7%	6
Clinical signs and subjective symptoms reported by the patient consistent with dry eye	5/183	2.7%	6/358	1.7%	9
Corneal striae	3/183	1.6%	4/358	1.1%	4
Epithelium in the interface	3/183	1.6%	4/358	1.1%	4
Corneal abrasion	2/183	1.1%	2/358	0.6%	2
Conjunctivitis, allergic	1/183	0.5%	2/358	0.6%	2
Corneal edema between 1 week and 1 month after the procedure	1/183	0.5%	2/358	0.6%	2
Posterior Vitreous Detachment (PVD)	1/183	0.5%	2/358	0.6%	2
Vitreous syneresis	1/183	0.5%	2/358	0.6%	2
Anterior uveitis	1/183	0.5%	1/358	0.3%	1
Corneal edema at 1 month or later	1/183	0.5%	1/358	0.3%	1
Decrease in BCDVA ≥ 10 letters not due to irregular astigmatism at ≥ 3 months	1/183	0.5%	1/358	0.3%	1
Epithelial defect	1/183	0.5%	1/358	0.3%	1
Irregular flap margin	1/183	0.5%	1/358	0.3%	1
Loss of BCDVA	1/183	0.5%	1/358	0.3%	1
Serious Adverse Events					
Retinal detachment	1/183	0.5%	1/358	0.3%	1
Seizure	1/183	0.5%	1/358	0.3%	1
Secondary Surgical Interventions					
Scleral buckle	1/183	0.5%	1/358	0.3%	1

AEs are sorted by descending frequency of events.
Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated, 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

Table 7.2. Adverse Events (AEs) for All Hyperopic Eyes

	Subjects with 1 or More AE		Eyes with 1 or More AE		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
One or More of Any Adverse Event	16/117	13.7%	23/221	10.4%	32
Intraoperative Adverse Events					
Flap tear	1/117	0.9%	1/221	0.5%	1
Free cap	1/117	0.9%	1/221	0.5%	1
Hinge tissue ablated	1/117	0.9%	1/221	0.5%	1
Interface debris	1/117	0.9%	1/221	0.5%	1
Postoperative Adverse Events					
Clinical signs and subjective symptoms reported by the patient consistent with dry eye	5/117	4.3%	9/221	4.1%	9
Epithelium in the interface	3/117	2.6%	4/221	1.8%	5
Conjunctivitis, viral	1/117	0.9%	2/221	0.9%	2
Epithelium in the interface with loss of 10 letters or more of BCDVA	1/117	0.9%	1/221	0.5%	2
Transient light sensitivity syndrome (TLSS)	1/117	0.9%	2/221	0.9%	2
Chemical splash in eye	1/117	0.9%	1/221	0.5%	1
Conjunctival laceration	1/117	0.9%	1/221	0.5%	1
Conjunctivitis, allergic	1/117	0.9%	1/221	0.5%	1
Corneal abrasion	1/117	0.9%	1/221	0.5%	1
Foreign body sensation	1/117	0.9%	1/221	0.5%	1
Metallic foreign body	1/117	0.9%	1/221	0.5%	1
Serious Adverse Events					
Melting of the flap	1/117	0.9%	1/221	0.5%	1
Secondary Surgical Interventions					
Epithelial ingrowth removal	1/117	0.9%	1/221	0.5%	1

AEs are sorted by descending frequency of events.
Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated, 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

Table 7.3. Adverse Events (AEs) for All Mixed Astigmatism Eyes

	Subjects with 1 or More AE		Eyes with 1 or More AE		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
One or More of Any Adverse Event	11/77	14.3%	15/135	11.1%	16
Intraoperative Adverse Events					
Flap is not of the size and shape as initially intended	1/77	1.3%	1/135	0.7%	1
Flap misaligned	1/77	1.3%	1/135	0.7%	1
Treatment was on wrong Axis for OS	1/77	1.3%	1/135	0.7%	1
Postoperative Adverse Events					
Clinical signs and subjective symptoms reported by the patient consistent with dry eye	3/77	3.9%	5/135	3.7%	5
Corneal edema between 1 week and 1 month after the procedure	1/77	1.3%	2/135	1.5%	2
MGD (Meibomian Gland Dysfunction)	1/77	1.3%	2/135	1.5%	2
Corneal dryness	1/77	1.3%	1/135	0.7%	1
Foreign body	1/77	1.3%	1/135	0.7%	1
IOP increase of > 10 mmHg above baseline on 2 consec. exams or IOP > 30 mmHg on 2 consec. exams	1/77	1.3%	1/135	0.7%	1
Secondary Surgical Interventions					
Retreatment	1/77	1.3%	1/135	0.7%	1

AEs are sorted by descending frequency of events.

Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated, 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

Patient Reported Outcomes for Symptoms

The Patient Reported Outcomes (PRO) instrument used in the IDE clinical study consisted of the Patient Reported Outcomes with LASIK (PROWL) questionnaire with accompanying photographs, and 2 of the 3 domains of the OSDI. Study subjects self-administered the PRO instrument directly to reduce the potential for bias from an interviewer. Results from the PROWL questionnaire are summarized in **Table 8** and results stratified by treatment cohort are presented in **Table 8.1**. A greater proportion of subjects experienced resolution of a symptom or symptoms postoperatively than the proportion of subjects who developed symptoms postoperatively. Similarly, the report of "very" or "extreme" difficulty or bothersomeness with symptoms decreased postoperatively.

Table 8. PROWL Visual Symptoms for All Subjects in Safety Population

Symptom		PreOp		Month 3		Month 6		Month 9			
Information		n/N (%)		n/N (%)		n/N (%)		n/N (%)		n/N (%)	
Symptom Prevalence[1]											
	Any type of symptom	252/358	(70.4%)	164/341	(48.1%)	140/341	(41.1%)	120/331	(36.3%)	130/338	(38.5%)
	Double images	117/358	(32.7%)	17/341	(5.0%)	28/341	(8.2%)	17/331	(5.1%)	18/338	(5.3%)
	Glare	140/358	(39.1%)	56/341	(16.4%)	47/341	(13.8%)	38/331	(11.5%)	46/338	(13.6%)
	Halos	156/358	(43.6%)	101/341	(29.6%)	84/341	(24.6%)	74/331	(22.4%)	79/338	(23.4%)
	Starbursts	200/358	(55.9%)	134/341	(39.3%)	114/341	(33.4%)	101/331	(30.5%)	107/338	(31.7%)
Symptom Development[1,2]											
	Any type of symptom			74/288	(25.7%)	65/289	(22.5%)	52/281	(18.5%)	56/286	(19.6%)
	Double images			6/229	(2.6%)	10/231	(4.3%)	6/228	(2.6%)	3/230	(1.3%)
	Glare			20/208	(9.6%)	17/210	(8.1%)	14/203	(6.9%)	16/206	(7.8%)
	Halos			42/193	(21.8%)	36/195	(18.5%)	26/187	(13.9%)	29/189	(15.3%)
	Starbursts			43/151	(28.5%)	29/149	(19.5%)	31/147	(21.1%)	32/148	(21.6%)
Symptom Resolution											
	Any type of symptom			201/240	(83.8%)	196/238	(82.4%)	195/230	(84.8%)	199/237	(84.0%)
	Double images			101/112	(90.2%)	92/110	(83.6%)	92/103	(89.3%)	93/108	(86.1%)
	Glare			97/133	(72.9%)	101/131	(77.1%)	104/128	(81.3%)	102/132	(77.3%)
	Halos			89/148	(60.1%)	98/146	(67.1%)	96/144	(66.7%)	99/149	(66.4%)
	Starbursts			99/190	(52.1%)	107/192	(55.7%)	114/184	(62.0%)	115/190	(60.5%)
Any reported difficulty performing activities due to symptoms											
	Any type of symptom	159/358	(44.4%)	97/341	(28.4%)	85/341	(24.9%)	68/331	(20.5%)	74/338	(21.9%)
	Double images	73/358	(20.4%)	13/341	(3.8%)	16/341	(4.7%)	10/331	(3.0%)	14/338	(4.1%)
	Glare	94/358	(26.3%)	35/341	(10.3%)	27/341	(7.9%)	22/331	(6.6%)	23/338	(6.8%)
	Halos	87/358	(24.3%)	54/341	(15.8%)	40/341	(11.7%)	39/331	(11.8%)	42/338	(12.4%)
	Starbursts	121/358	(33.8%)	73/341	(21.4%)	64/341	(18.8%)	52/331	(15.7%)	60/338	(17.8%)
Very or extreme difficulty performing activities due to symptoms											
	Any type of symptom	35/358	(9.8%)	3/341	(0.9%)	7/341	(2.1%)	2/331	(0.6%)	2/338	(0.6%)
	Double images	15/358	(4.2%)	1/341	(0.3%)	3/341	(0.9%)	0/331		0/338	
	Glare	16/358	(4.5%)	1/341	(0.3%)	0/341		0/331		0/338	
	Halos	9/358	(2.5%)	1/341	(0.3%)	2/341	(0.6%)	0/331		1/338	(0.3%)
	Starbursts	18/358	(5.0%)	3/341	(0.9%)	3/341	(0.9%)	2/331	(0.6%)	2/338	(0.6%)
Any Reported bothersome Symptoms											
	Any type of Symptom	204/358	(57.0%)	122/341	(35.8%)	112/341	(32.8%)	92/331	(27.8%)	97/338	(28.7%)
	Double Images	81/358	(22.6%)	15/341	(4.4%)	24/341	(7.0%)	15/331	(4.5%)	16/338	(4.7%)
	Glare	117/358	(32.7%)	46/341	(13.5%)	40/341	(11.7%)	29/331	(8.8%)	35/338	(10.4%)
	Halos	112/358	(31.3%)	68/341	(19.9%)	63/341	(18.5%)	55/331	(16.6%)	57/338	(16.9%)
	Starbursts	162/358	(45.3%)	100/341	(29.3%)	86/341	(25.2%)	73/331	(22.1%)	86/338	(25.4%)
Very or extremely bothersome symptoms											
	Any type of Symptom	70/358	(19.6%)	12/341	(3.5%)	10/341	(2.9%)	12/331	(3.6%)	12/338	(3.6%)
	Double Images	29/358	(8.1%)	3/341	(0.9%)	4/341	(1.2%)	5/331	(1.5%)	4/338	(1.2%)
	Glare	29/358	(8.1%)	2/341	(0.6%)	1/341	(0.3%)	2/331	(0.6%)	0/338	
	Halos	21/358	(5.9%)	4/341	(1.2%)	3/341	(0.9%)	3/331	(0.9%)	4/338	(1.2%)
	Starbursts	53/358	(14.8%)	8/341	(2.3%)	6/341	(1.8%)	6/331	(1.8%)	7/338	(2.1%)

[1] The symptom was considered present if it was experienced either with or without optical correction

[2] Analysis includes only patients with no symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit.

Table 8.1. PROWL Visual Symptoms at Month 6
Stratified by Treatment Cohort for All Subjects in Safety Population

Symptom Information		Myopia Cohort		Hyperopia Cohort		Mixed Astigmatism		Total	
		n/N	(%)	n/N	(%)	n/N	(%)	n/N	(%)
Symptom Prevalence[1]									
	Any type of Symptom	54/174	(31.0%)	57/110	(51.8%)	36/76	(47.4%)	140/341	(41.1%)
	Double Images	6/174	(3.4%)	17/110	(15.5%)	6/76	(7.9%)	28/341	(8.2%)
	Glare	24/174	(13.8%)	15/110	(13.6%)	9/76	(11.8%)	47/341	(13.8%)
	Halos	33/174	(19.0%)	32/110	(29.1%)	23/76	(30.3%)	84/341	(24.6%)
	Starbursts	45/174	(25.9%)	45/110	(40.9%)	28/76	(36.8%)	114/341	(33.4%)
Symptom Development[1,2b]									
	Any type of Symptom	24/153	(15.7%)	30/85	(35.3%)	14/68	(20.6%)	65/289	(22.5%)
	Double Images	4/134	(3.0%)	5/60	(8.3%)	2/51	(3.9%)	10/231	(4.3%)
	Glare	7/108	(6.5%)	7/64	(10.9%)	4/48	(8.3%)	17/210	(8.1%)
	Halos	14/103	(13.6%)	16/65	(24.6%)	8/40	(20.0%)	36/195	(18.5%)
	Starbursts	11/82	(13.4%)	13/47	(27.7%)	5/28	(17.9%)	29/149	(19.5%)
Symptom Resolution									
	Any type of Symptom	93/113	(82.3%)	68/83	(81.9%)	49/56	(87.5%)	196/238	(82.4%)
	Double Images	38/40	(95.0%)	38/50	(76.0%)	21/25	(84.0%)	92/110	(83.6%)
	Glare	49/66	(74.2%)	38/46	(82.6%)	23/28	(82.1%)	101/131	(77.1%)
	Halos	52/71	(73.2%)	29/45	(64.4%)	21/36	(58.3%)	98/146	(67.1%)
	Starbursts	58/92	(63.0%)	31/63	(49.2%)	25/48	(52.1%)	107/192	(55.7%)
Any reported difficulty performing activities due to symptoms									
	Any type of Symptom	35/174	(20.1%)	36/110	(32.7%)	18/76	(23.7%)	85/341	(24.9%)
	Double Images	5/174	(2.9%)	8/110	(7.3%)	4/76	(5.3%)	16/341	(4.7%)
	Glare	11/174	(6.3%)	11/110	(10.0%)	6/76	(7.9%)	27/341	(7.9%)
	Halos	16/174	(9.2%)	17/110	(15.5%)	9/76	(11.8%)	40/341	(11.7%)
	Starbursts	27/174	(15.5%)	27/110	(24.5%)	12/76	(15.8%)	64/341	(18.8%)
Very or extreme difficulty performing activities due to symptoms									
	Any type of Symptom	1/174	(0.6%)	4/110	(3.6%)	2/76	(2.6%)	7/341	(2.1%)
	Double Images	1/174	(0.6%)	1/110	(0.9%)	1/76	(1.3%)	3/341	(0.9%)
	Glare	0/174		0/110		0/76		0/341	
	Halos	0/174		2/110	(1.8%)	0/76		2/341	(0.6%)
	Starbursts	0/174		2/110	(1.8%)	1/76	(1.3%)	3/341	(0.9%)
Any Reported othersome Symptoms									
	Any type of Symptom	44/174	(25.3%)	49/110	(44.5%)	24/76	(31.6%)	112/341	(32.8%)
	Double Images	6/174	(3.4%)	14/110	(12.7%)	5/76	(6.6%)	24/341	(7.0%)
	Glare	19/174	(10.9%)	14/110	(12.7%)	8/76	(10.5%)	40/341	(11.7%)
	Halos	27/174	(15.5%)	25/110	(22.7%)	14/76	(18.4%)	63/341	(18.5%)
	Starbursts	36/174	(20.7%)	35/110	(31.8%)	17/76	(22.4%)	86/341	(25.2%)
Very or extremely bothersome symptoms									
	Any type of Symptom	1/174	(0.6%)	7/110	(6.4%)	3/76	(3.9%)	10/341	(2.9%)
	Double Images	1/174	(0.6%)	2/110	(1.8%)	1/76	(1.3%)	4/341	(1.2%)
	Glare	0/174		1/110	(0.9%)	0/76		1/341	(0.3%)
	Halos	0/174		3/110	(2.7%)	0/76		3/341	(0.9%)
	Starbursts	0/174		5/110	(4.5%)	2/76	(2.6%)	6/341	(1.8%)

[1]The symptom was considered present if it was experienced either with or without optical correction

[2]Analysis includes only patients with no symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit.

*Total is based on subject response; subjects with eyes in different cohorts will be represented twice.

The PROWL questionnaire includes 2 of 3 of the subscales of the Ocular Surface Disease Index (OSDI) questionnaire, "dry eye symptoms" and "environmental triggers". The PRO used in this IDE included the same 2 subscales. Study subjects were asked to grade five (5) symptoms of light sensitivity, grittiness, ocular pain or soreness, blurred vision and poor vision experienced during the week prior to the study visit. Additionally, subjects were asked to grade the impact of three (3) environmental triggers, including windy conditions, low humidity, and air-conditioned environments during the week prior to the study visit. The eight questions across the two subscales were combined to form a single score for assessment of dry eye symptoms and environmental triggers.

Each subject's dry eye symptoms and environmental trigger score (symptoms) was further categorized as normal (0-12), mild (13-22), moderate (23-32), and severe dry eye disease (33-100). The original OSDI questionnaire contains more questions (12 vs. 8), therefore, the results in this study may not reflect dry eye symptoms as well as the full OSDI questionnaire. The results in Table 9 may over- or under-estimate the true number of participants in each category. As shown in Table 9, for the full cohort of subjects, the proportion of subjects with moderate symptoms decreased from 9.2% (33/358) at baseline to 4.4% (15/341) at Month 6 and severe symptoms decreased from 7.8% (28/358) to 4.1% (14/341) at Month 6. The proportion of subjects categorized as "normal" increased from 60.6% (217/358) to 73.3% (250/341) at Month 6 and slightly improved through Month 12. Results are shown in **Table 9**.

Table 9. Ocular Surface Disease Index (OSDI) Categories for All Subjects in Safety Population

	Preoperative		**Month 3**		**Month 6**		**Month 9**		**Month 12**	
Dry Eye Symptom and Environmental Trigger Score										
Normal	217/358	(60.6%)	232/341	(68.0%)	250/341	(73.3%)	255/331	(77.0%)	269/338	(79.6%)
Mild	80/358	(22.3%)	76/341	(22.3%)	62/341	(18.2%)	54/331	(16.3%)	48/338	(14.2%)
Moderate	33/358	(9.2%)	16/341	(4.7%)	15/341	(4.4%)	12/331	(3.6%)	5/338	(1.5%)
Severe	28/358	(7.8%)	17/341	(5.0%)	14/341	(4.1%)	10/331	(3.0%)	16/338	(4.7%)

Categories for score: normal (0-12), mild (13-22), moderate (23-32), and severe dry eye disease (33-100)

2. Effectiveness Results

Primary effectiveness outcomes

The analysis of effectiveness was based on the 684 eyes of 343 evaluable patients at the 12-month time point. Key effectiveness outcomes are presented in Tables 10 to 17.1.

The effectiveness outcomes are presented for the Treated Eye Population which includes all eyes with LASIK procedure (n=714). The primary effectiveness outcomes for the study were defined in the protocol as:

- the percentage of eyes with MRSE within ± 1.00 D and ± 0.50 D of the intended refractive outcome at timepoint of refractive stability;
- the percentage of eyes with UCDVA of 0.3 logMAR or better at timepoint of refractive

stability;
- the percentage of eyes with MRCYL within ± 1.00 D and ± 0.50 D of the intended refractive outcome at timepoint of refractive stability.

Key effectiveness outcomes in terms of UDVA and MRSE are presented in **Table 10** for all treated eyes (n=714) and **Table 10.1** for eyes stratified by treatment cohort, including primary effectiveness outcomes in the shaded rows. **Table 10.1** presents data for all eyes at 6 Months, the timepoint of refractive stability, stratified by treatment cohort. Primary effectiveness outcomes in terms of MRCYL are presented in the section on "Accuracy of the astigmatic correction" in **Tables 17 and 17.1.**

Table 10. Summary of Key Effectiveness Variables for All Eyes in Treated Eye Population

	Day 1 n/N (%)	**Week 1 n/N (%)**	**Month 1 n/N (%)**	**Month 3 n/N (%)**	**Month 6 n/N (%)**	**Month 9 n/N (%)**	**Month 12 n/N (%)**
UCDVA -0.1 logMAR or better	157/712 (22.1%)	163/700 (23.3%)	205/686 (29.9%)	207/684 (30.3%)	243/684 (35.5%)	232/666 (34.8%)	259/674 (38.4%)
UCDVA 0.0 logMAR or better	379/712 (53.2%)	385/700 (55.0%)	431/686 (62.8%)	488/684 (71.3%)	488/684 (71.4%)	489/666 (73.4%)	511/674 (75.8%)
UCDVA 0.1 logMAR or better	539/712 (75.7%)	552/700 (78.9%)	587/686 (85.6%)	617/684 (90.2%)	616/684 (90.1%)	600/666 (90.1%)	616/674 (91.4%)
UCDVA 0.2 logMAR or better	641/712 (90.0%)	637/700 (91.0%)	647/686 (94.3%)	668/684 (97.7%)	663/684 (96.9%)	651/666 (97.8%)	662/674 (98.2%)
UCDVA 0.3 logMAR or better	682/712 (95.8%)	670/700 (95.7%)	669/686 (97.5%)	677/684 (99.0%)	**676/684 (98.8%)**	662/666 (99.4%)	668/674 (99.1%)
MRSE ± 0.25 D of Attempted	461/712 (64.8%)	420/700 (60.0%)	457/686 (66.6%)	496/684 (72.5%)	520/684 (76.0%)	502/666 (75.4%)	507/674 (75.2%)
MRSE ± 0.50 D of Attempted	599/712 (84.1%)	564/700 (80.6%)	590/686 (86.0%)	608/684 (88.9%)	**614/684 (89.8%)**	597/666 (89.6%)	597/674 (88.6%)
MRSE ± 1.00 D of Attempted	693/712 (97.3%)	674/700 (96.3%)	668/686 (97.4%)	674/684 (98.5%)	**670/684 (98.0%)**	655/666 (98.4%)	667/674 (99.0%)
MRSE ± 2.00 D of Attempted	708/712 (99.4%)	698/700 (99.7%)	683/686 (99.6%)	683/684 (99.9%)	684/684 (100%)	666/666 (100%)	674/674 (100%)

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Table 10.1. Summary of Key Effectiveness Variables at Month 6 Stratified by Treatment Cohort in Treated Eye Population

	Myopia Cohort n/N (%)	Hyperopia Cohort n/N (%)	Mixed Astigmatism n/N (%)	Total n/N (%)
UCDVA -0.1 logMAR or better	168/342 (49.1%)	31/210 (14.8%)	44/132 (33.3%)	243/684 (35.5%)
UCDVA 0.0 logMAR or better	295/342 (86.3%)	102/210 (48.6%)	91/132 (68.9%)	488/684 (71.4%)
UCDVA 0.1 logMAR or better	324/342 (94.7%)	175/210 (83.3%)	117/132 (88.6%)	616/684 (90.1%)
UCDVA 0.2 logMAR or better	334/342 (97.7%)	200/210 (95.2%)	129/132 (97.7%)	663/684 (96.9%)
UCDVA 0.3 logMAR or better	**338/342 (98.8%)**	**206/210 (98.1%)**	**132/132 (100%)**	**676/684 (98.8%)**
MRSE ± 0.25 D of Attempted	283/342 (82.8%)	131/210 (62.4%)	106/132 (80.3%)	520/684 (76.0%)
MRSE ± 0.50 D of Attempted	**318/342 (93.0%)**	**174/210 (82.9%)**	**122/132 (92.4%)**	**614/684 (89.8%)**
MRSE ± 1.00 D of Attempted	**338/342 (98.8%)**	**203/210 (96.7%)**	**129/132 (97.7%)**	**670/684 (98.0%)**
MRSE ± 2.00 D of Attempted	342/342 (100%)	210/210 (100%)	132/132 (100%)	684/684 (100%)

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Uncorrected Distance Visual Acuity

UCDVA outcomes over the course of the study are shown in **Table 11** for the Treated Eye population. **Table 11.1** provides the UCDVA outcomes at Month 6 stratified by treatment cohort.

Table 11. Uncorrected Visual Acuity for All Eyes in Treated Eye Population

logMAR	PreOp n (%)		Day 1 n (%)		Week 1 n (%)		Month 1 n (%)		Month 3 n (%)		Month 6 n (%)		Month 9 n (%)		Month 12 n (%)	
≤ -0.3	0	(0%)	1	(0.1%)	0	(0%)	5	(0.7%)	3	(0.4%)	2	(0.3%)	3	(0.5%)	3	(0.5%)
≤ -0.2	0	(0%)	27	(3.8%)	26	(3.7%)	59	(8.6%)	48	(7.0%)	53	(7.8%)	58	(8.7%)	60	(8.9%)
≤ -0.1	2	(0.3%)	157	(22.1%)	163	(23.3%)	205	(29.9%)	207	(30.3%)	243	(35.5%)	232	(34.8%)	259	(38.4%)
≤ 0.0	4	(0.6%)	379	(53.2%)	385	(55.0%)	431	(62.8%)	488	(71.4%)	488	(71.4%)	489	(73.4%)	511	(75.8%)
≤ +0.1	7	(1.0%)	539	(75.7%)	552	(78.9%)	587	(85.6%)	617	(90.2%)	616	(90.1%)	600	(90.1%)	616	(91.4%)
≤ +0.2	10	(1.4%)	641	(90.0%)	637	(91.0%)	647	(94.3%)	668	(97.7%)	663	(96.9%)	651	(97.8%)	662	(98.2%)
≤ +0.3	60	(8.6%)	682	(95.8%)	670	(95.7%)	669	(97.5%)	677	(99.0%)	676	(98.8%)	662	(99.4%)	668	(99.1%)
≤ +0.4	148	(21.1%)	697	(97.9%)	684	(97.7%)	680	(99.1%)	679	(99.3%)	680	(99.4%)	664	(99.7%)	671	(99.6%)
≤ +0.5	249	(35.5%)	703	(98.7%)	692	(98.9%)	683	(99.6%)	683	(99.9%)	682	(99.7%)	665	(99.9%)	673	(99.9%)
≤ +0.6	334	(47.7%)	706	(99.2%)	699	(99.9%)	685	(99.9%)	684	(100%)	684	(100%)	665	(99.9%)	674	(100%)
≤ +0.7	411	(58.6%)	711	(99.9%)	700	(100%)	686	(100%)	684	(100%)	684	(100%)	665	(99.9%)	674	(100%)
> +0.7	290	(41.4%)	1	(0.1%)	0	(0%)	0	(0%)	0	(0%)	0	(0%)	1	(0.2%)	0	(0%)
Summary Statistics																
N	701		712		700		686		684		684		666		674	
Mean (SD)	0.777 (0.407)		0.026 (0.154)		0.019 (0.151)		-0.015 (0.138)		-0.032 (0.116)		-0.035 (0.123)		-0.042 (0.118)		-0.049 (0.113)	
Median	0.640		0.000		0.000		-0.020		-0.040		-0.040		-0.060		-0.060	
Min, Max	-0.18, 1.70		-0.30, 0.82		-0.28, 0.70		-0.30, 0.70		-0.30, 0.58		-0.30, 0.60		-0.30, 0.74		-0.30, 0.60	

Table 11.1. Uncorrected Visual Acuity at Month 6
Stratified by Treatment Cohort in Treated Eye Population

logMAR		Myopia Cohort n (%)		Hyperopia Cohort n (%)		Mixed Astigmatism n (%)		Total n (%)
≤ -0.3	1	(0.3%)	0	(0%)	1	(0.8%)	2	(0.3%)
≤ -0.2	42	(12.3%)	3	(1.4%)	8	(6.1%)	53	(7.8%)
≤ -0.1	168	(49.1%)	31	(14.8%)	44	(33.3%)	243	(35.5%)
≤ 0.0	295	(86.3%)	102	(48.6%)	91	(68.9%)	488	(71.4%)
≤ +0.1	324	(94.7%)	175	(83.3%)	117	(88.6%)	616	(90.1%)
≤ +0.2	334	(97.7%)	200	(95.2%)	129	(97.7%)	663	(96.9%)
≤ +0.3	338	(98.8%)	206	(98.1%)	132	(100%)	676	(98.8%)
≤ +0.4	339	(99.1%)	209	(99.5%)	132	(100%)	680	(99.4%)
≤ +0.5	341	(99.7%)	209	(99.5%)	132	(100%)	682	(99.7%)
≤ +0.6	342	(100%)	210	(100%)	132	(100%)	684	(100%)
≤ +0.7	342	(100%)	210	(100%)	132	(100%)	684	(100%)
> +0.7	0	(0%)	0	(0%)	0	(0%)	0	(0%)
Summary Statistics								
N		342		210		132		684
Mean (SD)		-0.077 (0.116)		0.027 (0.114)		-0.026 (0.108)		-0.035 (0.123)
Median		-0.080		0.020		-0.020		-0.040
Min, Max		-0.30, 0.60		-0.24, 0.56		-0.30, 0.26		-0.30, 0.60

Postoperative UCDVA versus preoperative BCDVA

Achievement of a level of UCDVA equal to or better than preoperative BCDVA for the full cohort and stratified by treatment cohort is presented in **Table 12**. The distribution of postoperative UCDVA at Month 6 relative to preoperative BCDVA is presented in **Table 12.1.**

Table 12. Postoperative UCDVA Equal or Better than Preoperative BCDVA
for All Eyes in Treated Eye Population

	Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
All Cohort Eyes							
n/N (%)	263/712 (36.9%)	260/700 (37.1%)	334/686 (48.7%)	353/684 (51.6%)	362/684 (52.9%)	372/666 (55.9%)	399/674 (59.2%)
Myopia Cohort							
n/N (%)	175/356 (49.2%)	172/353 (48.7%)	229/340 (67.4%)	223/345 (64.6%)	230/342 (67.3%)	223/347 (64.3%)	237/348 (68.1%)
Hyperopia Cohort							
n/N (%)	54/221 (24.4%)	44/213 (20.7%)	57/219 (26.0%)	71/210 (33.8%)	68/210 (32.4%)	82/193 (42.5%)	84/199 (42.2%)
Mixed Astigmatism Cohort							
n/N (%)	34/135 (25.2%)	44/134 (32.8%)	48/127 (37.8%)	59/129 (45.7%)	64/132 (48.5%)	67/126 (53.2%)	78/127 (61.4%)

UCDVA better or equal to Preoperative BCDVA is defined as UCDVA logMAR being exactly equal to or smaller than BCDVA.

Table 12.1- Postoperative UCDVA Relative to Preoperative BCDVA for All Cohort Eyes at Month 6 in Treated Eye Population

logMAR Difference	**Myopia n/N (%)**		**Hyperopia n/N (%)**		**Mixed Astigmatism n/N (%)**		**Total n/N (%)**	
UCDVA better than BCDVA								
UCDVA 0.3 or more	0/342		0/210		0/132		0/684	
UCDVA 0.2 to 0.28	1/342	(0.3%)	1/210	(0.5%)	1/132	(0.8%)	3/684	(0.4%)
UCDVA 0.1 to 0.18	54/342	(15.8%)	19/210	(9.1%)	18/132	(13.6%)	91/684	(13.3%)
UCDVA within 4 letters of BCDVA								
UCDVA ± 0.08	246/342	(71.9%)	114/210	(54.3%)	82/132	(62.1%)	442/684	(64.6%)
UCDVA worse than BCDVA								
UCDVA 0.1 to 0.18	22/342	(6.4%)	48/210	(22.9%)	23/132	(17.4%)	93/684	(13.6%)
UCDVA 0.2 to 0.28	11/342	(3.2%)	20/210	(9.5%)	7/132	(5.3%)	38/684	(5.6%)
UCDVA 0.3 or more	8/342	(2.3%)	8/210	(3.8%)	1/132	(0.8%)	17/684	(2.5%)
UCDVA equal or better than BCDVA								
UCDVA equal or better	230/342	(67.3%)	68/210	(32.4%)	64/132	(48.5%)	362/684	(52.9%)

Stability of MRSE and MRCYL

Stability analysis was done on for the Treated Eye Population. **Table 13** presents the change in MRSE between pairwise sequential postoperative visits and the cohort of eyes that had every postoperative visit from 1 to 6 months (6-month consistent cohort). Stability of MRSE was identified at the 3- to 6-month postoperative interval and was confirmed at the subsequent 6- to 9-month interval for Treated Eye Population.

Table 13. Stability of Manifest Refraction Spherical Equivalent (MRSE) for Pairwise Sequential Visits and 6-month consistent cohort for All Eyes

		Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
Pairwise sequential visits					
Eyes within 0.5 D Change	n/N 95% CI	622/660 (94.2%) (92.2%, 95.8%)	634/660 (96.1%) (94.3%, 97.3%)	639/656 (97.4%) (95.9%, 98.4%)	650/660 (98.5%) (97.2%, 99.2%)
Eyes within 1.0 D Change	n/N 95% CI	654/660 (99.1%) (98.0%, 99.6%)	656/660 (99.4%) (98.5%, 99.8%)	655/656 (99.9%) (99.1%, 100.0%)	660/660 (100%) (99.4%, 100%)
Change between Visits	N	660	660	656	660
	Mean (SD)	0.035 (0.289)	0.023 (0.259)	-0.014 (0.221)	0.024 (0.182)
	95% CI	0.013, 0.057	0.003, 0.043	-0.032, 0.003	0.010, 0.038
Change per Month	N	660	660	656	660
	Mean (SD)	0.018 (0.145)	0.008 (0.086)	-0.005 (0.074)	0.008 (0.061)
	95% CI	0.007, 0.029	0.001, 0.014	-0.011, 0.001	0.003, 0.013
Change per Year	N	660	660	656	660
	Mean (SD)	0.211 (1.735)	0.092 (1.034)	-0.058 (0.886)	0.096 (0.729)
	95% CI	0.079, 0.344	0.013, 0.172	-0.126, 0.010	0.041, 0.152
6-month Consistent Cohort					
Eyes within 0.5 D Change	n/N 95% CI	603/638 (94.5%) (92.5%, 96.0%)	612/638 (95.9%) (94.1%, 97.2%)	601/618 (97.3%) (95.6%, 98.3%)	608/618 (98.4%) (97.0%, 99.1%)
Eyes within 1.0 D Change	n/N 95% CI	633/638 (99.2%) (98.2%, 99.7%)	634/638 (99.4%) (98.4%, 99.8%)	617/618 (99.8%) (99.1%, 100.0%)	618/618 (100%) (99.4%, 100%)
Change between Visits	N	638	638	618	618
	Mean (SD)	0.032 (0.284)	0.023 (0.262)	-0.015 (0.226)	0.022 (0.185)
	95% CI	0.010, 0.054	0.003, 0.044	-0.033, 0.003	0.007, 0.036
Change per Month	N	638	638	618	618
	Mean (SD)	0.016 (0.142)	0.008 (0.087)	-0.005 (0.075)	0.007 (0.062)
	95% CI	0.005, 0.027	0.001, 0.015	-0.011, 0.001	0.002, 0.012
Change per Year	N	638	638	618	618
	Mean (SD)	0.192 (1.704)	0.093 (1.049)	-0.060 (0.903)	0.087 (0.742)
	95% CI	0.059, 0.324	0.012, 0.175	-0.131, 0.011	0.028, 0.145

A Wilson confidence interval, which ignores dependence between eyes, is provided for responder endpoints. The confidence intervals are provided according to ANSI Z80.11.

Results for the myopia and mixed astigmatism cohorts essentially mirror those for the full study cohort, with the point of refractive stability identified at the 3- to 6-month postoperative interval and confirmed at the subsequent 6- to 9-month interval. The mean rates of MRSE changes observed from Month 3 and later are very close to zero, indicating essentially no change in MRSE across all postoperative visits for these cohorts. The point estimates for the hyperopia cohort show a greater rate of mean MRSE change in the early postoperative interval (0.072 D between Month 1 and 3), lowering to 0.024 D between Month 3 and 6, consistent with typical healing after hyperopic treatment.

The change in MRCYL between consecutive visits is presented in **Table 14** for the pairwise sequential visits as well as for eyes with available data at every postoperative visit from Month 1 to Month 6 (6-month consistent cohort).

Table 14. Stability of Manifest Refraction Cylinder for Pairwise Sequential Visits and 6-month consistent cohort for All Eyes Treated with Astigmatism

		Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
Pairwise sequential visits					
Eyes within 0.5 D Change	n/N 95% CI	511/519 (98.5%) (97.0%, 99.2%)	508/519 (97.9%) (96.2%, 98.8%)	508/519 (97.9%) (96.2%, 98.8%)	510/523 (97.5%) (95.8%, 98.5%)
Eyes within 1.0 D Change	n/N 95% CI	518/519 (99.8%) (98.9%, 100.0%)	516/519 (99.4%) (98.3%, 99.8%)	518/519 (99.8%) (98.9%, 100.0%)	523/523 (100%) (99.3%, 100%)
Change between Visits	N	519	519	519	523
	Mean (SD)	0.020 (0.227)	-0.008 (0.227)	-0.008 (0.230)	0.000 (0.197)
	95% CI	0.001, 0.040	-0.027, 0.012	-0.028, 0.012	-0.017, 0.016
Change per Month	N	519	519	519	523
	Mean (SD)	0.010 (0.114)	-0.003 (0.076)	-0.003 (0.077)	0.000 (0.066)
	95% CI	0.000, 0.020	-0.009, 0.004	-0.009, 0.004	-0.006, 0.006
Change per Year	N	519	519	519	523
	Mean (SD)	0.121 (1.364)	-0.031 (0.908)	-0.031 (0.921)	-0.002 (0.787)
	95% CI	0.004, 0.239	-0.109, 0.048	-0.110, 0.049	-0.070, 0.066
6-month Consistent cohort					
Eyes within 0.5 D Change	n/N 95% CI	492/499 (98.6%) (97.1%, 99.3%)	488/499 (97.8%) (96.1%, 98.8%)	473/484 (97.7%) (96.0%, 98.7%)	467/480 (97.3%) (95.4%, 98.4%)
Eyes within 1.0 D Change	n/N 95% CI	499/499 (100%) (99.2%, 100%)	496/499 (99.4%) (98.2%, 99.8%)	483/484 (99.8%) (98.8%, 100.0%)	480/480 (100%) (99.2%, 100%)
Change between Visits	N	499	499	484	480
	Mean (SD)	0.026 (0.223)	-0.007 (0.229)	-0.011 (0.236)	0.001 (0.200)
	95% CI	0.007, 0.046	-0.027, 0.014	-0.032, 0.010	-0.017, 0.019
Change per Month	N	499	499	484	480
	Mean (SD)	0.013 (0.111)	-0.002 (0.076)	-0.004 (0.079)	0.000 (0.067)
	95% CI	0.003, 0.023	-0.009, 0.005	-0.011, 0.003	-0.006, 0.006
Change per Year	N	499	499	484	480
	Mean (SD)	0.156 (1.335)	-0.026 (0.917)	-0.045 (0.942)	0.004 (0.802)
	95% CI	0.039, 0.274	-0.107, 0.055	-0.130, 0.039	-0.068, 0.076

A Wilson confidence interval, which ignores dependence between eyes, is provided for responder endpoints. The confidence intervals are provided according to ANSI Z80.11.

Results for the myopia cohort essentially mirror those for the full study cohort, with the point of refractive stability identified at the 3- to 6-month postoperative interval and confirmed at the subsequent 6- to 9-month interval. Both the hyperopia and mixed astigmatism cohorts show stability of MRCYL identified at the 1- to 3-month postoperative interval and confirmed at the subsequent 3- to 6-month interval. The mean rates of MRCYL changes observed from 3 months and later are very close to zero, indicating essentially no change in MRCYL across all postoperative visits for all cohorts. The 95% confidence interval of the mean change in MRCYL between visits included zero for all visit intervals from Month 3 through Month 12. The proportion of eyes with a change in MRCYL between visits within ±1.00 D was at least 99.6%, 98.7% and 99.2% for the myopia, hyperopia and mixed astigmatism cohorts, respectively, for all intervals.

Key Effectiveness Outcomes Stratified by Preoperative MRSE

Tables 15.1 through 15.3 show stratification of the key effectiveness outcomes by preoperative MRSE for each treatment cohort.

Table 15.1. Summary of Key Effectiveness Variables at Month 6 for All Myopic Eyes in Treated Eye Population Stratified by Preoperative MRSE (D)

	-11.00 to -10.00 n/N (%)	**-9.99 to -9.00 n/N (%)**	**-8.99 to -8.00 n/N (%)**	**-7.99 to -7.00 n/N (%)**	**-6.99 to -6.00 n/N (%)**	**-5.99 to -5.00 n/N (%)**
UCDVA -0.1 logMAR or better	2/13 (15.4%)	9/29 (31.0%)	6/25 (24.0%)	8/23 (34.8%)	26/44 (59.1%)	18/44 (40.9%)
UCDVA 0.0 logMAR or better	8/13 (61.5%)	24/29 (82.8%)	19/25 (76.0%)	16/23 (69.6%)	37/44 (84.1%)	37/44 (84.1%)
UCDVA 0.1 logMAR or better	11/13 (84.6%)	28/29 (96.6%)	22/25 (88.0%)	21/23 (91.3%)	39/44 (88.6%)	43/44 (97.7%)
UCDVA 0.2 logMAR or better	12/13 (92.3%)	29/29 (100%)	23/25 (92.0%)	23/23 (100%)	41/44 (93.2%)	43/44 (97.7%)
UCDVA 0.3 logMAR or better	13/13 (100%)	29/29 (100%)	24/25 (96.0%)	23/23 (100%)	42/44 (95.5%)	43/44 (97.7%)
MRSE ± 0.25 D of Attempted	9/13 (69.2%)	22/29 (75.9%)	17/25 (68.0%)	19/23 (82.6%)	35/44 (79.6%)	39/44 (88.6%)
MRSE ± 0.50 D of Attempted	11/13 (84.6%)	26/29 (89.7%)	19/25 (76.0%)	22/23 (95.7%)	41/44 (93.2%)	41/44 (93.2%)
MRSE ± 1.00 D of Attempted	13/13 (100%)	28/29 (96.6%)	24/25 (96.0%)	23/23 (100%)	43/44 (97.7%)	44/44 (100%)
MRSE ± 2.00 D of Attempted	13/13 (100%)	29/29 (100%)	25/25 (100%)	23/23 (100%)	44/44 (100%)	44/44 (100%)

	-4.99 to -4.00 n/N (%)	**-3.99 to -3.00 n/N (%)**	**-2.99 to -2.00 n/N (%)**	**-1.99 to -1.00 n/N (%)**	**-0.99 to 0.00 n/N (%)**	**Total n/N (%)**
UCDVA -0.1 logMAR or better	25/42 (59.5%)	17/32 (53.1%)	32/48 (66.7%)	22/36 (61.1%)	3/6 (50.0%)	168/342 (49.1%)
UCDVA 0.0 logMAR or better	40/42 (95.2%)	30/32 (93.8%)	45/48 (93.8%)	33/36 (91.7%)	6/6 (100%)	295/342 (86.3%)
UCDVA 0.1 logMAR or better	41/42 (97.6%)	31/32 (96.9%)	48/48 (100%)	34/36 (94.4%)	6/6 (100%)	324/342 (94.7%)
UCDVA 0.2 logMAR or better	42/42 (100%)	31/32 (96.9%)	48/48 (100%)	36/36 (100%)	6/6 (100%)	334/342 (97.7%)
UCDVA 0.3 logMAR or better	42/42 (100%)	32/32 (100%)	48/48 (100%)	36/36 (100%)	6/6 (100%)	338/342 (98.8%)
MRSE ± 0.25 D of Attempted	38/42 (90.5%)	26/32 (81.3%)	42/48 (87.5%)	30/36 (83.3%)	6/6 (100%)	283/342 (82.8%)
MRSE ± 0.50 D of Attempted	41/42 (97.6%)	31/32 (96.9%)	48/48 (100%)	32/36 (88.9%)	6/6 (100%)	318/342 (93.0%)
MRSE ± 1.00 D of Attempted	41/42 (97.6%)	32/32 (100%)	48/48 (100%)	36/36 (100%)	6/6 (100%)	338/342 (98.8%)
MRSE ± 2.00 D of Attempted	42/42 (100%)	32/32 (100%)	48/48 (100%)	36/36 (100%)	6/6 (100%)	342/342 (100%)

Shaded cells: Treatment of -10.00 through -11.00 D MRSE will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

Table 15.2. Summary of Key Effectiveness Variables at Month 6 for All Hyperopic Eyes in Treated Eye Population Stratified by Preoperative MRSE (D)

	+0.01 to +1.00 n/N (%)	+1.01 to +2.00 n/N (%)	+2.01 to +3.00 n/N (%)	+3.01 to +4.00 n/N (%)	+4.01 to +5.00 n/N (%)	Total n/N (%)
UCDVA -0.1 logMAR or better	12/25 (48.0%)	14/59 (23.7%)	3/57 (5.3%)	1/44 (2.3%)	1/25 (4.0%)	31/210 (14.8%)
UCDVA 0.0 logMAR or better	22/25 (88.0%)	41/59 (69.5%)	19/57 (33.3%)	12/44 (27.3%)	8/25 (32.0%)	102/210 (48.6%)
UCDVA 0.1 logMAR or better	25/25 (100%)	54/59 (91.5%)	47/57 (82.5%)	32/44 (72.7%)	17/25 (68.0%)	175/210 (83.3%)
UCDVA 0.2 logMAR or better	25/25 (100%)	57/59 (96.6%)	54/57 (94.7%)	41/44 (93.2%)	23/25 (92.0%)	200/210 (95.2%)
UCDVA 0.3 logMAR or better	25/25 (100%)	58/59 (98.3%)	56/57 (98.3%)	44/44 (100%)	23/25 (92.0%)	206/210 (98.1%)
MRSE ± 0.25 D of Attempted	22/25 (88.0%)	42/59 (71.2%)	31/57 (54.4%)	21/44 (47.7%)	15/25 (60.0%)	131/210 (62.4%)
MRSE ± 0.50 D of Attempted	24/25 (96.0%)	53/59 (89.8%)	43/57 (75.4%)	34/44 (77.3%)	20/25 (80.0%)	174/210 (82.9%)
MRSE ± 1.00 D of Attempted	25/25 (100%)	59/59 (100%)	54/57 (94.7%)	40/44 (90.9%)	25/25 (100%)	203/210 (96.7%)
MRSE ± 2.00 D of Attempted	25/25 (100%)	59/59 (100%)	57/57 (100%)	44/44 (100%)	25/25 (100%)	210/210 (100%)

Table 15.3. Summary of Key Effectiveness Variables at Month 6 for All Mixed Astigmatism Eyes in Treated Eye Population Stratified by Preoperative MRSE (D)

	-1.00 to -2.00 n/N (%)	0.00 to -0.99 n/N (%)	+0.01 to +0.99 n/N (%)	+1.00 to +2.00 n/N (%)	Total n/N (%)
UCDVA -0.1 logMAR or better	5/17 (29.4%)	31/63 (49.2%)	7/36 (19.4%)	1/16 (6.3%)	44/132 (33.3%)
UCDVA 0.0 logMAR or better	8/17 (47.1%)	53/63 (84.1%)	20/36 (55.6%)	10/16 (62.5%)	91/132 (68.9%)
UCDVA 0.1 logMAR or better	11/17 (64.7%)	59/63 (93.7%)	34/36 (94.4%)	13/16 (81.3%)	117/132 (88.6%)
UCDVA 0.2 logMAR or better	17/17 (100%)	63/63 (100%)	34/36 (94.4%)	15/16 (93.8%)	129/132 (97.7%)
UCDVA 0.3 logMAR or better	17/17 (100%)	63/63 (100%)	36/36 (100%)	16/16 (100%)	132/132 (100%)
MRSE ± 0.25 D of Attempted	13/17 (76.5%)	54/63 (85.7%)	25/36 (69.4%)	14/16 (87.5%)	106/132 (80.3%)
MRSE ± 0.50 D of Attempted	16/17 (94.1%)	58/63 (92.1%)	33/36 (91.7%)	15/16 (93.8%)	122/132 (92.4%)
MRSE ± 1.00 D of Attempted	17/17 (100%)	62/63 (98.4%)	35/36 (97.2%)	15/16 (93.8%)	129/132 (97.7%)
MRSE ± 2.00 D of Attempted	17/17 (100%)	63/63 (100%)	36/36 (100%)	16/16 (100%)	132/132 (100%)

Accuracy of MRSE and MRCYL

Accuracy of the intended refractive correction for the Treated Eye population is shown in **Table 16**; and **Table 16.1** provides the MRSE accuracy outcomes at Month 6 stratified by treatment cohort.

Table 16. Accuracy of MRSE - Attempted vs Achieved for All Eyes in Treated Eye Population

MRSE Deviation	PreOp n (%)		Day 1 n (%)		Week 1 n (%)		Month 1 n (%)		Month 3 n (%)		Month 6 n (%)		Month 9 n (%)		Month 12 n (%)	
N	714		712		700		686		684		684		666		674	
Mean (SD)	-1.820 (4.006)		-0.167 (0.429)		-0.237 (0.442)		-0.193 (0.407)		-0.153 (0.350)		-0.128 (0.329)		-0.141 (0.316)		-0.114 (0.321)	
Median	-1.125		0.000		-0.125		-0.125		0.000		0.000		0.000		0.000	
Min, Max	-10.75, 5.00		-2.50, 0.88		-2.63, 1.00		-2.88, 1.00		-2.50, 1.25		-1.63, 1.50		-1.75, 1.25		-1.75, 1.25	
± 0.25 D			461	(64.8%)	420	(60.0%)	457	(66.6%)	496	(72.5%)	520	(76.0%)	502	(75.4%)	507	(75.2%)
± 0.50 D			599	(84.1%)	564	(80.6%)	590	(86.0%)	608	(88.9%)	**614**	**(89.8%)**	597	(89.6%)	597	(88.6%)
± 1.00 D			693	(97.3%)	674	(96.3%)	668	(97.4%)	674	(98.5%)	**670**	**(98.0%)**	655	(98.4%)	667	(99.0%)
± 2.00 D			708	(99.4%)	698	(99.7%)	683	(99.6%)	683	(99.9%)	684	(100%)	666	(100%)	674	(100%)
Overcorrected > 1.00 D			15	(2.1%)	22	(3.1%)	17	(2.5%)	9	(1.3%)	9	(1.3%)	5	(0.8%)	2	(0.3%)
Overcorrected > 2.00 D			3	(0.4%)	2	(0.3%)	3	(0.4%)	1	(0.2%)	0	(0%)	0	(0%)	0	(0%)
Undercorrected > 1.00 D			4	(0.6%)	4	(0.6%)	1	(0.2%)	1	(0.2%)	5	(0.7%)	6	(0.9%)	5	(0.7%)
Undercorrected > 2.00 D			1	(0.1%)	0	(0%)	0	(0%)	0	(0%)	0	(0%)	0	(0%)	0	(0%)

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Table 16.1. Accuracy of MRSE -- Attempted vs Achieved at Month 6 Stratified by Treatment Cohort in Treated Eye Population

MRSE Deviation	Myopia Cohort n (%)	Hyperopia Cohort n (%)	Mixed Astigmatism n (%)	Total n (%)
± 0.25 D	283 (82.8%)	131 (62.4%)	106 (80.3%)	520 (76.0%)
± 0.50 D	**318 (93.0%)**	**174 (82.9%)**	**122 (92.4%)**	**614 (89.8%)**
± 1.00 D	**338 (98.8%)**	**203 (96.7%)**	**129 (97.7%)**	**670 (97.9%)**
± 2.00 D	342 (100%)	210 (100%)	132 (100%)	684 (100%)
Overcorrected > 1.00 D	1 (0.3%)	6 (2.9%)	2 (1.5%)	9 (1.3%)
Overcorrected > 2.00 D	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Undercorrected > 1.00 D	3 (0.9%)	1 (0.5%)	1 (0.8%)	5 (0.7%)
Undercorrected > 2.00 D	0 (0%)	0 (0%)	0 (0%)	0 (0%)
N	342	210	132	684
Mean (SD)	-0.090 (0.283)	-0.199 (0.404)	-0.113 (0.291)	-0.127 (0.324)
Median	0.000	-0.125	0.000	0.000
Min, Max	-1.38, 1.50	-1.63, 1.50	-1.13, 0.50	-1.63, 1.50

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Figure 2 shows the linear correlation between the attempted and the achieved MRSE for the Treated Eye Population at the point of stability (i.e. Month 6). For the full cohort, the slope of the correlation is 1.01, the intercept is 0.145 D and the relationship is highly correlated at R2 = 0.99, showing the high accuracy of the MRSE correction.

Figure 2 Attempted versus Achieved MRSE at the Point of Stability (6 Months) for All Eyes in Treated Eye Population

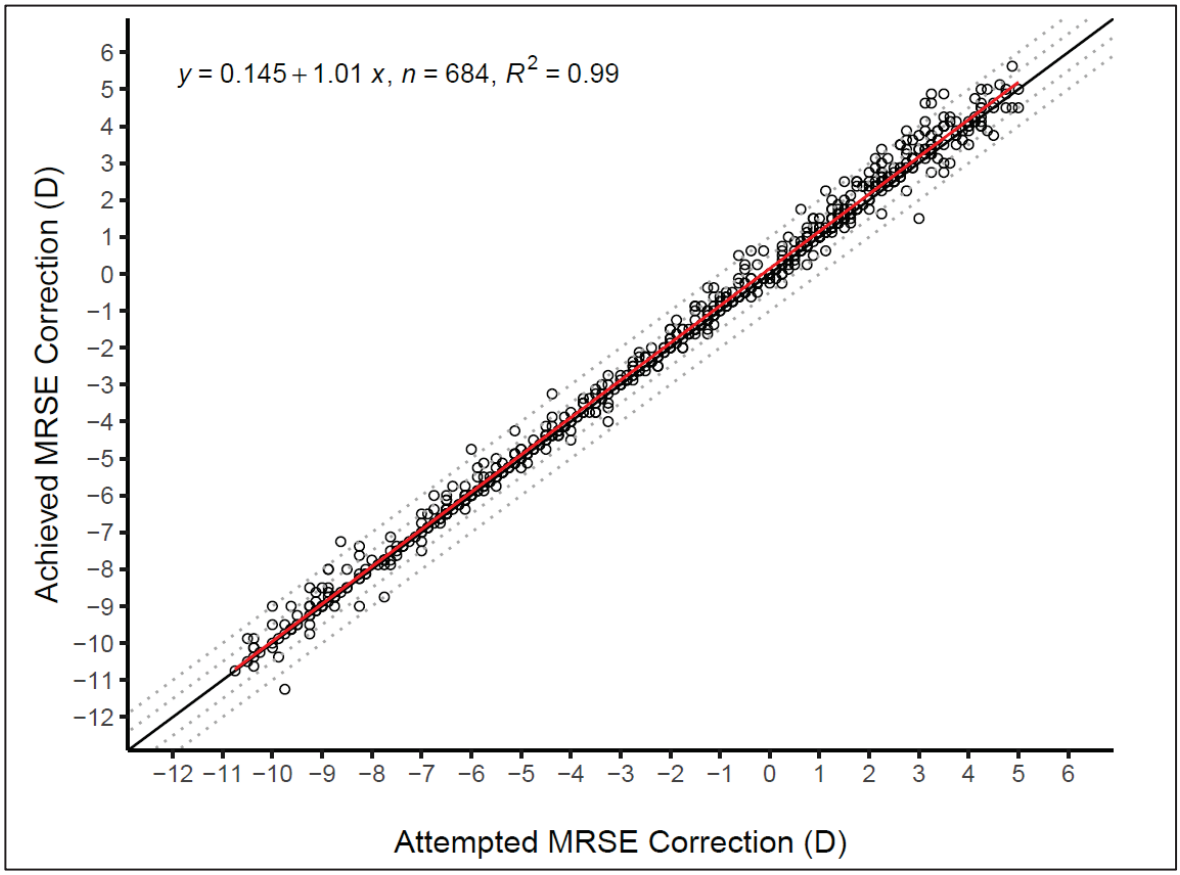

Table 17 summarizes three parameters for the MRCYL correction outcomes; deviation from target in terms of mean MRCYL and percent reduction in MRCYL. **Table 17.1** provides the MRCYL outcomes stratified by treatment cohort at Month 6.

Table 17. Deviation from Targeted Cylinder Correction and Percent Reduction in MRCYL for Eyes Treated for Astigmatism in Treated Eyes Population

	PreOp	Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
Within ± 0.25 D	55 (9.8%)	410 (73.0%)	384 (69.6%)	384 (71.2%)	397 (73.5%)	397 (73.8%)	381 (72.4%)	394 (73.9%)
Within ± 0.50 D	118 (20.9%)	503 (89.5%)	477 (86.4%)	483 (89.6%)	486 (90.0%)	477 (88.7%)	468 (89.0%)	478 (89.7%)
Within ± 1.00 D	254 (45.0%)	554 (98.6%)	538 (97.5%)	526 (97.6%)	527 (97.6%)	526 (97.8%)	514 (97.7%)	517 (97.0%)
Absolute Deviation from Target (D):								
N	564	562	552	539	540	538	526	533
Mean (SD)	-1.646 (1.133)	-0.210 (0.315)	-0.264 (0.418)	-0.246 (0.402)	-0.214 (0.320)	-0.215 (0.335)	-0.221 (0.333)	-0.216 (0.332)
Median	-1.250	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Min, Max	-4.00, -0.25	-2.00, 0.00	-5.50, 0.00	-5.50, 0.00	-2.00, 0.00	-2.00, 0.00	-2.00, 0.00	-2.00, 0.00
Percent Reduction in MRCYL (D):								
N		562	552	539	540	538	526	533
Mean (SD)		-82.0 (37.8)	-77.2 (47.1)	-78.9 (42.6)	-81.5 (42.5)	-81.0 (45.0)	-78.7 (46.2)	-79.8 (45.0)
Median		-100.0	-100.0	-100.0	-100.0	-100.0	-100.0	-100.0

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Table 17.1. Deviation from Targeted Cylinder Correction and Percent Reduction in MRCYL at Month 6 Stratified by Treatment Cohort for Eyes Treated for Astigmatism in Treated Eyes Population

	Myopia Cohort	Hyperopia Cohort	Mixed Astigmatism	Total
Within ± 0.25 D	206 (81.7%)	102 (66.2%)	89 (67.4%)	397 (73.8%)
Within ± 0.50 D	**234 (92.9%)**	**130 (84.4%)**	**113 (85.6%)**	**477 (88.7%)**
Within ± 1.00 D	**249 (98.8%)**	**149 (96.8%)**	**128 (97.0%)**	**526 (97.8%)**
Absolute Deviation from Target (D):				
N	252	154	132	538
Mean (SD)	-0.154 (0.270)	-0.281 (0.368)	-0.256 (0.384)	-0.215 (0.335)
Median	0.000	-0.125	0.000	0.000
Min, Max	-1.50, 0.00	-2.00, 0.00	-1.75, 0.00	-2.00, 0.00
Percent Reduction in MRCYL (D):				
N	252	154	132	538
Mean (SD)	-85.3 (33.5)	-65.0 (68.9)	-91.4 (12.7)	-81.0 (45.0)
Median	-100.0	-96.7	-100.0	-100.0

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Effectiveness of the low astigmatic correction

The effectiveness of low MRCYL correction in myopic and hyperopic eyes with the MEL90 device was evaluated by comparing eyes with ≤ 0.50 D MRCYL treated with a low cylinder correction versus treated with a spherical correction. Eyes with MRCYL confirmed by objective measurement were treated with a low cylinder correction (confirmed cylinder). Eyes with MRCYL that was not confirmed by objective measurement were treated with a spherical correction based on MRSE (unconfirmed cylinder).

In the myopia cohort, 74 eyes with confirmed low cylinder were compared to 49 eyes with unconfirmed low cylinder. For hyperopia, 44 eyes with confirmed low cylinder were compared to 35 eyes with unconfirmed low cylinder.

Table 18 presents the comparisons of results for untreated and treated low cylinder in myopic and hyperopic eyes by means of deviation from the target from 0.00 D cylinder. In the myopia cohort, a greater percent reduction in MRCYL at Month 6 was seen for the treated low cylinder (-79.3%) than the untreated low cylinder (-20.8%) eyes. The treated low cylinder eyes decreased from a baseline -0.375 D mean cylinder to -0.075 D mean cylinder at Month 6; while the untreated low cylinder eyes had a minimal change from -0.293 D mean cylinder at baseline to -0.213 D mean cylinder at Month 6.

The percent reduction of MRCYL for the hyperopia eyes was less pronounced at Month 6 for the treated low cylinder (-25.0%) compared to the myopic eyes, but showed the same trend compared to the untreated low cylinder (-18.2%) eyes. The treated low cylinder eyes decreased from a baseline -0.398 D mean cylinder to -0.256 D mean cylinder at Month 6; while the untreated low cylinder eyes had a change from -0.300 D cylinder at baseline to -0.227 D cylinder at Month 6.

Table 18. Deviation from Targeted Cylinder Correction and Percent Reduction in MRCYL for Myopic and Hyperopic Eyes with Low Cylinder for Per Protocol Population

	Myopia Cohort				**Hyperopia Cohort**			
	Untreated (Unconfirmed ≤ 0.50 D Cyl)		**Treated (Confirmed ≤ 0.50 D Cyl)**		**Untreated (Unconfirmed ≤ 0.50 D Cyl)**		**Treated (Confirmed ≤ 0.50 D Cyl)Cyl)**	
	Preop	**Month 6**	**Preop**	**Month 6**	**Preop**	**Month 6**	**Preop**	**Month 6**
Within ± 0.25 D	40 (81.6%)	37 (78.7%)	37 (50.0%)	63 (90.0%)	29 (82.9%)	24 (72.7%)	18 (40.9%)	29 (69.0%)
Within ± 0.50 D	49 (100%)	44 (93.6%)	74 (100%)	69 (98.6%)	34 (97.1%)	29 (87.9%)	44 (100%)	35 (83.3%)
Within ± 1.00 D	49 (100%)	47 (100%)	74 (100%)	70 (100%)	35 (100%)	32 (97.0%)	44 (100%)	41 (97.6%)
Absolute Deviation from Target (D):								
N	49	47	74	70	35	33	44	42
Mean (SD)	-0.293 (0.093)	-0.213 (0.261)	-0.375 (0.126)	-0.075 (0.172)	-0.300 (0.118)	-0.227 (0.377)	-0.398 (0.124)	-0.256 (0.360)
Median	-0.250	-0.250	-0.375	0.000	-0.250	0.000	-0.500	0.000
Min, Max	-0.50, -0.25	-1.00, 0.00	-0.50, -0.25	-0.75, 0.00	-0.75, -0.25	-1.50, 0.00	-0.50, -0.25	-1.25, 0.00
Percent Reduction in MRCYL (D):								
N		47		70		33		42
Mean (SD)		-20.8 (101.4)		-79.3 (52.1)		-18.2 (140.2)		-25.0 (114.4)
Median		-26.5		-100.0		-100.0		-100.0

Unconfirmed Cylinder was not treated for Cylinder. A 'target' of 0.0 was assumed for the calculation of outcome.

Vector Analysis of Cylinder

The vector analysis summary for the three treatment cohorts at stability (Month 6) is shown in **Table 19**. The astigmatic vectors for "intended refractive correction" (IRC) and "surgically induced refractive correction" (SIRC) incorporate both the magnitude and axis of the cylinder into the vector. The "error vector" (EV) is equal to the vector difference between SIRC and IRC, while the "correction ratio" (CR) is the ratio of |SIRC|/|IRC|.

For both the myopic and hyperopic eyes treated for astigmatism, the mean CR was greater than 1, with 1.03 ± 0.25 for the myopia cohort and 1.13 ± 0.60 for the hyperopia cohort. The

mixed astigmatism cohort had a CR of 0.98 ± 0.10 at Month 6. In the stratifications by preoperative MRCYL, the mixed astigmatism cohort showed values very slightly lower than 1.0. Both the myopia and hyperopia cohorts showed values larger than 1.0 in the low cylinder bins and values lower than 1.0 in one of the higher cylinder bins. Note, that according to Bullimore et al. (2015) the values lower than 1.0 for small correction may not be interpreted as undercorrections, as this is a methodological artifact, which is more pronounced if the variation of the astigmatism is higher, which is indeed the case for hyperopia compared to myopia (compare the |EV| for the lowest cylinder corrections). The overall mean |EV| was lowest for the myopia cohort (0.17 ± 0.26) and highest and similar for the hyperopia cohort (0.29 ± 0.36) and mixed astigmatism cohort (0.30 ± 0.35). The ER was lowest for the mixed astigmatism cohort (0.10 ± 0.11) and highest in the hyperopia cohort (0.35 ± 0.68).

Table 19. Vector Analysis Summary at Stability (Month 6) for Eyes Treated for Astigmatism in Treated Eyes Population

Preoperative Cylinder	N	|IRC| (Mean ± SD)	|SIRC| (Mean ± SD)	|EV| (Mean ± SD)	CR (Mean ± SD)	ER (Mean ± SD)
Full Cohort						
All Eyes	564	1.65 (1.13)	1.64 (1.11)	0.23 (0.32)	1.05 (0.37)	0.20 (0.44)
>0.0 to ≤ 0.5 D	118	0.38 (0.13)	0.45 (0.25)	0.14 (0.27)	1.21 (0.70)	0.41 (0.84)
>0.5 to ≤ 1.0 D	136	0.86 (0.12)	0.88 (0.27)	0.18 (0.26)	1.02 (0.31)	0.21 (0.32)
>1.0 to ≤ 2.0 D	124	1.57 (0.31)	1.58 (0.35)	0.15 (0.23)	1.01 (0.15)	0.10 (0.17)
>2.0 to ≤ 3.0 D	99	2.61 (0.28)	2.57 (0.36)	0.27 (0.26)	0.99 (0.09)	0.10 (0.10)
>3.0 to ≤ 4.0 D	87	3.59 (0.29)	3.50 (0.45)	0.53 (0.44)	0.98 (0.12)	0.15 (0.12)
Myopia Cohort						
All Eyes	266	1.35 (1.01)	1.34 (0.99)	0.17 (0.26)	1.03 (0.25)	0.16 (0.33)
>0.0 to ≤ 0.5 D	74	0.38 (0.13)	0.41 (0.17)	0.07 (0.17)	1.09 (0.36)	0.21 (0.52)
>0.5 to ≤ 1.0 D	69	0.84 (0.12)	0.85 (0.23)	0.16 (0.24)	1.01 (0.26)	0.19 (0.30)
>1.0 to ≤ 2.0 D	65	1.56 (0.32)	1.59 (0.34)	0.13 (0.21)	1.02 (0.16)	0.09 (0.16)
>2.0 to ≤ 3.0 D	34	2.55 (0.25)	2.46 (0.32)	0.22 (0.21)	0.96 (0.06)	0.08 (0.08)
>3.0 to ≤ 4.0 D	24	3.54 (0.27)	3.55 (0.48)	0.52 (0.39)	1.01 (0.13)	0.15 (0.11)
Hyperopia Cohort						
All Eyes	163	1.34 (1.00)	1.39 (0.97)	0.29 (0.36)	1.13 (0.60)	0.35 (0.68)
>0.0 to ≤ 0.5 D	44	0.40 (0.12)	0.52 (0.33)	0.25 (0.36)	1.41 (1.02)	0.75 (1.13)
>0.5 to ≤ 1.0 D	52	0.86 (0.13)	0.90 (0.33)	0.24 (0.31)	1.06 (0.40)	0.28 (0.38)
>1.0 to ≤ 2.0 D	29	1.59 (0.29)	1.61 (0.40)	0.25 (0.30)	1.01 (0.19)	0.17 (0.23)
>2.0 to ≤ 3.0 D	26	2.57 (0.31)	2.60 (0.41)	0.30 (0.27)	1.02 (0.10)	0.12 (0.10)
>3.0 to ≤ 4.0 D	12	3.60 (0.34)	3.28 (0.34)	0.71 (0.60)	0.92 (0.15)	0.19 (0.16)
Mixed Astigmatism Cohort						
All Eyes	135	2.60 (0.99)	2.53 (1.02)	0.30 (0.35)	0.98 (0.10)	0.10 (0.11)
>0.0 to ≤ 0.5 D	0					
>0.5 to ≤ 1.0 D	15	0.97 (0.09)	0.92 (0.15)	0.04 (0.13)	0.96 (0.13)	0.04 (0.13)
>1.0 to ≤ 2.0 D	30	1.60 (0.29)	1.54 (0.31)	0.10 (0.16)	0.97 (0.09)	0.06 (0.10)
>2.0 to ≤ 3.0 D	39	2.68 (0.27)	2.64 (0.34)	0.28 (0.28)	0.99 (0.10)	0.11 (0.11)
>3.0 to ≤ 4.0 D	51	3.61 (0.28)	3.53 (0.46)	0.50 (0.41)	0.98 (0.11)	0.14 (0.11)

Notes: N is based on IRC; Ns may be smaller for other columns due to missing data at point of stability.
Notes: IRC=Intended refractive correction; SIRC=Surgically induced refractive correction; EV=Error vector; CR=Correction ratio; ER=Error ratio.

Patient Reported Outcomes for Satisfaction

The main goal of LASIK with the MEL90 is to reduce or eliminate the need for spectacles or contact lenses. As shown in **Table 20**, satisfaction with outcomes was high, with 92.7%

(316/341) of all subjects indicating they were completely or very satisfied with the result of their LASIK surgery at Month 6.

Table 20. Patient Reported Outcomes for Satisfaction at Month 6 by Treatment Cohort for All Subjects in Safety Population

	Myopia Cohort		Hyperopia Cohort		Mixed Astigmatism		Total*	
	n/N	(%)	n/N	(%)	n/N	(%)	n/N	(%)
Q 6. In general, how satisfied or dissatisfied are you with your present vision?								
Completely satisfied	135/174	77.6%	41/110	37.3%	45/76	59.2%	208/341	61.0%
Very satisfied	32/174	18.4%	48/110	43.6%	20/76	26.3%	97/341	28.4%
Somewhat satisfied	6/174	3.4%	14/110	12.7%	8/76	10.5%	26/341	7.6%
Somewhat dissatisfied	1/174	0.6%	1/110	0.9%	1/76	1.3%	3/341	0.9%
Very dissatisfied	0/174		5/110	4.5%	1/76	1.3%	6/341	1.8%
Completely dissatisfied	0/174		1/110	0.9%	1/76	1.3%	1/341	0.3%
Q 36. Currently how satisfied or dissatisfied are you with the result of your LASIK surgery?								
Completely satisfied	140/174	80.5%	50/110	45.5%	46/76	60.5%	223/341	65.4%
Very satisfied	25/174	14.4%	51/110	46.4%	20/76	26.3%	93/341	27.3%
Somewhat satisfied	6/174	3.4%	5/110	4.5%	6/76	7.9%	16/341	4.7%
Somewhat dissatisfied	2/174	1.1%	1/110	0.9%	2/76	2.6%	4/341	1.2%
Very dissatisfied	0/174		1/110	0.9%	1/76	1.3%	2/341	0.6%
Completely dissatisfied	1/174	0.6%	2/110	1.8%	1/76	1.3%	3/341	0.9%
Q 43. If you could do it all over again would you decide to have LASIK performed?								
Yes, I would decide to have it again, because of my result.	163/174	93.7%	100/110	90.9%	66/76	86.8%	312/341	91.5%
Yes, I would decide to have it again, despite my result.	10/174	5.7%	9/110	8.2%	8/76	10.5%	26/341	7.6%
No, I would not decide to have it again, because of my result.	1/174	0.6%	0/110		1/76	1.3%	2/341	0.6%
No, I would not decide to have it again, despite my result.	0/174		1/110	0.9%	1/76	1.3%	1/341	0.3%
Q 44. Would you recommend LASIK surgery to a friend or family member?								
Yes, I would decide to have it again, because of my result.	164/174	94.3%	102/110	92.7%	67/76	88.2%	316/341	92.7%
Yes, I would decide to have it again, despite my result.	10/174	5.7%	8/110	7.3%	8/76	10.5%	24/341	7.0%
No, I would not decide to have it again, because of my result.	0/174		0/110		1/76	1.3%	1/341	0.3%
No, I would not decide to have it again, despite my result.	0/174		0/110		0/76		0/341	

*Total is based on subject response; subjects with eyes in different cohorts (see Table 14) will be represented twice.

3. Subgroup Analyses

The following baseline characteristics were evaluated for potential association with safety and effectiveness outcomes: age, pediatric age, gender, race. Exploratory analyses were performed to evaluate the effect of baseline characteristics on key effectiveness outcomes, including UCDVA and predictability of the achieved versus intended MRSE correction.

For stratification by age, differences were seen in +/- 0.5D MRSE predictability across age groups, most pronounced between the lowest age group (18 to < 30) with 94.4% (203/215)

of eyes reaching this level of accuracy vs. 80.6% (58/72) of eyes in the highest age group (50 and above). For the primary effectiveness outcomes of UCDVA 0.3 logMAR or better and MRSE within ± 1.00 D of attempted MRSE, the results are comparable across the age stratification groups.

Specifically, for the comparison of pediatric age (defined as 18 to < 22 years) to the rest of the study population, a difference was only seen in the achievement of -0.1 logMAR or better UCDVA, with a lower proportion of eyes achieving this level within the pediatric subgroup (16.7%, 6/36, vs. 36.6%, 237/648). No clinically significant differences were seen for UCDVA levels of 0.0 logMAR or better or for the achievement of MRSE within ± 0.25 D, nor for the primary effectiveness outcomes. This indicates the outcomes for the younger age group were comparable to the rest of the study population.

For the stratification by gender, a notable difference was only seen in the achievement of -0.1 logMAR or better UCDVA, with a lower proportion of female eyes achieving this level (31.5%, 107/340, vs. 39.5%, 136/344). For the primary effectiveness outcomes of UCDVA 0.3 logMAR or better and MRSE within ± 0.50 D and ± 1.00 D of attempted MRSE, the results are comparable for males and females.

No significant differences were seen for effectiveness outcomes as a function of race.

4. Pediatric Extrapolation

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

XI. FINANCIAL DISCLOSURES

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning compensation to, and financial interests and arrangements of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 11 investigators of which none were full-time or part-time employees of the sponsor and two had disclosable financial interest/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0
- Significant payments of other sorts: 2
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 0

The application has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Not applicable.

XIII. 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 Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIV. CONCLUSIONS DRAWN FROM THE STUDIES

A. Effectiveness Conclusions

In the clinical study, 714 eyes of 358 subjects underwent LASIK treatment with the MEL90 for the correction of myopia with or without astigmatism, hyperopia with and without astigmatism and mixed astigmatism. Clinical data are provided on effectiveness parameters including improvement in UCDVA following treatment, predictability of MRSE relative to the intended outcome, and refractive stability parameters including change in MRSE over sequential visits. The effectiveness of the astigmatic correction is shown by means of non-vector and vector-based predictability and stability analyses.

In terms of effectiveness outcomes, for all three treatment cohorts the proportion of eyes with UCDVA of 0.3 logMAR (20/40) or better exceeded 85%. Specifically, at Month 6, 98.8% (338/342) of eyes in the myopia cohort, 98.1% (206/210) of eyes in the hyperopia cohort and 100% (132/132) of eyes in the mixed astigmatism cohort achieved 0.3 logMAR or better.

For the accuracy of MRSE, the proportion of eyes within ± 0.50 D MRSE exceeded 50% and the proportion of eyes within ± 1.00 D MRSE exceeded 75% for the entire study cohort. At Month 6, the proportion of eyes in each cohort within ± 0.50 D MRSE was 93.0% (318/342) for the myopia cohort, 82.9% (174/210) for the hyperopia cohort and 92.4% (122/132) for the mixed astigmatism cohort. In terms of eyes within ± 1.00 D MRSE at Month 6, 98.8% (338/342) of myopic eyes, 96.7% (203/210) of hyperopic eyes and 97.7% (129/132) of mixed astigmatism eyes achieved this level.

Stability of both MRSE and MRCYL was demonstrated across all treatment cohorts at the 3- to 6-month interval. The mean change in MRSE was 0.008 D per month for the 3- to 6-month interval, and -0.005 D and 0.008 D per month for the subsequent interval. Similarly, the mean change in MRCYL was -0.003 D per month in the 3- to 6-month interval, and -0.003 and 0.000 D per month for the subsequent 3-months intervals. 96.1% of eyes had a change in MRSE ≤ 0.50 D between 3 and 6 months; 97.4% and 98.5% had changes ≤ 0.50 D at the 6- to 9-month and the 9- to 12-month interval. In terms of MRCYL, 97.9% of eyes were ≤ 0.50 D between 3 and 6 months; 97.9% and 97.5% were ≤ 0.50 D for the 6- to 9-month and 9- to 12- month intervals, respectively.

The pivotal clinical trial outcomes support the reasonable assurance of the effectiveness of the device for the proposed indications for use.

B. Safety Conclusions

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

For safety outcomes, only one eye in the myopia cohort had a loss of ≥ 10 letters of BCDVA and the same eye had worse than 0.3 logMAR BCDVA; one eye had an induction of > 2.00 D cylinder (due to an incorrect axis for the astigmatism treatment). All three cohorts were below the safety limits of < 5% of eyes with a loss of ≥ 10 letters of BCDVA, < 1% of eyes with a BCDVA of 0.0 logMAR or better preoperatively that have a BCDVA of worse than 0.3 logMAR and < 5% of eyes with induced manifest refractive astigmatism > 2.00 D of absolute cylinder. There were only two eyes with an ocular serious adverse event (melting of the flap and retinal detachment) with < 1% incidence in any cohort.

A total of 59 subjects were reported with 106 adverse events (AEs) over the course of the study. Only four AEs were reported with a rate greater than 1%, including the interoperative reports of interface debris (2.8%) and postoperative reports of subjective symptoms of dry eye (3.6%), epithelium in the interface (1.7%) and diffuse lamellar keratitis (Grade 2 or less) (1.7%). For intraoperative AEs reported at a rate less than 1%, there were 5 AEs involving the LASIK flap and 1 AE for an incorrect treatment axis. Postoperative AEs related to loss of BCDVA included 1 case of loss of ≥ 2 lines of BCDVA and 1 case due to epithelium in the interface.

There were three (3) serious adverse events in the study including a flap melt, a retinal detachment, and a seizure. There were three (3) secondary surgical interventions performed over the course of the study including epithelial ingrowth removal, retreatment of an incorrect axis treatment, and scleral buckle for retinal detachment. In the majority of cases, harmful events resolved without severe residual sequelae.

The pivotal clinical study outcomes support the reasonable assurance of the safety of the device for the proposed indications for use.

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 the treatment to the patient is improved UCDVA. While there were only 8.6% (60/701) of eyes preoperatively with UCDVA of 0.3 logMAR or better, at the refractive time point of stability of 6 months postoperatively, 98.8% (676/684) and 71.4% (488/684) achieved uncorrected visual acuity of 0.3 logMAR or better and 0.0 logMAR or better, respectively, with no subjects having best corrected visual acuity worse than 20/40 (0.3 logMAR) at their last available visit. Similar results were achieved at the Month 12 visit. These results represent significant clinical benefit.

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 most serious types of adverse events seen in the study were the melting of the flap, retinal detachment, and the seizure. Also significant were several of the cases of epithelium in the interface: one causing significant temporary loss of BSCVA at 3 months and one

requiring secondary surgical intervention (including irrigation) at 12 months. Two other cases of epithelium in the interface required irrigation at early postoperative visits. No adverse event resulted in long-term serious sequelae. Only one study eye presented with a loss of ≥ 2 lines BCDVA at Months 3 and 6, which resolved by Month 9.

Additional factors to be considered in determining probable risks and benefits for the MEL90 included: the study design was of good quality, the conduct of the study was good with few eyes missing data, and the fact that the device has been commercially available in more than 98 countries without reports of substantial problems.

1. Patient Perspective

   Patient perspectives considered during the review included patients' self-reported information on visual symptoms (double images, glare, halos, and starbursts), how these visual symptoms impacted patients' daily lives, and patients' satisfaction with the LASIK surgery. These perspectives were collected via the Patient-Reported Outcome (PRO) LASIK (PROWL) questionnaire. Ocular symptoms of dry eye and environmental triggers were collected via the OSDI questions on the PROWL questionnaire. The responses on the OSDI questions were scored and classified by dry eye disease symptoms severity.

   Results of these perspectives are summarized in Table 8 (PROWL visual symptoms for all patients in safety population), Table 8.1 (PROWL visual symptoms at Month 6 stratified by treatment cohort), Table 9 (dry eye disease symptoms severity classification), and Table 20 (satisfaction with the LASIK surgery).

   A greater proportion of patients experienced resolution of a symptom or symptoms postoperatively than the proportion of subjects who developed symptoms postoperatively. Similarly, the report of "very" or "extreme" difficulty or bothersomeness with symptoms decreased postoperatively.

   Although patients with none or minimal dry eye disease symptoms (i.e., "normal") increased from preoperatively to postoperatively while patients with "mild", "moderate" or "severe" dry eye disease symptoms decreased after the LASIK surgery, these results were interpreted with caution due to the potential over or under estimation of the true number of participants in each category.

   For satisfaction with the LASIK surgery, 92.7% (316/341) of all subjects indicated that they were completely or very satisfied with the result of their LASIK surgery at Month 6.

In conclusion, given the available information above, the data support the safety and effectiveness of primary Laser in-situ Keratomileusis (LASIK) treatment with the Carl Zeiss Meditec MEL90 for the reduction or elimination of:

- Myopia less in magnitude than -10.00 D sphere (in minus-cylinder notation), with and without cylinder up to -4.00 D, when MRSE is less in magnitude than -10.00 D;
- Hyperopia up to +4.00 D sphere (in plus-cylinder notation), with and without cylinder up to +3.00 D, when MRSE is up to +5.00 D; and

- Mixed astigmatism with cylinder from >1.00 D up to 4.00 D;

in patients who are 18 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change in MRSE within +/- 0.50 D, the probable benefits of the device 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: MRSE within ± 1.00 D and ± 0.50 D of the intended refractive outcome, UCDVA of 0.3 logMAR or better, and the percentage of eyes with MRCYL within ± 1.00 D and ± 0.50 D of the intended refractive outcome at 6 months post-operatively. No unexpected safety findings were observed.

Treatment of low cylinder with a spherocylinder correction (>0.00 D to ≤ 0.50 D) was no worse and in some cases better than treatment of low cylinder with a spherical correction. The safety and effectiveness targets established in the study were exceeded for all treatment groups and results were consistent with recently approved lasers.

In summary, the data presented show the Carl Zeiss Meditec MEL90 is safe and effective for LASIK correction of myopia, hyperopia and mixed astigmatism.

XV. CDRH DECISION

CDRH issued an approval order on December 4, 2024.

XVI. 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.

XVII. REFERENCES

Not applicable