

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Intraocular Lens

Device Trade Name: RayOne Galaxy; Model RAO605G
RayOne Galaxy Toric; Model RAO615X

Device Procode: MFK, MJP

Applicant's Name and Address: Rayner Intraocular Lenses Limited
The Ridley Innovation Centre
10 Dominion Way, Worthing, West Sussex
BN14 8AQ, United Kingdom

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P060011/S045

Date of FDA Notice of Approval: September 24, 2026

The original PMA (P060011) was approved on May 3, 2007, for the C-flex intraocular lens and the device is indicated for primary implantation for the visual correction of aphakia in adults in whom a cataractous lens has been removed by phacoemulsification. The lens is intended to be placed in the capsular bag. The SSED to support the indication is available on the CDRH website and is incorporated by reference here. In P060011/S014, the RayOne Aspheric was approved: the previously approved 600C Aspheric Intraocular Lens preloaded within the Rayner RayOne Injection system. Supplement P060011/S039 approved RayOne EMV Toric, indicated for the correction of aphakia and the treatment of astigmatism. The current supplement was submitted to include RayOne Galaxy and RayOne Galaxy Toric, modifications of previously approved intraocular lens (IOL) models.

II. INDICATIONS FOR USE

RayOne Galaxy (Model RAO605G) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia, in adult patients in whom a cataractous lens has been removed.

The IOL mitigates the effects of presbyopia by providing improved intermediate and near visual acuity while maintaining comparable distance visual acuity to a monofocal IOL. RayOne Galaxy is intended for implantation in patients with less than 1.00 diopter of pre-existing corneal astigmatism. The RayOne injection system is used to fold and assist in inserting the IOL into the eye.

RayOne Galaxy Toric (Model RAO615X) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia, in adult patients in whom a cataractous lens has been removed.

The IOL mitigates the effects of presbyopia by providing improved intermediate and near visual acuity while maintaining comparable distance visual acuity to a monofocal IOL. In addition, RayOne Galaxy Toric is intended to provide reduction of residual refractive astigmatism in patients with corneal astigmatism greater than or equal to 1.03 diopter, up to 3.07 diopter. The RayOne injection system is used to fold and assist in inserting the IOL into the eye.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the RayOne Galaxy and RayOne Galaxy Toric labeling.

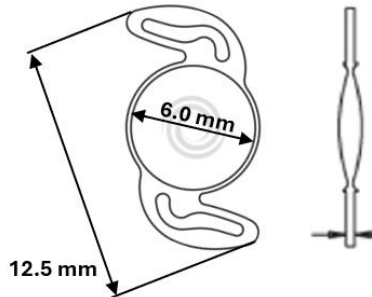
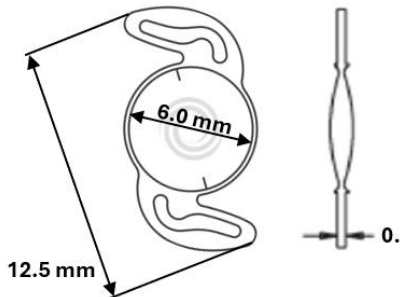
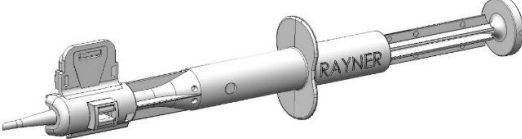
V. DEVICE DESCRIPTION

The RayOne Galaxy is a multifocal (trifocal) IOL.

The Galaxy IOL optic is designed to mitigate the effects of presbyopia by extending the range of vision from distance to near. The optic is biconvex and consists of a refractive spiral anterior optical surface and aspheric posterior surface, for the toric IOL the posterior surface is toric. The spiral optic extends from a radius of 0.55 mm to 1.6 mm and provides intermediate and near add powers of +1.5 D and +3.0 D, respectively, at the IOL plane.

The physical characteristics of RayOne Galaxy and RayOne Galaxy Toric are shown in **TABLE 1**.

TABLE 1 RAYONE GALAXY AND RAYONE GALAXY TORIC PHYSICAL CHARACTERISTICS

Parameter	RayOne Galaxy	RayOne Galaxy Toric
Lens image		
Injector image		
Lens material	Rayacryl	
Injector material	Polypropylene & TPE	
Design features	Refractive spiral, multifocal, capsular bag fixated	Refractive spiral, toric, multifocal, capsular bag fixated
Injection system	Fully preloaded	
Overall diameter (mm)	12.5 ± 0.2	
Optic diameter (mm)	6.0 ± 0.1	
Limb width (mm)	0.38 ± 0.1	
Limb thickness (mm)	0.41 ± 0.15	
Haptic style	Closed C-loop	
Square edge	360° posterior Enhanced Square Edge	
Power range (increments)	+5.0 to +30.0 D (0.5 D)	N/A
Spherical equivalence (increments)	N/A	+6.0 to +30.0 D (0.5 D)
Cylinder power range (increments)	N/A	+1.5 to 3.75 D (0.75 D)
Index of refraction	1.46	

RayOne Galaxy Toric is available from:

- SE: +6.0 D to +30.0 D in 0.5 D increments
- Cylinder: +1.5 D to +3.75 D in 0.75 D increments

The effective corneal powers for each of the test lens plane cylindrical powers of the Galaxy Toric IOLs are shown in **TABLE 2**.

TABLE 2 CYLINDER POWER AND CORNEAL ASTIGMATISM CORRECTION RANGE

IOL Type	IOL Power at IOL Plane (D)	Cyl Power on Corneal Plane (D)	Specified Range (D) Lower	Specified Range (D) Upper
T3	1.5	1.03	1.03	1.53
T4	2.25	1.54	1.54	2.04
T5	3	2.05	2.05	2.56
T6	3.75	2.57	2.57	3.07

This medical device product has functions subject to FDA premarket review

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of restoring functional vision of the aphakic eye. Non-surgical options include special cataract glasses or contact lenses. Surgical options such as monofocal, simultaneous vision (e.g., multifocal, extended depth of focus, full visual range) or accommodative IOLs are also available. 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

RayOne Galaxy and RayOne Galaxy Toric have not been marketed in the United States. These products have been available in the European Union since receiving CE Mark in July 2024. Since launch, there have been no recalls of RayOne Galaxy and RayOne Galaxy Toric (Models RAO605G and RAO615X). Additionally, there are no countries where the devices have been removed from the market for any reason(s) related to the safety or 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:

- Secondary glaucoma
- IOL replacement or extraction
- Precipitates
- Reduced vision
- Vitreous herniation
- Excessive intraoperative vitreous loss
- IOL decentration
- Secondary membrane
- Expulsive hemorrhage
- IOL dislocation and subluxation
- Retrolenticular membrane

- Corneal edema
- Endophthalmitis and panophthalmitis
- Retinal detachment
- Corneal dystrophy
- Hemorrhage
- Iris atrophy
- Pupillary block
- Cystoid macular edema
- Severe ametropia and aniseikonia
- Iridocyclitis and hyalitis
- Deviation from target refraction
- Fibrin reaction
- Elevated IOP
- Best-corrected visual acuity loss of 2 lines (10 letters) or more on the ETDRS chart measured at 3-4 months or later from any prior post-operative visit
- Anterior chamber cells grade 0.5 or greater at 7-14 days or later
- Posterior vitreous detachment
- Subconjunctival hemorrhage
- Anterior chamber cells greater than grade 2 at Day 1-2
- Keratoconjunctivitis sicca or worsening, not specified as Sjogren's
- Double/multiple images
- Meibomian gland dysfunction
- Progression of diabetic retinopathy

Secondary surgical interventions include, but are not limited to, lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, Posterior capsule opacification requiring Nd:YAG capsulotomy, capsular support device, pars plana vitrectomy and retinal detachment repair.

For the specific adverse events that occurred in the clinical studies, please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

RayOne Galaxy and RayOne Galaxy Toric (Models RAO605G and RAO615X) are composed of identical materials to the currently approved family of hydrophilic Rayacryl intraocular lenses (P060011). Preclinical studies were performed on the material parent device (P060011) instead of the final proposed device. These tests are as follows: physicochemical and biocompatibility testing, sterilization, packaging, shelf-life, and transport stability testing.

Physicochemical Testing

The results of physicochemical testing are shown in **TABLE 3**.

TABLE 3 PHYSICOCHEMICAL TESTING

Test	Purpose	Acceptance Criteria	Results
ISO 11979-5 Exhaustive Extraction	Soxhlet extraction to recover polymerization residuals, impurities, and additives, quantitative analysis of extracts	No prespecified acceptance criteria. The results shall be evaluated to assess the risk for potentially harmful effects due to extractable components.	Acceptable Outcome
ISO 11979-5 Leachable study	The IOL material was extracted at 35°C for 72 h with water and hexane, respectively. The extracts were analyzed for potential leachables.	No prespecified acceptable criteria The results shall be evaluated to assess the risk for potentially harmful effects due to leachable components.	Acceptable Outcome
ISO 11979-5 Test for Hydrolytic Stability	Test to verify material does not degrade by hydrolysis	Hydrolytic stability of IOLs by investigation of dioptric power, recording of transmission spectra, light microscopic inspection and scanning electron microscopic (SEM) inspection. The exposure medium shall be qualitatively and quantitatively analyzed for any chemical entities at the end of the exposure period.	Pass
ISO 11979-5 Photostability test	Exposure to UV radiation in a saline solution using a radiation source (Xenon arc lamp) in order to simulate an in vivo exposure time of 20 years to evaluate the photostability.	The investigated lens material is stable against ultraviolet/visible light exposure. No significant change shall be detected between the physical appearance, UV/Vis spectra, dioptric power and image quality of the test material exposed to UV radiation and controls receiving no radiation. The exposure medium shall be qualitatively and quantitatively analyzed for any chemical entities after irradiation and compared to non-irradiated controls.	Pass

Test	Purpose	Acceptance Criteria	Results
ISO 11979-5 Nd-YAG laser exposure test	To confirm IOL sample's stability when exposed to Nd:YAG lasers, and leakage of cytotoxic compounds.	No significant difference in physical appearance, spectral transmittance, or dioptric power after the exposure. No cytotoxic substances after laser exposure were detected. The exposure medium shall be qualitatively and quantitatively analyzed for any chemical entities after laser exposure.	Pass
ISO 11979-5 Evaluation of insoluble inorganics	To assess the IOL material for the presence of residual insoluble inorganics on and in the lens arising from manufacturing materials and process aids.	NO prespecified acceptance criteria. Quantitative determination of the inorganic ions presents in the test material.	Acceptable Outcome

Biocompatibility Testing

RayOne Galaxy and RayOne Galaxy Toric (Models RAO605G and RAO615X) are made of the same material that was used with previously approved hydrophilic Rayacryl intraocular lenses (P060011). Biocompatibility testing (**TABLE 4**) was performed to support P060011 in accordance with all relevant ISO Standards (ISO 11979-5 and ISO 10993-1), as well as the United States Food and Drug Administration. Use of International Standards ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

All tests to evaluate biocompatibility were conducted in accordance with provisions of 21 CFR 58, Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies.

TABLE 4 BIOCOMPATIBILITY TESTING OF THE LENSES

Test	Purpose	Acceptance Criteria	Result
Intraocular Lens*			
Cytotoxicity - MEM elution (ISO 10993-5, ISO 11979-5)	To evaluate the potential for cellular toxicity.	Non-cytotoxic	Pass
Cytotoxicity - Inhibition of Cell Growth Test (ISO 10993-5)	To evaluate the potential for cellular toxicity.	Non-cytotoxic	Pass
Cytotoxicity – Agarose Overlay (ISO 10993-5, ISO 11979-5)	To evaluate the potential for cellular toxicity.	Non-cytotoxic	Pass
Sensitization - Guinea Pig Maximization (ISO 10993-10, ISO 11979-5)	To assess dermal contact sensitization in guinea pig at 24 and 48 hours after patch removal.	Non-sensitizer	Pass
Sensitization - Magnusson-Kligman Maximization Test (ISO 10993-11)	To investigate delayed contact hypersensitivity of the IOL in guinea pigs.	Non-sensitizer	Pass
Ocular Irritation Study in Rabbits (ISO 10993-10)	To evaluate the potential for ocular reactions at 1, 24, 48 and 72 hours after the single exposure in rabbits.	Non-irritant	Pass
Acute Toxicity (Limit-Test) (ISO 10993-11)	To evaluate the potential for acute toxicity in rats.	Non-toxic	Pass
Genotoxicity - Mouse Peripheral Blood Micronucleus Study (ISO 10993-3, ISO 11979-5)	To evaluate the potential to produce cytogenetic damage, resulting in micronuclei formation.	No micronuclei formation	Pass
Genotoxicity - In vitro chromosome aberration test (ISO 10993-3, ISO 11979-5)	To determine genotoxic potential in Chinese hamster ovary.	Non-genotoxic	Pass
Genotoxicity - Mouse Lymphoma Assay (ISO 10993-3, ISO 11979-5)	To detect potential gene mutations or chromosomal damage.	Non-genotoxic	Pass
Genotoxicity – Mutagenic activity (ISO 10993-3, ISO 11979-5)	To evaluate mutagenic activity.	Non-mutagenic	Pass

* In vivo ‘Test for Local Effects’ (non-ocular) and ‘Ocular Implantation’ test is deemed unnecessary for RayOne Family of hydrophilic IOL devices, considering that they are manufactured from a raw

material with extensive historical clinical use. (Based on the recommendations of ISO 10993-1; and as per ISO 11979-5:2020, the risks arising from the use of the material are deemed acceptable based on the information from previous clinical use and other relevant literature.)

Biocompatibility testing (**TABLE 5**) was performed on the patient-contacting components of the RayOne injection system.

TABLE 5 BIOCOMPATIBILITY TESTING OF RAYONE INJECTION SYSTEM

Test	Purpose	Acceptance Criteria	Result
Cytotoxicity - Growth Inhibition Test in L929 Mouse Fibroblasts (Elution Test) (ISO 10993-5)	To evaluate the potential for cytotoxic effects using an in vitro mammalian cell culture test.	Non-cytotoxic	Pass
Systemic Toxicity – Acute Systemic Toxicity (in Swiss Albino Mice) (ISO 10993-11)	To evaluate toxic characteristics.	Non-toxic	Pass
Sensitization - Guinea Pig Maximization Sensitization Test (ISO 10993-10)	To evaluate the potential for sensitization.	Non-sensitizer	Pass
Sensitization - Test for delayed-type hypersensitivity (Guinea Pig Maximization Test) (ISO 10993-10)	To evaluate the potential for sensitization.	Non-sensitizer	Pass
Intracutaneous Reactivity Testing in Rabbits (ISO 10993-10)	To evaluate the potential for irritation.	Non-irritant	Pass
Intraocular Irritation Study in Rabbits (ISO 10993-10)	To evaluate the potential for irritation.	Non-irritant	Pass

Optical and Mechanical Testing

The optical properties of the Models 605G and 615X were tested per “ISO 11979-2: Ophthalmic implants – Intraocular lenses: Optical properties and test methods” and “ANSI Z80.30: Toric intraocular lenses.” The mechanical properties were tested per “ISO 11979-3: Ophthalmic implants – Intraocular lenses: mechanical properties and test methods.” In cases where the mechanical properties were related to the Rayacryl® material and overall IOL design (e.g. haptic design, optic body diameter), the testing is being leveraged from the parent device, Model 600C, for Models 605G and 615X, since these IOL models are manufactured from the same Rayacryl® material and are identical in non-optical design features (i.e. only differ by anterior and posterior optical surface design).

Testing was performed on lenses representing the low, the medium and the high diopter ranges:

RayOne Galaxy (Model RAO605G): power= +5.00 D, +20.00 D, +30.00 D

RayOne Galaxy Toric (Model RAO615X): spherical equivalent power (SE) = +6.0 D with cylinder = 0.75 D; SE = +20.0 D with cylinder = 0.75 D; SE = +30.0 D with cylinder = 0.75; SE = + 6.0 with cylinder 4.50; SE = + 20.0 with cylinder 4.50 D and SE = + 30.0 D with cylinder = 4.50 D.

The results of the testing demonstrate that the models 605G and 615X meet all of the ISO and ANSI standards for optical and mechanical properties, as summarized in **TABLE 6**, **TABLE 7** and **TABLE 8**.

The figures showing the through-focus MTF at different apertures are available below. Please see **Figure 1**, **Figure 2** and **Figure 3** for RayOne Galaxy; and **Figure 4**, **Figure 5**, **Figure 6**, **Figure 7**, **Figure 8**, and **Figure 9** for RayOne Galaxy Toric.

TABLE 6 SUMMARY OF OPTICAL TESTING FOR RAYONE GALAXY – ISO 11979-2 & ANSI Z80.30

Test	Purpose	Acceptance Criteria	Results
BS EN ISO 11979-2 Clauses 4.2.1 and 4.2.3 - Dioptric power for simultaneous vision IOL (SVIOL)	To assess conformance to optical power tolerances (post injection*)	$+10.0 \leq SE \leq +15.0 \text{ D}: \pm 0.3 \text{ D}$ $+15.0 < SE \leq +25.0 \text{ D}: \pm 0.4 \text{ D}$	Passed
BS EN ISO 11979-2 Clause 4.3.4 - Determination of imaging quality - Multifocal IOL (MIOL)	To assess conformance to image quality tolerances (post injection*)	MTF measurement > 70% of the maximum theoretical MTF	Passed
BS EN ISO 11979-2 Spectral transmittance	To characterize the spectral transmission in the range 300 nm to 1100 nm, and the 10% cutoff wavelength	$\geq 380\text{nm}$	Passed

TABLE 7 SUMMARY OF OPTICAL TESTING FOR RAYONE GALAXY TORIC – ISO 11979-2 & ANSI Z80.30

Test	Purpose	Acceptance Criteria	Results
BS EN ISO 11979-2 Clauses 4.2.2 - Dioptric power for toric IOL (TIOL) – Average Power (SE) 4.2.2 - Dioptric power for toric IOL (TIOL) – Cylinder (C) Power	To assess conformance to optical power tolerances (post injection*)	$+10.0 \leq SE \leq +15.0 \text{ D}: \pm 0.3 \text{ D}$ $+15.0 < SE \leq +25.0 \text{ D}: \pm 0.4 \text{ D}$ $SE < 25 \text{ D and } 0 < C \leq 2.5 : \pm 0.3 \pm 0.4 \text{ D}$ $SE < 25 \text{ D and } 2.5 < C \leq 4.5: \pm 0.4 \text{ D}$	Passed
BS EN ISO 11979-2 Clause 4.3.3 - Determination of imaging quality - Toric IOL (TIOL) 4.3.4 - Determination of imaging quality - Multifocal IOL (MIOL)	To assess conformance to image quality tolerances (post injection*)	MTF measurement $\geq 70\%$ of the maximum theoretical MTF	Passed
BS EN ISO 11979-2 Clause 4.2.2 – Axis marks for toric IOL (TIOL)	To determine axis marks align with the meridian of lowest dioptric power.	$\leq 5^\circ$	Passed
BS EN ISO 11979-2 Spectral transmittance	To characterize the spectral transmission in the range 300 nm to 1100 nm, and the 10% cutoff wavelength	$\geq 380\text{nm}$	Passed

TABLE 8 SUMMARY OF MECHANICAL TESTING FOR RAYONE GALAXY AND RAYONE GALAXY TORIC – ISO 11979-3

Mechanical Test	Purpose	Acceptance Criteria	Results
BS EN ISO 11979-3:2012 Item 4.2 Clear optic diameter measurement	To verify the diameter of the clear optic zone to ensure it meets design specifications	± 0.15 mm Min 4.25 mm	Passed
BS EN ISO 11979-3:2012 Item 4.2 Vault height measurement	To assess the distance between the IOL optic and the crystalline lens/ocular structures to verify appropriate vaulting and positioning	± 0.25 mm 100% Pass	Passed
BS EN ISO 11979-3:2012 Item 4.11 IOL haptic pull test	To assess the force required to separate the haptic from the optic	No Broken Haptic 100% Pass	Passed
BS EN ISO 11979-3:2012 Clause 4.4 Compression force	To characterize the mechanical force exerted by the IOL haptics under compression initially	BS EN ISO 11979-3:2012: Measure and Report	Passed
BS EN ISO 11979-3:2012 Clause 4.5 Axial displacement in compression	To characterize the axial displacement of the IOL under compression	BS EN ISO 11979-3:2012: Measure and Report	Passed
BS EN ISO 11979-3:2012 Clause 4.6 Optic Decentration	To assess optic decentration under compression	$(\bar{X} + 2\sigma) < 10\%$ Clear Optic Diameter	Passed
BS EN ISO 11979-3:2012 Clause 4.7 Optic Tilt	To assess optic tilt under compression	$(\bar{X} + 2\sigma) < 5^\circ$	Passed
BS EN ISO 11979-3:2012 Clause 4.8 Angle of Contact**	To characterize angle of contact of haptics under compression	Measure and Report	Passed

Mechanical Test	Purpose	Acceptance Criteria	Results
BS EN ISO 11979-3:2012 Item 4.2 Clear optic diameter measurement	To verify the diameter of the clear optic zone to ensure it meets design specifications	± 0.15 mm Min 4.25 mm	Passed
BS EN ISO 11979-3:2012 Item 4.2 Vault height measurement	To assess the distance between the IOL optic and the crystalline lens/ocular structures to verify appropriate vaulting and positioning	± 0.25 mm 100% Pass	Passed
BS EN ISO 11979-3:2012 Item 4.11 IOL haptic pull test	To assess the force required to separate the haptic from the optic	No Broken Haptic 100% Pass	Passed
BS EN ISO 11979-3:2012 Clause 4.9 Compression Force Decay**	To characterize the mechanical force exerted by the IOL haptics under compression after 24 hours	Measure and Report	Passed
BS EN ISO 11979-3:2012 Clause 4.10 Dynamic Fatigue Durability**	To assess the capability of the haptics to cyclic compressive displacement	Withstand 250,000 cycles without damage	Passed
BS EN ISO 11979-3:2012 Clause 4.11 Surgical Manipulation	To assess the force required to separate the haptic from the IOL body	Force >0.25 N	Passed
BS EN ISO 11979-3:2012 Clauses 4.12 and 5(a) Surface and Bulk Homogeneity * IOL injections of the pre-loaded IOL through RayOne injector performed with OphteisBio 3.0%, a sodium hyaluronate OVD.	To ensure the IOL is free of surface and bulk defects	The IOL shall be essentially free from defects	Passed
BS EN ISO 11979-3:2012 Clause 5 (b) Overall Diameter and Sagitta	To assess conformance to dimensional tolerances	Overall Diameter ± 0.20 mm Sagitta ± 0.35 mm	Passed

*Each lens is optically tested and inspected for Surface and Bulk Homogeneity prior to packaging and loading into the delivery system as part of standard manufacturing quality control. These measurements confirm compliance with ISO 11979-2 requirements for Dioptric Power and Imaging Quality, and compliance with ISO 11979-3 requirements for Surface and bulk Homogeneity Pre-Injection. Post-injection testing was performed to confirm compliance with ISO 11979-2 and ISO 11979-3 requirements, to verify the integrity of the delivery system and ensure clinical performance.

*** Compression Force Decay, Angle of Contact, Dynamic Fatigue Durability testing was carried out as part of the design verification of parent IOL model RAO600C.*

FIGURE 1 +5.0 D RAO605G BATCH. FAR, INTERMEDIATE, AND NEAR ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES

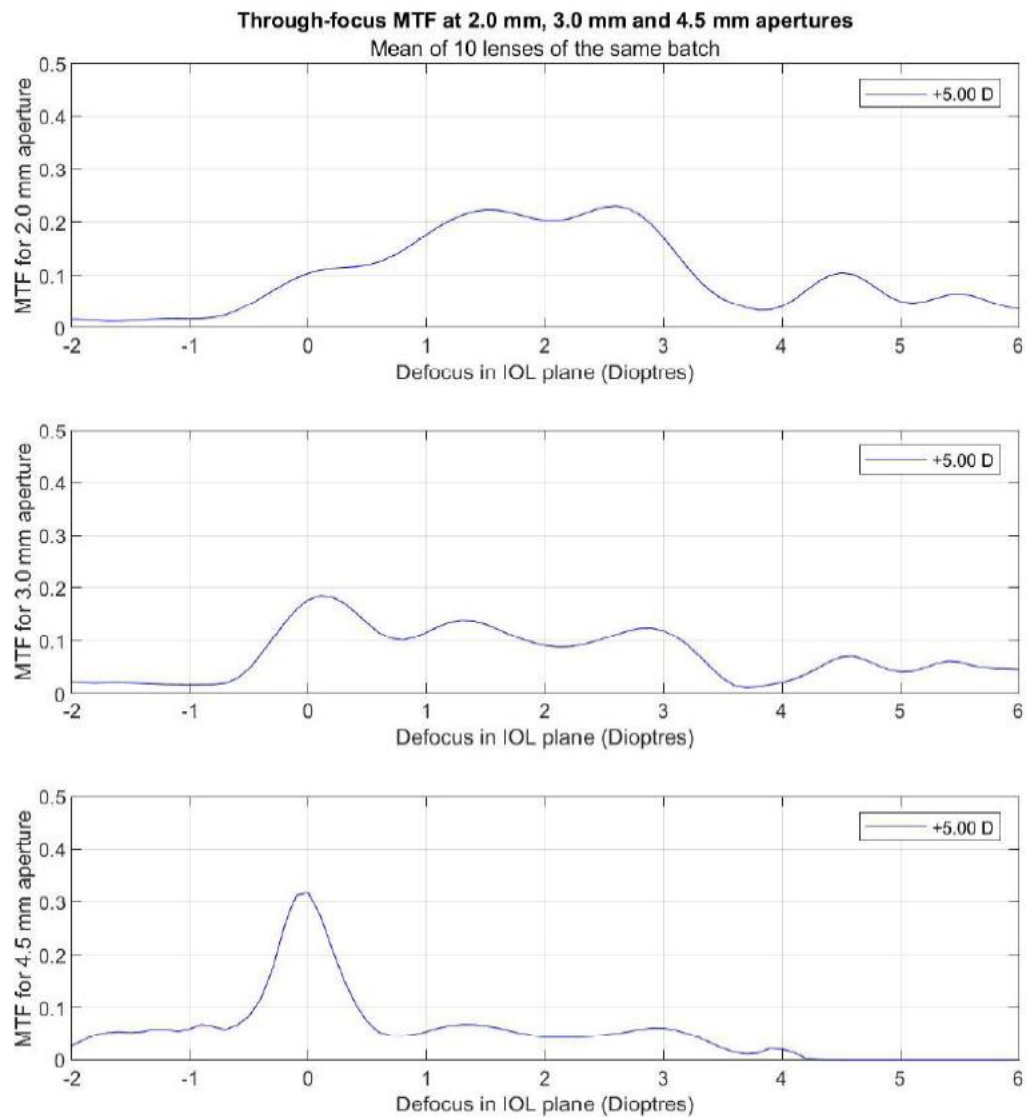


FIGURE 2 +20.0 D RAO605G BATCH. FAR, INTERMEDIATE, AND NEAR ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES

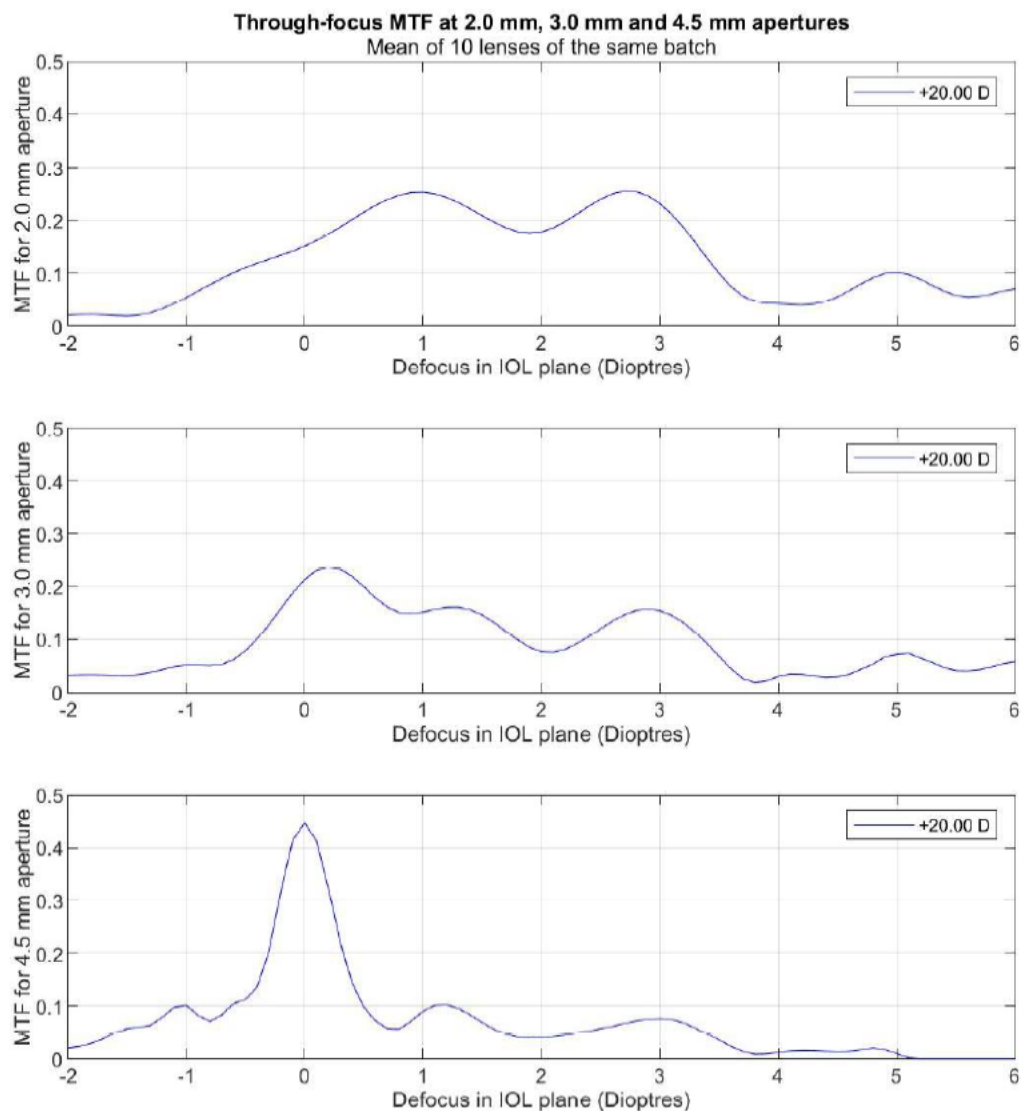


FIGURE 3 +30.0 D RAO605G BATCH. FAR, INTERMEDIATE, AND NEAR ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES

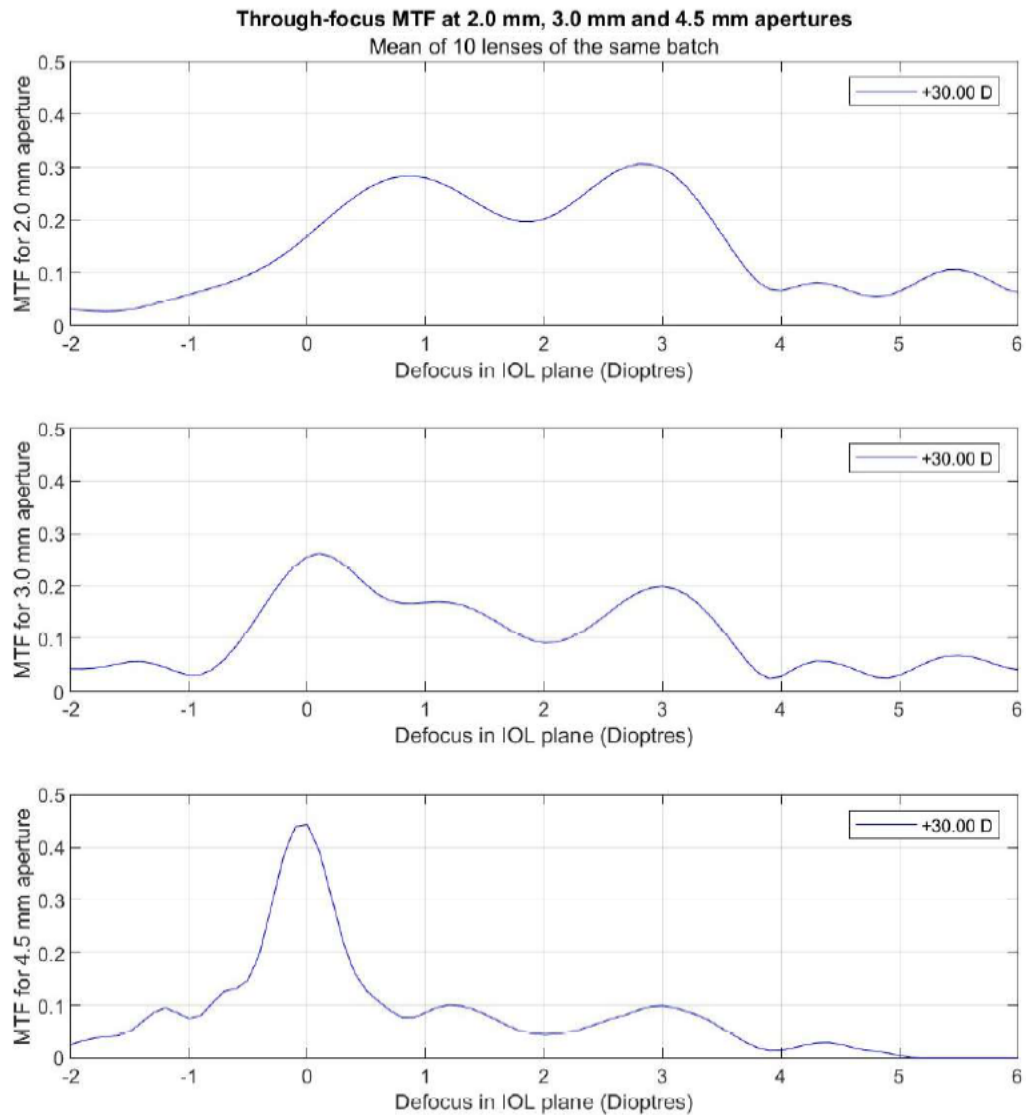


FIGURE 4 +6.0D SE +0.75D CYL RAO615X BATCH. ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES. TANGENTIAL DATA (BLUE LINE) IS THE LOW-POWER MERIDIAN AND SAGITTAL DATA (DOTTED-RED LINE) IS THE HIGH-POWER MERIDIAN

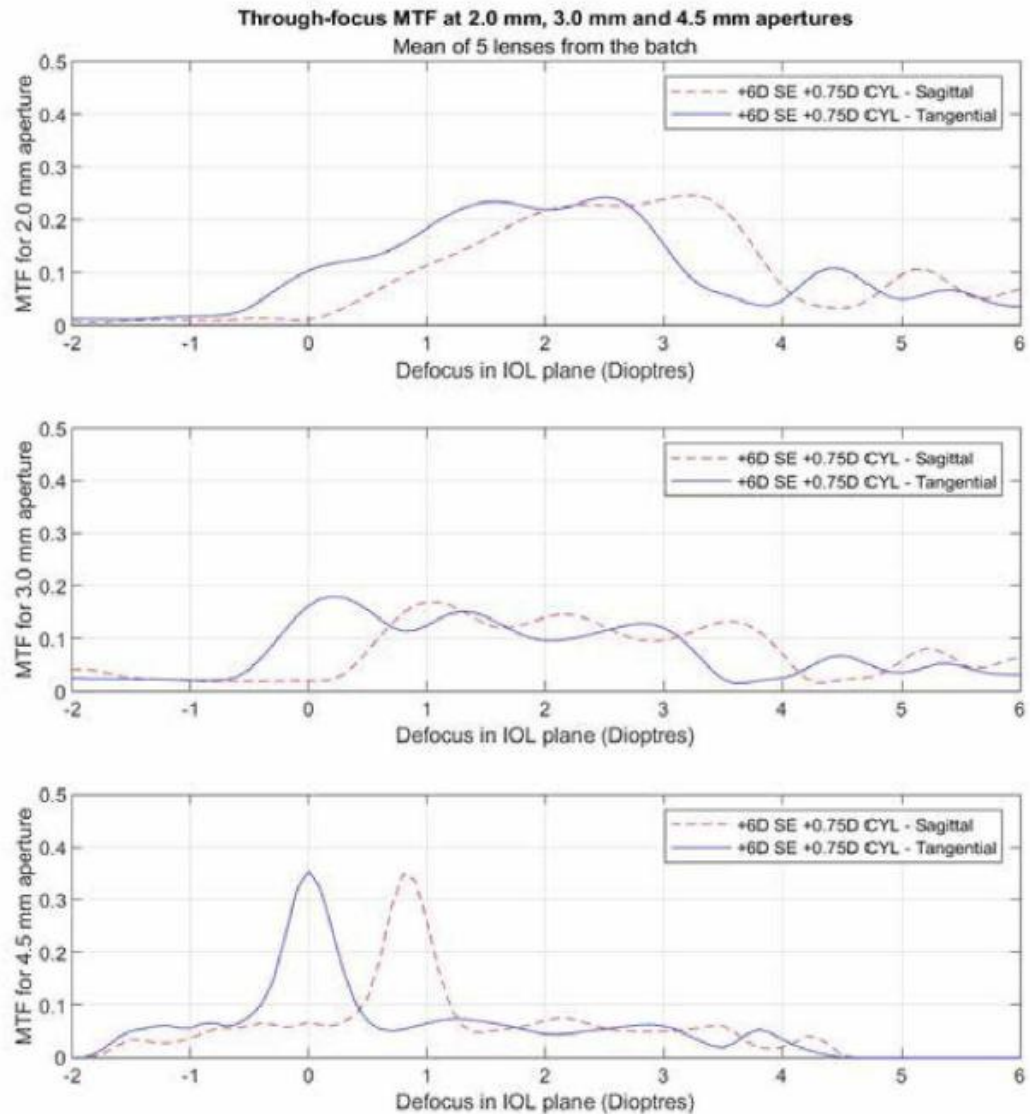


FIGURE 5 +6.0D SE +4.50D CYL RA0615X BATCH. ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES. TANGENTIAL DATA (BLUE LINE) IS THE LOW-POWER MERIDIAN AND SAGITTAL DATA (DOTTED-RED LINE) IS THE HIGH-POWER MERIDIAN

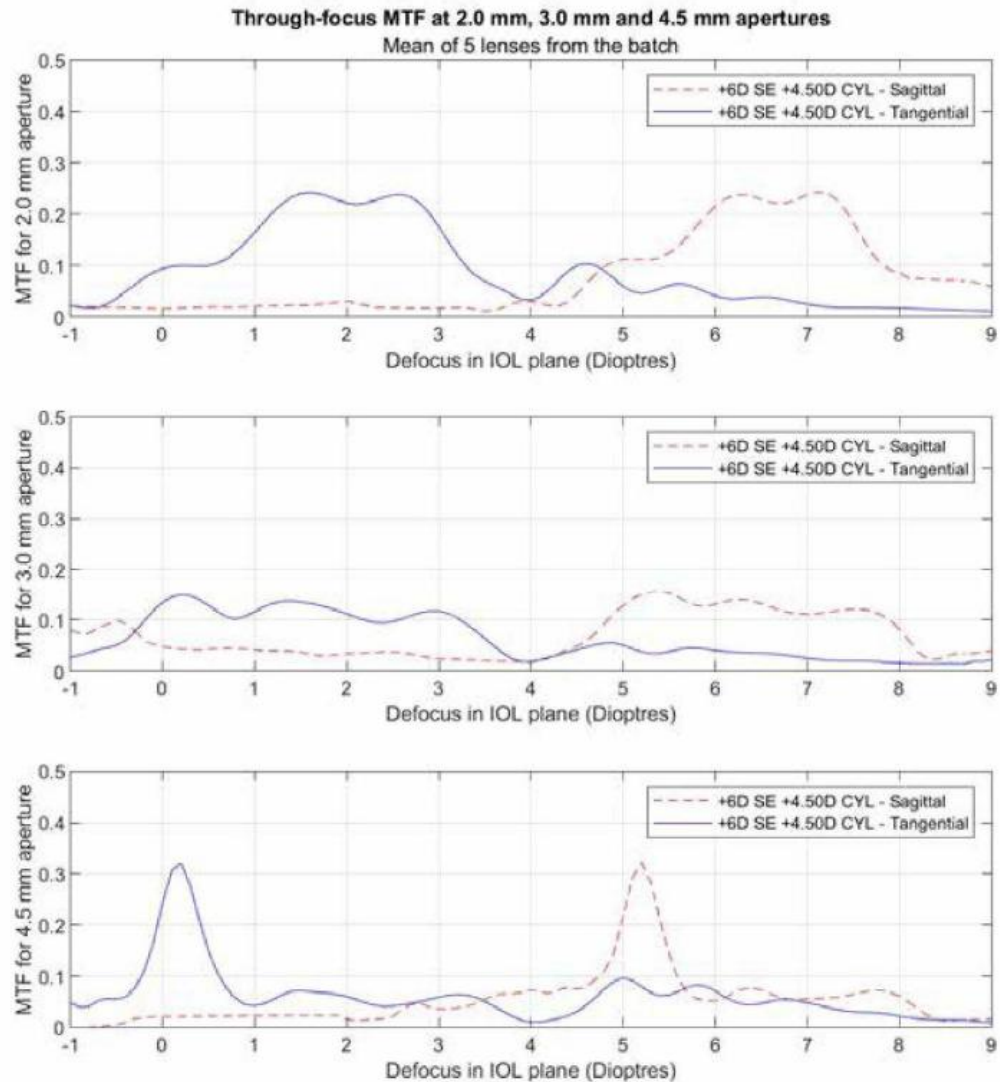


FIGURE 6 +20.0D SE +0.75D CYL RAO615X BATCH. ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES. TANGENTIAL DATA (BLUE LINE) IS THE LOW-POWER MERIDIAN AND SAGITTAL DATA (DOTTED-RED LINE) IS THE HIGH-POWER MERIDIAN

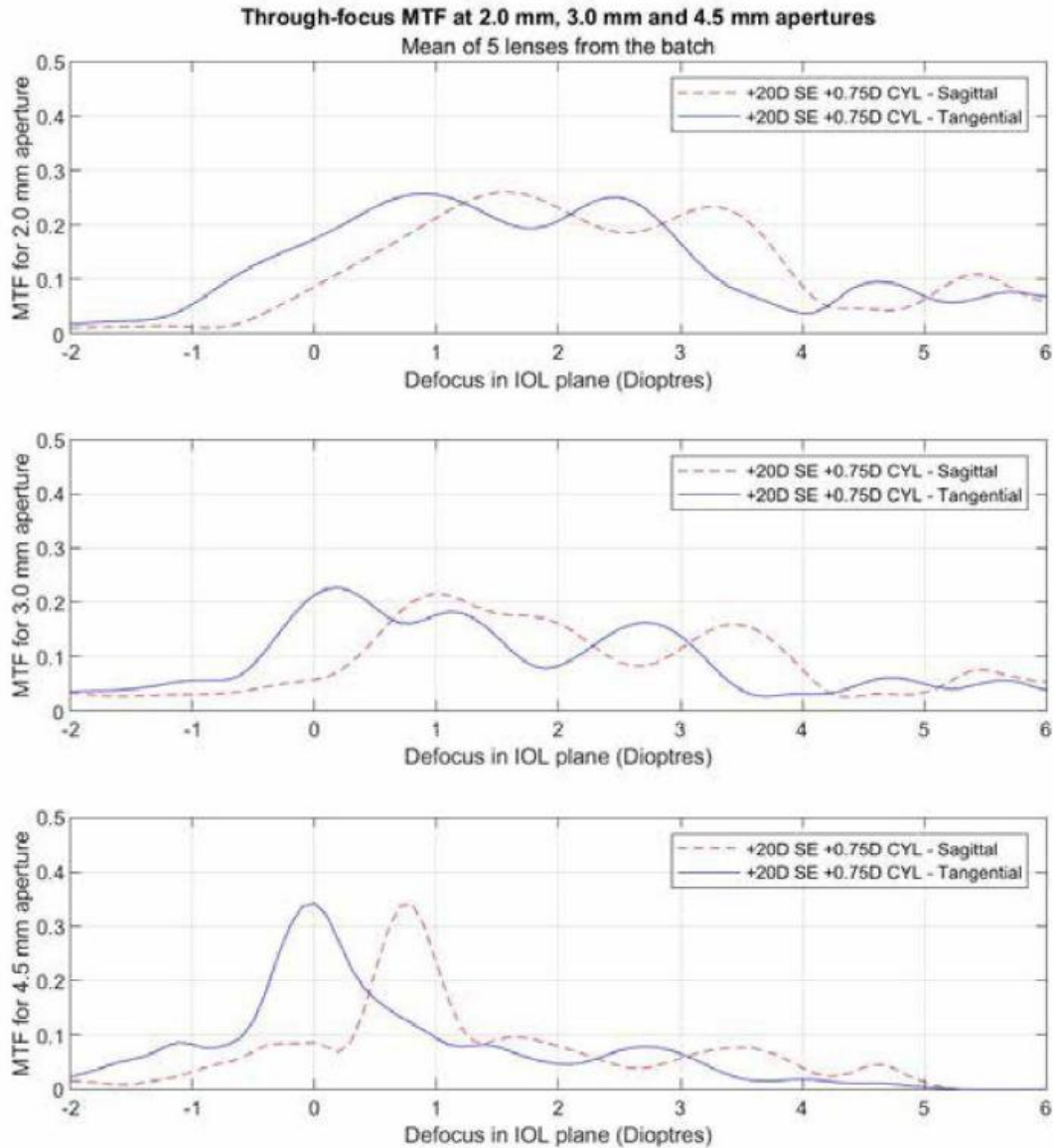


FIGURE 7 +20.0D SE +4.50D CYL RAO615X BATCH. ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES. TANGENTIAL DATA (BLUE LINE) IS THE LOW-POWER MERIDIAN AND SAGITTAL DATA (DOTTED-RED LINE) IS THE HIGH-POWER MERIDIAN

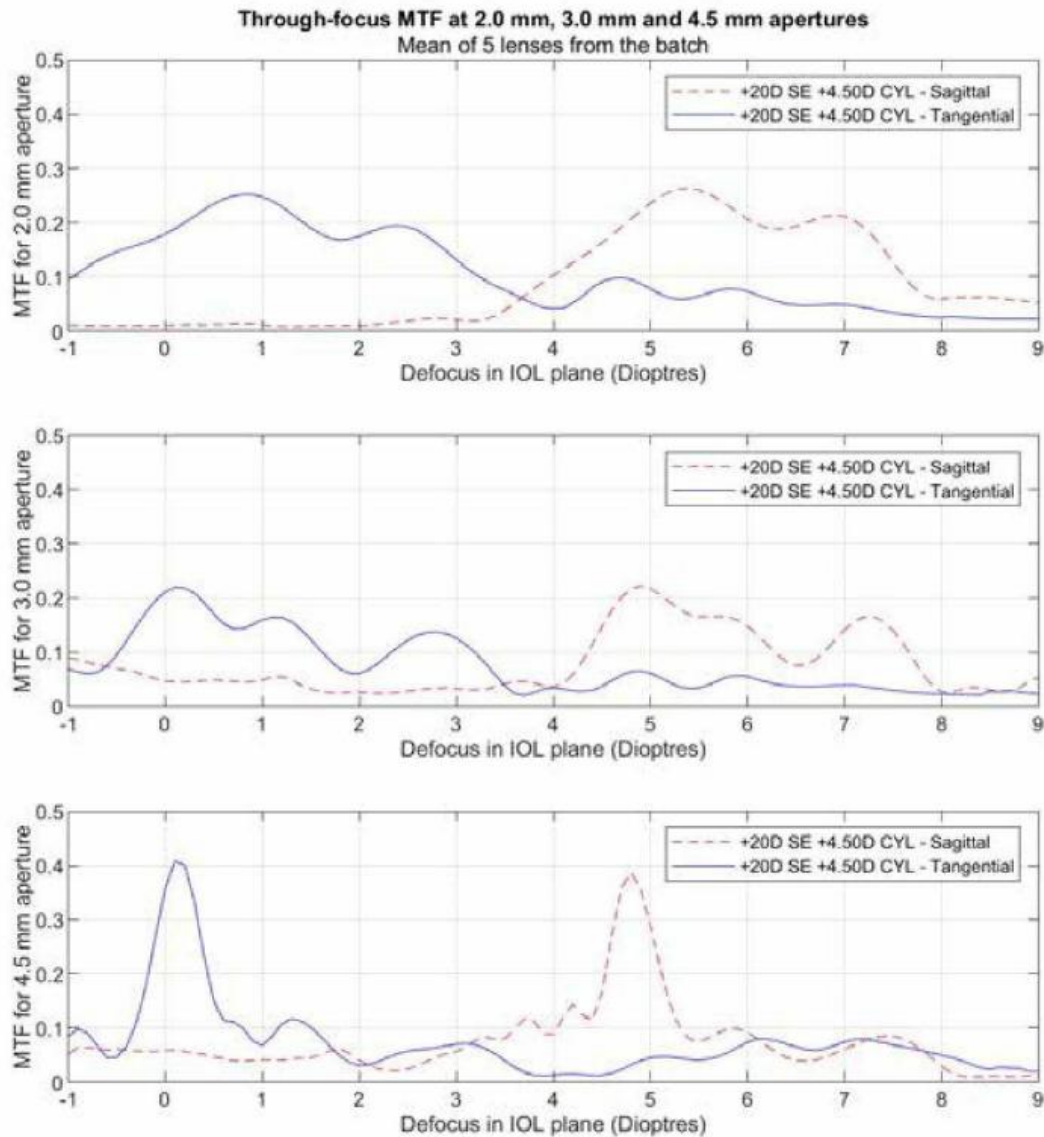


FIGURE 8 +30.0D SE +0.75D CVL RAO615X BATCH. ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES. TANGENTIAL DATA (BLUE LINE) IS THE LOW-POWER MERIDIAN AND SAGITTAL DATA (DOTTED-RED LINE) IS THE HIGH-POWER MERIDIAN

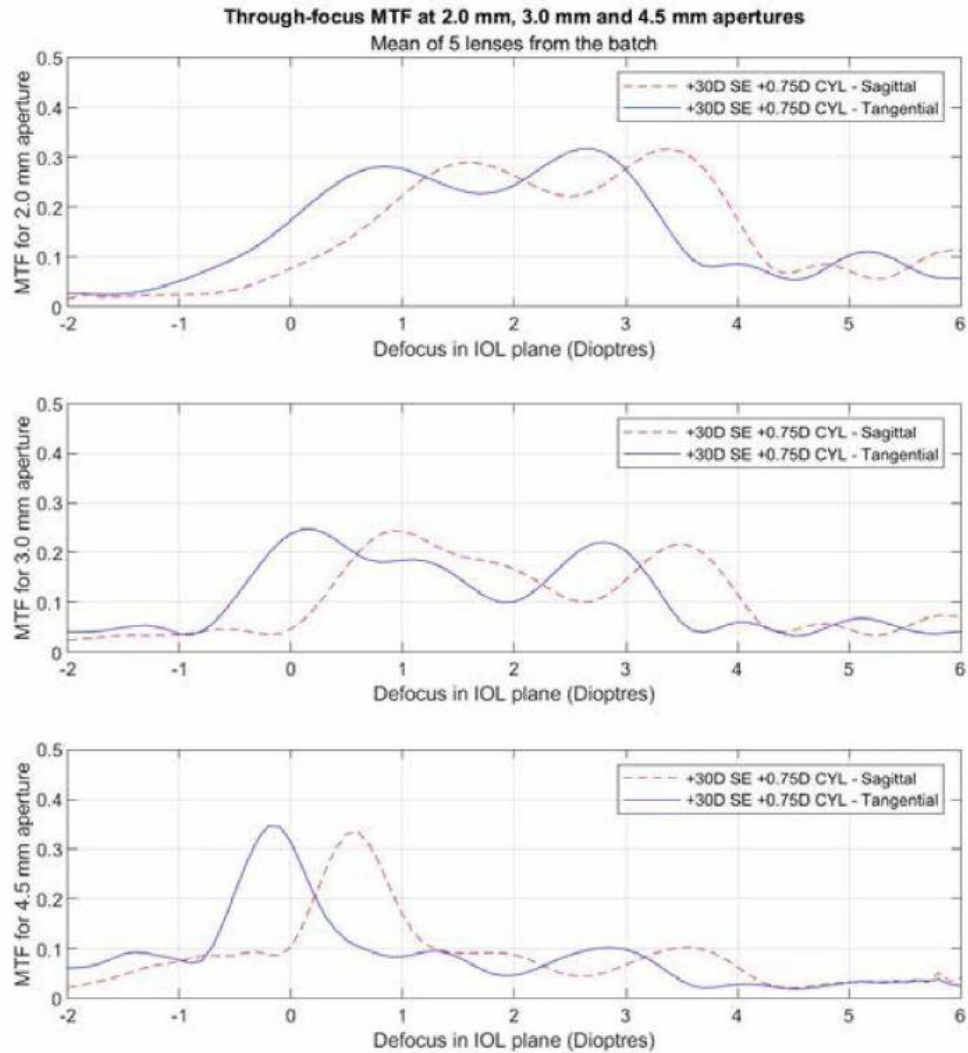
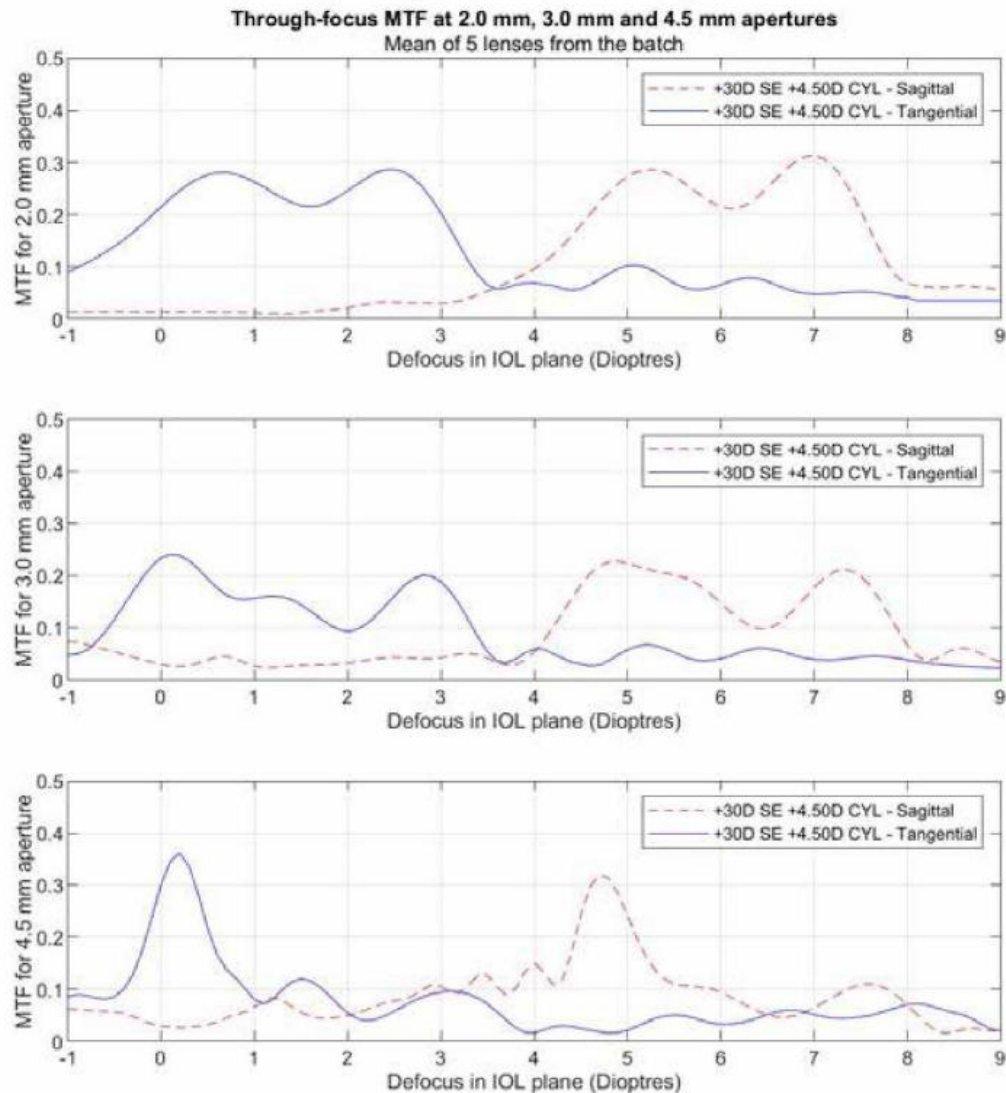


FIGURE 9 +30.0D SE +4.50D CYL RA0615X BATCH. ON-AXIS TF-MTF RESPONSE AT 50 LP/MM, FOR 2.0 MM (TOP), 3.0 MM (MIDDLE) AND 4.5 MM (BOTTOM) APERTURE SIZES. TANGENTIAL DATA (BLUE LINE) IS THE LOW-POWER MERIDIAN AND SAGITTAL DATA (DOTTED-RED LINE) IS THE HIGH-POWER MERIDIAN



Injector Validation

Injector validation was conducted as part of the mechanical and optical testing of the Galaxy, including the visual inspection of the IOL and injector pre-and post-injection. The test results summarized above reflect the compatibility of the RayOne injector and Galaxy IOL.

The testing demonstrated that the Galaxy IOL can be successfully delivered across the entire range of IOLs using OphteisBio 3.0% viscoelastics.

Sterilization and Shelf-Life Evaluation

The RayOne Galaxy and RayOne Galaxy Toric are sterilized by moist heat. Sterilization evaluation, shelf-life and transport stability testing, and bacterial endotoxin testing were performed to support the RayOne Galaxy and RayOne Galaxy Toric. The results are summarized in **TABLE 9**.

TABLE 9 STERILIZATION AND SHELF-LIFE TESTING

Test	Purpose	Acceptance Criteria	Results
Moist heat sterilization validation (Overkill method) (ISO 17665-1, ISO 17665-2 & ISO 17665-3)	Determination of process parameters for routine sterilization of product, and demonstration that these process parameters can adequately achieve a Sterility Assurance Level (SAL) of 1.0E-6, based upon inactivation of control biological indicators (BIs, <i>G. stearothersophilus</i>) in process challenge devices (PCDs). Validated process parameters will be used for parametric release upon confirmation that Independent Recorder and controller meet batch release requirements.	Successful performance of Installation Qualification (IQ), Operational Qualification (OQ) and both Microbiological and Physical Performance Qualification (PQ) studies. The Microbiological PQ study requires total inactivation of BIs upon exposure to a half-cycle (e.g., half of the routine full-cycle exposure time) that meets the designated parameters. The Physical PQ study requires that routine full-cycle parameters can be achieved with minimum and maximum sterilization loads. Together these PQ results will demonstrate the routine sterilization process can achieve an $SAL \leq 1.0E-6$.	Passed
Transport stability (ISO 11979-6, ISO 11607-1, ASTM F1886, ASTM D4991, ASTM F1929, ASTM F88, &ASTM F1140)	Confirm that both the inner tray and outer pouch sterile barrier packaging can maintain device sterility throughout anticipated transport conditions. Testing includes visual inspection, whole package integrity (dye immersion – weight change, validated alternative method) and seal integrity assessments (seal peel and dye penetration testing for inner tray; burst test and dye penetration for outer pouch) after transport conditioning.	Meets sterile barrier packaging visual inspection, whole package integrity & seal integrity requirements. For visual inspection, no channels, voids, punctures, or breaches observed, and labels are legible. For dye immersion, - weight change, there is no reduction in weight of the inner tray after it is held under vacuum for 30 minutes in vacuum chamber. For seal peel strength, average peel strength exceeds minimum force. For burst test, internal pressure exceeds minimum burst pressure before package failure. For dye penetration, no penetration of dye into seal area is observed.	Passed

Test	Purpose	Acceptance Criteria	Results
Shelf-life (ISO 11979-6, ISO 11607-1, ASTM F1886, ASTM D4991, ASTM F1929, ASTM F88, &ASTM F1140)	Confirm that both the inner tray and outer pouch sterile barrier packaging can maintain device sterility throughout claimed shelf life. Testing includes visual inspection, whole package integrity (dye immersion– weight change, validated alternative method) and seal integrity assessments (seal peel and dye penetration testing for inner tray; burst test and dye penetration for outer pouch) after aging (both accelerated aging and real-time aging conditions).	Meets sterile barrier packaging visual inspection, whole package integrity & seal integrity requirements. For visual inspection, no channels, voids, punctures, or breaches observed, and labels are legible. For dye immersion, - weight change, there is no reduction in weight of the inner tray after it is held under vacuum for 30 minutes in vacuum chamber. For seal peel strength, average peel strength exceeds minimum force. For burst test, internal pressure exceeds minimum burst pressure before package failure. For dye penetration, no penetration of dye into seal area is observed.	Passed
Bacterial Endotoxin Testing (ANSI/AAMI ST72, USP<85>, FDA Guidance on Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices)	Confirm that Endotoxin present on product is below the permanent intraocular device limit to confirm product is non-pyrogenic.	≤ 0.2 Endotoxin Units (EU)/device	Passed
Bioburden Estimation Testing (ISO 11737-1)	Confirm that naturally occurring Bioburden is controlled on product and in manufacturing environment.	Less than the Specification Limit of < 100 Colony Forming Units (CFU)/device	Passed

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of implantation with the RayOne Galaxy (Model RAO605G) multifocal intraocular lens for the visual correction of aphakia in adults in whom a cataractous lens has been removed by phacoemulsification extraction in the US under IDE # G210105. Data from this clinical study were the basis for the PMA approval decision.

Clinical studies have been conducted on the C-flex 570C IOL (G020115), RayOne EMV Toric (G230072) and RayOne Galaxy (G210105). RayOne EMV Toric is a combination of the optical design of the C-flex and RayOne EMV parent lenses. RayOne Galaxy Toric is a combination of the optical design of RayOne Galaxy (anterior surface) and RayOne EMV Toric (posterior surface) and was approved under P060011/S039. Clinical data from the RayOne EMV Toric was leveraged for approval of the RayOne Galaxy Toric (Model RAO615X), therefore clinical data presented in the labeling of the RayOne Galaxy Toric is not incorporated into this SSED.

Summaries of these clinical studies are presented below.

Clinical Data on C-flex

The Rayner C-flex 570C intraocular lens study was a multi-center IDE clinical trial (G020115), with a historical control designed to assess safety and effectiveness. Three hundred and one (301) C-flex subjects were enrolled (unilateral implants) in this investigation. Additionally, data from one hundred and eighty-two (182) model Centerflex IOL subjects was used as supportive data. The Centerflex IOL is identical to the C-flex model in all aspects except that the C-flex additionally features an Enhanced Square Edge. This feature is a 360° raised ridge encircling the periphery of both the anterior and posterior surfaces of the optic body (including the optic-haptic junction). The Rayner C-flex IOL met or exceeded historical controls for posterior chamber IOLs in all areas, for best corrected visual acuity at the 12 months post-operative examination. Safety was evaluated regarding specific cumulative adverse event rates and persistent adverse events rates as specified in ISO 11979-7. Primary safety analyses were based on data from all enrolled procedures with follow-up to at least one-year post implantation. The pooled C-flex and Centerflex cumulative and persistent adverse event rates at 12-months were lower than the FDA historical control grid in all areas except persistent macular edema, persistent corneal edema and cumulative pupillary block. These rates were higher than the grid rate, but the differences were not statistically significant. The results achieved by 283 patients in the C-flex 570C study and 166 patients in the Centerflex IOL study followed for one year, provide the basis for the data which were used to support that the EMV IOL (200E) design can be used for the visual correction of aphakia. Clinical studies were not conducted with the EMV IOL (200E) to assess the effect of its aspheric surface or increased optic size and overall diameter on spherical aberration, visual acuity or contrast sensitivity.

Clinical Data on RayOne EMV Toric RAO210T

The US IDE clinical study to establish a reasonable assurance of safety and effectiveness of implantation with the RayOne EMV Toric IOL for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens in the US under IDE # G230072. The study data support a significant dioptric reduction in refractive cylinder and reduction in absolute cylinder, rotational stability of the lens, and UDVA following implantation of the RayOne EMV Toric IOL. RayOne EMV Toric received marketing approval from the Agency on October 9, 2025, under Panel Track Supplement, P060011/S039.

The clinical study that supported the marketing approval of the RayOne EMV Toric (Model RAO210T) established the safety profile of the toric device.

The toric feature of the RayOne EMV Toric IOL (Model RAO210T) is incorporated into the posterior surface of the RayOne Galaxy Toric (Model RAO615X) IOL, which also includes on its anterior surface, the optical design of the RayOne Galaxy (Model RAO605G) IOL.

The summary of the RayOne Galaxy (Model RAO605G) IOL clinical study is presented below. Based on the results of the RayOne Galaxy (Model RAO605G) study and the above-mentioned RayOne EMV Toric (Model RAO210T) study, no additional clinical data were required to support the safety and effectiveness of the RayOne Galaxy Toric (Model RAO615X).

In addition, the material used to manufacture the RayOne Galaxy Toric (Model RAO615X) was approved by the U.S. Food and Drug Administration under PMA P060011 on May 3, 2007.

Clinical Data on RayOne Galaxy RAO605G

A. Study Design

Patients were treated between September 26, 2024 and April 18, 2025. The database for this Panel Track Supplement reflected data collected through September 2, 2025 and included 254 patients. There were 10 investigational sites.

The study was a prospective, multicenter, randomized, active-controlled, masked, pivotal clinical study based on ISO 11979-7:2024.

The control group was the RayOne Aspheric (Model RAO600C) monofocal IOL, a legally marketed alternative with similar indications for use.

The study compared the RayOne Galaxy (Model RAO605G) multifocal IOL (investigational device) with the RayOne Aspheric (Model RAO600C) monofocal IOL (control device) following approximately 6 months (120 to 180 days) of post-operative assessment.

Patients who signed the informed consent form (ICF) were considered enrolled in the study and subsequently screened for eligibility. Inclusion and exclusion criteria were required to be applied prior to subject randomization. Patients who met all protocol-specified eligibility criteria were randomized to one of the two study arms to receive either the RayOne Galaxy Multifocal IOL (test) or the RayOne Aspheric Monofocal IOL (control) in both eyes. The first eye (A) which underwent cataract surgery and IOL implantation was the eye with worse pre-operative best corrected distance visual acuity (BCDVA). If pre-operative BCDVA was the same for each eye, the right eye was selected as the first eye. Patients underwent cataract surgery and IOL implantation in the second eye (B) 7 to 30 days following surgery on the first eye.

Patients and site personnel performing post-operative manifest refraction and visual acuity assessments, including defocus curve testing and contrast sensitivity, as well as personnel administering assessments of pupil size, patient-reported outcome measures, and non-directed assessment of visual symptoms, were masked to treatment assignment. Patients were also masked to their IOL assignment.

The clinical data source was the U.S. IDE clinical trial of the RayOne Galaxy (IDE G210105), which included 230 randomized Patients at 10 U.S. investigational sites.

The statistical analysis plan included protocol-specified safety and effectiveness performance criteria and comparative hypothesis testing. Primary effectiveness analyses were conducted using the Intent-to-Treat (ITT) Set, with First Implanted eyes serving as the primary eyes for analysis. The co-primary effectiveness endpoints were mean photopic monocular BCDVA at 4 meters (m) and photopic monocular distance corrected near visual acuity (DCNVA) at 40 cm in First Implanted eyes at 120 to 180 days post-operatively (Visit 4). The BCDVA endpoint was evaluated against a prespecified performance criterion, and the DCNVA endpoint compared the Multifocal and Monofocal groups using a one-sided t-test for superiority. Up to 288 patients were planned to be enrolled, with up to 230 patients randomized and at least 100 patients in each treatment group completing the 6-month follow-up. The sample size was based on the following assumptions (**TABLE 10**). Missing Visit 4 values for the primary effectiveness analyses were addressed using multiple imputation under a missing-at-random assumption.

TABLE 10 SAMPLE SIZE CALCULATIONS FOR EACH DISTANCE (4M, 66 CM AND 40CM)

	Margin	Expected Difference	SD	Type I error (one-sided)	Power
Non-inferiority					
BCDVA (4m)	0.1	0.0	0.10	2.5%	>99%
Superiority					
DCNVA (40cm)		-0.10	0.14	2.5%	>99%
DCIVA (66cm)		-0.10	0.14	2.5%	>99%

Abbreviations: BCDVA = Best Corrected Distance Visual Acuity; DCNVA = Distance-Corrected Near Visual Acuity; DCIVA = Distance-Corrected Intermediate Visual Acuity; SD = Standard Deviation

Randomization was stratified by site, and the randomization schedule was created using computer-generated randomization methodology by an independent statistician who was not involved in the day-to-day conduct of the study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the RayOne Galaxy clinical study was limited to patients who met the following inclusion criteria and none of the exclusion criteria. All inclusion and exclusion ocular criteria were required to be satisfied in both eyes:

Inclusion Criteria:

- Male or female, 22 years or older at the pre-operative visit
- Have bilateral cataracts with BCDVA of 0.30 logMAR or worse in each eye with or without a glare source and are eligible for phacoemulsification cataract surgery in both eyes
- Be willing to undergo cataract surgery in the second eye 7 to 30 days after surgery in the first eye
- Subjects who are projected to have best corrected distance visual acuity 0.20 logMAR (20/30) or better after IOL implantation as determined by the medical judgment of the Investigator
- Clear intraocular media other than cataract
- Calculated IOL spherical equivalent power between +5.0 to +30.0 D in 0.50 D steps
- If a contact lens wearer, willing to discontinue wearing of rigid gas-permeable (RGP) contact lenses for ≥ 14 days or soft contact lenses (SCL) for ≥ 3 days prior to the pre-operative visit
- Contact lens wearers must demonstrate stability of keratometry. (For pre-operative keratometry recorded on two consecutive examination dates at least one week apart after lens discontinuation, the difference between two consecutive readings for vertical as well as horizontal are no more than 0.50 D, and changes in keratometric axes is no more than $\pm 15^\circ$.)
- Available and willing to comply with examination procedures and study visits
- Have the capability to understand and sign an IRB approved informed consent form and privacy authorization in accordance with local regulations
- Female subjects must be postmenopausal, surgically sterilized, or, if of childbearing potential, have a negative urine pregnancy test at the Pre-operative Visit. Women of childbearing potential must use an acceptable form of contraception throughout the study. Acceptable methods include at least one of the following: intrauterine (intrauterine device), hormonal (oral, injection, patch, implant, ring), barrier with spermicide (condom, diaphragm), or abstinence.

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

Exclusion Criteria:

- Previous intraocular, corneal, or retinal detachment surgery, including corneal transplant, LASIK / LASEK / PRK, SMILE, astigmatic keratotomy and limbal relaxing incisions (Note: pterygium excision was not exclusionary)
- Diagnosed degenerative visual disorders (e.g. macular degeneration, retinal detachment, proliferative diabetic retinopathy, or other retinal disorders) that are predicted to cause future acuity losses to a level of 0.20 logMAR (20/30) or worse
- Significant anterior segment pathology that might increase intraoperative risk or compromise IOL stability (e.g. pseudoexfoliation syndrome)
- Subjects with conditions associated with increased risk of zonular rupture that may affect post-operative centration or tilt of IOL
- Potentially occludable angle or ciliary body tumor, or other pathology that might increase risk to subject safety, based on gonioscopic observation
- Subjects reasonably expected to require secondary ocular surgical intervention or laser treatment (other than YAG capsulotomy)
- Subjects with clinically significant corneal pathology
- Subjects with traumatic, congenital, or complicated cataract
- Participating in a concurrent drug or device clinical trial or who have participated in a drug or device trial within 30 days of the pre-operative visit
- Subjects with any other serious ocular pathology (e.g. glaucoma, severe dry eye, history of intraocular inflammation, history of retinal surgery or retinal laser procedure) or underlying systemic medical condition (e.g., uncontrolled diabetes) or circumstance that, based on the Investigator's judgment, poses a concern for the subjects' safety or could confound the results of the study
- Use of medications known to interfere with visual performance, pupil dilation, or iris structure within 30 days of the pre-operative visit, at the discretion of the Investigator
- Pregnant or nursing females
- Subjects with pre-existing anterior keratometric corneal astigmatism of 1.00 D or greater in either eye (Note: corneal incisions intended to reduce astigmatism are not permitted)
- Irregular astigmatism in either eye

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at Day 1 to 2, Day 7 to 14, and Day 30 to 60 following surgery in each eye, and Day 120 to 180 following surgery in the second implanted eye postoperatively. Cataract surgery and IOL implantation of the second eye were scheduled 7 to 30 days following surgery of the first eye.

The full schedule of events is provided in **TABLE 11**. The study comprised 10 scheduled visits, as shown below:

1. Pre-operative Visit A/B – Form 00 (-90 to 0 days)
2. Operative Visit A – Form 0 (Day 0)
3. Visit 1A – Form 1 (1 to 2 days post-operative)
4. Visit 2A – Form 2 (7 to 14 days post-operative)
5. Visit 3A – Form 3 (30 to 60 days post-operative)
6. Operative Visit B – Form 0 (Day 0)
7. Visit 1B – Form 1 (1 to 2 days post-operative)
8. Visit 2B – Form 2 (7 to 14 days post-operative)
9. Visit 3B – Form 3 (30 to 60 days post-operative)
10. Visit 4 – Form 4 (120 to 180 days post-operative from second implanted eye)

Preoperatively, informed consent, demographics, concomitant medications, ocular and significant non-ocular medical history, urine pregnancy testing (if applicable), photopic pupil size, photopic monocular UCDVA at 4 meters, manifest refraction, photopic monocular BCDVA at 4 m, potential visual acuity, corneal topography, keratometry/biometry/target refraction/IOL power calculation, slit lamp biomicroscopy, intraocular pressure, gonioscopy, and dilated fundus examination were performed in relation to the index procedure. Visual acuity assessments were performed using the M&S Clinical Trial Suite (M&S Technologies, Niles, IL, USA) computerized test system, early treatment diabetic retinopathy study (ETDRS) visual acuity testing.

Postoperatively, the objective parameters measured during the study included uncorrected distance visual acuity (UCDVA), manifest refraction, BCDVA, uncorrected intermediate visual acuity (UCIVA), DCIVA, uncorrected near visual acuity (UCNVA), DCNVA, pupil size, intraocular pressure, slit lamp biomicroscopy, posterior capsule opacification (PCO) assessment, IOL observations, lens stability (decentration and tilt), and dilated fundus examination. Visual acuity assessments were also performed using the M&S Clinical Trial Suite computerized test system, ETDRS visual acuity testing. At Visit 4, additional assessments included monocular and binocular visual acuity assessments, monocular and binocular best distance corrected defocus curves, monocular best corrected contrast sensitivity under mesopic without glare, mesopic with glare, and photopic with glare conditions, and patient reported outcome questionnaires. Contrast sensitivity was assessed monocularly using the M&S System with sin-wave gratings at 1.5, 3, 6, 12 and/or 189 cycles per degree (CPD) at a test distance of 2.5m. Non-directed assessment of visual symptoms was performed at postoperative visits. The specific assessments and the visits at which they were performed are provided in **TABLE 11**. Adverse events and complications were recorded at all visits.

TABLE 11 SCHEDULE OF EVENTS

	Both Eyes	First Implanted Eye (A) ¹				Second Implanted Eye (B)				Both Eyes
	Visit 00A/B Pre-Op	Visit 0A Operative	Visit 1A Post-Op	Visit 2A Post-Op	Visit 3A Post-Op	Visit 0B Operative ₂	Visit 1B Post-Op	Visit 2B Post-Op	Visit 3B Post-Op	Visit 4 Post-Op
Procedure	D -90 –D 0 (V0A) ³	Day 0	Day 1-2	Day 7-14	Day 30-60	Day 0	Day 1-2	Day 7-14	Day 30-60	Day 120-180 from 2nd eye
Informed Consent/HIPAA	X									
Inclusion/Exclusion Criteria Review	X	X ⁴				X ⁴				
Demographics	X									
Ocular and Significant Non-ocular Medical History	X*	X				X				
Urine Pregnancy Test (if applicable)	X									
Potential Visual Acuity	X*									
Keratometry / Biometry / Target refraction / IOL power calculation	X*									
Corneal Topography	X*									
Gonioscopy	X*									
Randomization	X									
Operative Procedures		X				X				
Non-directed Assessment of Visual Symptoms ⁵			X	X	X		X	X	X	X
Patient Reported Outcome Questionnaires ^{5,6}									X	X
Photopic Pupil size	X									X
Mesopic Pupil size ^{5,7}					X				X	X
Manifest Refraction [#] – 4 m ⁵	X			X	X			X	X	X

	Both Eyes	First Implanted Eye (A) ¹				Second Implanted Eye (B)				Both Eyes
	Visit 00A/B Pre-Op	Visit 0A Operative	Visit 1A Post-Op	Visit 2A Post-Op	Visit 3A Post-Op	Visit 0B Operative ₂	Visit 1B Post-Op	Visit 2B Post-Op	Visit 3B Post-Op	Visit 4 Post-Op
Procedure	D -90 –D 0 (V0A) ³	Day 0	Day 1-2	Day 7-14	Day 30-60	Day 0	Day 1-2	Day 7-14	Day 30-60	Day 120-180 from 2nd eye
UCDVA - Photopic, Monocular [#] – 4 m ⁵	X		X	X	X		X	X	X	X
UCDVA - Photopic, Binocular [#] – 4 m								X	X	X
BCDVA - Photopic, Monocular [#] – 4 m ⁵	X			X	X			X	X	X
BCDVA - Photopic, Binocular [#] – 4 m								X	X	X
BCDVA – Mesopic, Monocular [#] – 4 m										X
BCDVA – Mesopic, Binocular [#] – 4 m										X
UCNVA - Photopic Monocular [#] – 40 cm					X				X	X
UCNVA - Photopic Binocular [#] – 40 cm									X	X
DCNVA - Photopic Monocular [#] – 40 cm					X				X	X
DCNVA - Photopic Binocular [#] – 40 cm									X	X
DCNVA - Mesopic Monocular [#] – 40 cm					X				X	X
DCNVA - Mesopic Binocular [#] – 40 cm									X	X
BCNVA – Photopic Monocular [#] – 40 cm										X
BCNVA – Photopic Binocular [#] – 40 cm										X
UCIVA - Photopic Monocular [#] – 66 cm					X				X	X
UCIVA - Photopic Binocular [#] – 66 cm									X	X
DCIVA - Photopic Monocular [#] – 66 cm					X				X	X
DCIVA - Photopic Binocular [#] – 66 cm									X	X

	Both Eyes	First Implanted Eye (A) ¹				Second Implanted Eye (B)				Both Eyes
	Visit 00A/B Pre-Op	Visit 0A Operative	Visit 1A Post-Op	Visit 2A Post-Op	Visit 3A Post-Op	Visit 0B Operative ₂	Visit 1B Post-Op	Visit 2B Post-Op	Visit 3B Post-Op	Visit 4 Post-Op
Procedure	D -90 –D 0 (V0A) ³	Day 0	Day 1-2	Day 7-14	Day 30-60	Day 0	Day 1-2	Day 7-14	Day 30-60	Day 120- 180 from 2nd eye
DCIVA - Mesopic Monocular [#] – 66 cm					X				X	X
DCIVA - Mesopic Binocular [#] – 66 cm									X	X
Monocular Best Distance Corrected Defocus Curves – 4 m (first implanted eyes)										X
Binocular Best Distance Corrected Defocus Curves – 4 m										X
Contrast Sensitivity - Monocular Best Corrected (Mesopic without glare) – 2.5 m (first implanted eyes)										X
Contrast Sensitivity - Monocular Best Corrected (Mesopic with glare) – 2.5 m (first implanted eyes)										X
Contrast Sensitivity - Monocular Best Corrected (Photopic with glare) – 2.5 m (first implanted eyes)										X
Intraocular Pressure ⁵	X*		X	X	X		X	X	X	X
Slit lamp Biomicroscopy ⁵	X*		X	X	X		X	X	X	X
Posterior Capsule Opacification (PCO) Assessment ⁵ (dilated)			X	X	X		X	X	X	X
IOL Observations ⁵ (dilated)			X	X	X		X	X	X	X

	Both Eyes	First Implanted Eye (A) ¹				Second Implanted Eye (B)				Both Eyes
	Visit 00A/B Pre-Op	Visit 0A Operative	Visit 1A Post-Op	Visit 2A Post-Op	Visit 3A Post-Op	Visit 0B Operative ₂	Visit 1B Post-Op	Visit 2B Post-Op	Visit 3B Post-Op	Visit 4 Post-Op
Procedure	D -90 –D 0 (V0A) ³	Day 0	Day 1-2	Day 7-14	Day 30-60	Day 0	Day 1-2	Day 7-14	Day 30-60	Day 120-180 from 2nd eye
Lens Stability - decentration and tilt (dilated) ⁵					X				X	X
Dilated Fundus Exam ^[5] (including Fundus Visualization at follow-up)	X*				X				X	X
Adverse Events ⁵	X	X	X	X	X	X	X	X	X	X
Device Deficiencies ⁵		X	X	X	X	X	X	X	X	X
Concomitant Medications ⁵	X	X	X	X	X	X	X	X	X	X
Exit from Study										X

1. The first implanted eye (A) was the eye with the worse preoperative BCDVA. If BCDVA of both eyes is the same, the first implanted eye (A) was the right eye
2. Must occur 7-30 days after first eye (A) Operative Visit
3. Pre-operative window for both eyes is within 90 days of the Operative visit for the first implanted eye (Visit 0A)
4. Review of inclusion/exclusion criteria before surgery
5. To be completed at post-operative Unscheduled Visit (USV), as specified
6. To be completed at any USV after Visit 2B post-operative
7. To be assessed at any USV or after Visit 3, if subject complains of severe visual symptoms. (Note: mesopic pupil size is included in the assessments at scheduled visits of V3 and V4)

* Assessments performed as standard of care within the -90 – 0 pre-operative visit screening window may be used as qualifying assessments prior to date of informed consent.

[] Optional at USV, based on Investigator's discretion

Visual acuity assessments performed using computerized ETDRS charts

Note: For study visits designated A or B, 'A' represents the first eye implanted (Eye A), and 'B' represents the second eye implanted (Eye B).

Monocular assessments were performed at Visits 1 A/B, 2 A/B, and 3 A/B for only Eye A or only Eye B, respectively, unless binocular assessments are specified. At Visit 4, monocular assessments and binocular assessments were completed for both eyes, unless otherwise noted.

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

3. Clinical Endpoints

With regards to safety:

- *Primary Safety Endpoints*
 - Rates of device-related secondary surgical interventions related to the optical properties of the investigational device through 120 to 180 days post-operatively (Visit 4)
 - Rates of BCDVA of 0.30 logMAR or better at 120 to 180 days post-operatively (Visit 4) compared to the ISO Safety and Performance Endpoint (SPE) rates as described in ISO 11979-7 (2024)
 - Rates of IOL adverse events through 120 to 180 days post-operatively (Visit 4) compared to the ISO SPE rates as described in ISO 11979-7 (2024)
 - Rates of all other adverse events not included in IOL adverse events from ISO 11979-7 (2024) through 120 to 180 days post-operatively (Visit 4)
 - Rates of adverse events defined in Masket et al.¹ through 120 to 180 days post-operatively (Visit 4)
- *Secondary Safety Endpoint*
 - Frequency and proportion of subjects with visual disturbances reported as severe or most bothersome, collected via a Patient-Reported Outcomes (PRO) survey using the Quality of Vision (QoV) questionnaire and Patient Vision Questionnaire 120 to 180 days post-operatively (Visit 4)
- *Additional Safety Endpoints*
 - Mean monocular distance contrast sensitivity (mesopic without glare, mesopic with glare, photopic with glare) in first implanted eyes 120 to 180 days post-operatively (Visit 4)
 - BCDVA at 120 to 180 days post-operatively (Visit 4) stratified by:
 - Age (< 65 and ≥ 65 years)
 - Investigator

¹ Masket S, Rorer E, Stark W, Holladay JT, MacRae S, Tarver ME, Glasser A, Calogero D, Hilmantel G, Nguyen T, Eydelman M. Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with Intraocular Lenses. *Ophthalmology*. 2017 Jan;124(1):142-144. doi: 10.1016/j.ophtha.2016.09.031.

- Adverse Events
 - Rates and causes of loss of BCDVA of 0.20 logMAR or worse between one form evaluation and a second later form evaluation
 - Frequency and proportion of subjects with visual disturbances collected via a PRO survey using the QoV questionnaire and Patient Vision Questionnaire 120 to 180 days post-operatively (Visit 4)
 - Frequency and proportion of eyes with ocular/visual symptoms (non-directed complaints) collected via open-ended questions at 120 to 180 days (Visit 4)
 - Frequency and percentage of fundus visualization at 120 to 180 days post-operatively (Visit 4)

With regards to effectiveness:

- *Primary Effectiveness Endpoints*
 - Mean photopic monocular best corrected distance visual acuity (BCDVA) at 4 meters in First Implanted eyes (performance criterion: ≤ 0.20 logMAR) 120 to 180 days post-operatively (Visit 4)
 - Photopic monocular distance-corrected near visual acuity (DCNVA) at 40 cm in First Implanted eyes 120 to 180 days post-operatively (Visit 4)
- *Secondary Effectiveness Endpoints*
 1. Photopic monocular BCDVA at 4 meters in First Implanted eyes 120 to 180 days post-operatively (Visit 4)
 2. Photopic monocular distance-corrected intermediate visual acuity (DCIVA) at 66 cm in First Implanted eyes 120 to 180 days post-operatively (Visit 4)
 3. Mean photopic monocular DCIVA at 66 cm in First Implanted eyes (performance criterion: ≤ 0.20 logMAR) 120 to 180 days postoperatively (Visit 4)
 4. Mean photopic distance-corrected visual acuity (DCVA) in First Implanted eyes (performance criterion: ≤ 0.20 logMAR) 120 to 180 days postoperatively (Visit 4) at the following distances:
 - 1.0 m
 - 50 cm
 5. Mean photopic monocular DCNVA at 40 cm in First Implanted eyes (performance criterion: ≤ 0.20 logMAR) 120 to 180 days postoperatively (Visit 4)

6. Binocular best corrected distance defocus curves at 120 to 180 days post-operatively (Visit 4)

- *Additional Effectiveness Endpoints*

- Photopic monocular logMAR BCDVA (4 m), DCIVA (66 cm), and DCNVA (40 cm) in first eyes implanted, second (“fellow”) eyes, and all eyes
- Photopic monocular logMAR BCNVA (40 cm) in first eyes implanted, second (“fellow”) eyes, and all eyes
- Mesopic monocular logMAR BCDVA (4m), DCIVA (66 cm) and DCNVA (40 cm) in first eyes implanted, second (“fellow”) eyes, and all eyes
- Photopic binocular logMAR BCDVA (4 m), DCIVA (66 cm), and DCNVA (40 cm)
- Photopic binocular logMAR BCNVA (40 cm)
- Mesopic binocular logMAR BCDVA (4m), DCIVA (66 cm) and DCNVA (40 cm)
- Mesopic monocular logMAR DCIVA (Multifocal (test) group) compared to mesopic monocular logMAR BCDVA (control group) in first implanted eyes, second (“fellow”) eyes, and all eyes
- Mesopic monocular logMAR DCNVA (Multifocal (test) group) compared to mesopic monocular logMAR BCDVA (control group) in first implanted eyes, second (“fellow”) eyes, and all eyes
- Photopic monocular logMAR UCDVA (4 m), UCIVA (66 cm), and UCNVA (40 cm) in first implanted eyes, second (“fellow”) eyes, and all eyes
- Photopic binocular logMAR UCDVA (4 m), UCIVA (66 cm), and UCNVA (40 cm)
- Residual manifest refractive error from subjective manifest refraction in first implanted eyes, second (“fellow”) eyes, and all eyes 120 to 180 days post-operatively (Visit 4)
 - Mean error
 - Mean and median absolute error
- Percentage of eyes (first implanted eyes, second (“fellow”) eyes, and all eyes) that achieve intended vs achieved Spherical Equivalent within
 - - +/- 0.50 D
 - - +/-1.00 D

- Percentage of eyes (first implanted eyes, second (“fellow”) eyes, and all eyes) that achieve UCDVA within
 - 0.00 logMAR or better
 - 0.20 logMAR or better
- Percentage of eyes (first implanted eyes, second (“fellow”) eyes, and all eyes) that achieve BCDVA within
 - 0.00 logMAR or better
 - 0.20 logMAR or better

Monocular best corrected distance defocus curves in first implanted eyes at 120 to 180 days post-operatively (Visit 4)

With regard to success/failure criteria, the RayOne Galaxy (Model RAO605G) IOL was considered successful as an MIOL if both primary effectiveness endpoints and all primary safety endpoints were met. Secondary effectiveness endpoints were evaluated using a fixed-sequence testing approach. Each secondary effectiveness endpoint was considered successful if the endpoint and all preceding secondary effectiveness endpoints were successful. The RayOne Galaxy (Model RAO605G) IOL would have been considered successful as a full visual range (FVR) IOL if all secondary effectiveness endpoints were met. A separate composite definition of individual patient success was not prespecified.

B. Accountability of PMA Cohort

At the time of database lock, of 254 patients enrolled in the PMA study, 230 patients were randomized and constituted the ITT population, of whom 95.2% (219/230) were available for analysis at the completion of the study, the 6-month (120 to 180 days) post-operative visit (Visit 4), the final visit evaluated for safety and effectiveness as the basis for the PMA submission.

i. Analysis Sets

Refer to **TABLE 12** for the number and percentage of subjects included in the study analysis sets. In all tables, ‘N’ refers to the total number of subjects (Multifocal or Monofocal) in the specified analysis set (e.g., ITT or Safety, as indicated). The sets are defined as follows:

- All Enrolled Set – All subjects who signed informed consent.
- Intent-to-Treat (ITT) Set – All enrolled subjects who were randomized.
- Safety Set (SAF) – All ITT subjects who underwent surgery and were exposed to an IOL. Summaries and analyses based on the Safety Set were analyzed according to IOL actually implanted. If no IOL was successfully implanted, but the IOL touched the eye, the subject was analyzed by the attempted lens. If a subject underwent surgery yet no IOL touched the eye, the subject was analyzed in a separate Not Treated group. If it was confirmed that a subject did not undergo surgery, then the subject was excluded from all safety analyses.

- Per Protocol (PP) Set – All SAF subjects who were successfully implanted with a study lens and who had no major protocol deviations.
- Best Case Set (BCS) – All PP subjects who also met the following criteria:
 - No clinically significant pre-operative ocular pathology in the first implanted eye, including any of the following present prior to the Operative Visit:
 - Pseudoexfoliation
 - Glaucoma
 - Uveitis
 - Retinal detachment
 - Diabetic retinopathy
 - Macular degeneration
 - Amblyopia
 - Other preoperative pathologies that are likely to affect central acuity
 - No macular degeneration detected at any time.
 - No previous surgery for the correction of refractive errors, which would have resulted in exclusion of the subject from the study.

TABLE 12 SUBJECT ANALYSIS SETS

Population (N=230 Randomized)	n (%)
Intent-to-Treat Set	230
RAO605G Multifocal IOL	114 (49.6%)
RAO600C Monofocal IOL	116 (50.4%)
Safety Set	227 (98.7%)
RAO605G Multifocal IOL	112 (49.3%)
RAO600C Monofocal IOL	115 (50.7%)
Per Protocol Set	209 (90.9%)
RAO605G Multifocal IOL	101 (48.3%)
RAO600C Monofocal IOL	108 (51.7%)
Best Case Set	207 (90.0%)
RAO605G Multifocal IOL	101 (48.8%)
RAO600C Monofocal IOL	106 (51.2%)

Abbreviations: n = number of subjects in the specified analysis set or treatment group; N = total number of randomized subjects. Analysis-set percentages are based on the total number of randomized subjects (N = 230). Treatment-group percentages within each analysis set are based on the total number of subjects in that analysis set.

ii. Accountability of PMA Cohort

Accountability for the ITT set of the Multifocal and Monofocal groups are shown in **TABLE 13**.

TABLE 12 presents the number of subjects in each analysis set for all randomized subjects. A total of 230 subjects were randomized in the study and constituted the Intent-to-Treat (ITT) set (114 Multifocal, 116 Monofocal). Of the 230 ITT subjects, 227 underwent surgery and comprised the Safety set. Of these, 209 subjects had no major protocol deviations and thus comprised the Per-Protocol (PP) set; all but two (2) PP subjects were included in the Best Case Set (BCS; n = 207). Eventually, the Multifocal IOL was implanted in 112 subjects, and the Monofocal IOL in 115 subjects.

TABLE 13 ACCOUNTABILITY - MULTIFOCAL AND MONOFOCAL EYES (ITT SET)

Eye	Accountability	Visit 1 (Day 1-2)	Visit 2 (Day 7-14)	Visit 3 (Day 30-60)	Visit 4 (Day 120-180)
Multifocal Eyes					
First Eye (N=114)	Available for Analysis (In Window)	112 (98.2%)	107 (93.9%)	104 (91.2%)	110 (96.5%)
	Available for Analysis (Out of Window)	0	5 (4.4%)	5 (4.4%)	0
	Missed Visit	0	0	1 (0.9%)	0
	Discontinued	2 (1.8%)	2 (1.8%)	2 (1.8%)	2 (1.8%)
	Lost to Follow-up	0	0	2 (1.8%)	2 (1.8%)
	% Accountability	112/112 (100%)	112/112 (100%)	109/112 (97.3%)	110/112 (98.2%)
Second Eye (N=114)	Available for Analysis (In Window)	109 (95.6%)	107 (93.9%)	107 (93.9%)	110 (96.5%)
	Available for Analysis (Out of Window)	1 (0.9%)	2 (1.8%)	1 (0.9%)	0
	Missed Visit	1 (0.9%)	2 (1.8%)	2 (1.8%)	0
	Discontinued	2 (1.8%)	2 (1.8%)	2 (1.8%)	2 (1.8%)
	Lost to Follow-up	1 (0.9%)	1 (0.9%)	2 (1.8%)	2 (1.8%)
	% Accountability	110/112 (98.2%)	109/112 (97.3%)	108/112 (96.4%)	110/112 (98.2%)
All RAO605G Multifocal Eyes (N=228)	Available for Analysis (In Window)	221 (96.9%)	214 (93.9%)	211 (92.5%)	220 (96.5%)
	Available for Analysis (Out of Window)	1 (0.4%)	7 (3.1%)	6 (2.6%)	0
	Missed Visit	1 (0.4%)	2 (0.9%)	3 (1.3%)	0
	Discontinued	4 (1.8%)	4 (1.8%)	4 (1.8%)	4 (1.8%)

Eye	Accountability	Visit 1 (Day 1-2)	Visit 2 (Day 7-14)	Visit 3 (Day 30-60)	Visit 4 (Day 120-180)
	Lost to Follow-up	1 (0.4%)	1 (0.4%)	4 (1.8%)	4 (1.8%)
	% Accountability	222/224 (99.1%)	221/224 (98.7%)	217/224 (96.9%)	220/224 (98.2%)
Monofocal Eyes					
First Implanted Eye (N=116)	Available for Analysis (In Window)	113 (97.4%)	112 (96.6%)	109 (94.0%)	109 (94.0%)
	Available for Analysis (Out of Window)	2 (1.7%)	2 (1.7%)	4 (3.4%)	2 (1.7%)
	Missed Visit	0	0	0	0
	Discontinued	1 (0.9%)	1 (0.9%)	2 (1.7%)	3 (2.6%)
	Lost to Follow-up	0	1 (0.9%)	1 (0.9%)	2 (1.7%)
	% Accountability	115/115 (100%)	114/115 (99.1%)	113/114 (99.1%)	111/113 (98.2%)
Second Implanted Eye (N=116)	Available for Analysis (In Window)	113 (97.4%)	111 (95.7%)	109 (94.0%)	108 (93.1%)
	Available for Analysis (Out of Window)	1 (0.9%)	2 (1.7%)	2 (1.7%)	2 (1.7%)
	Missed Visit	0	0	1 (0.9%)	0
	Discontinued	2 (1.7%)	2 (1.7%)	3 (2.6%)	4 (3.4%)
	Lost to Follow-up	0	1 (0.9%)	1 (0.9%)	2 (1.7%)
	% Accountability	114/114 (100%)	113/114 (99.1%)	111/113 (98.2%)	110/112 (98.2%)
All RAO600C Monofocal Eyes (N=232)	Available for Analysis (In Window)	226 (97.4%)	223 (96.1%)	218 (94.0%)	217 (93.5%)
	Available for Analysis (Out of Window)	3 (1.3%)	4 (1.7%)	6 (2.6%)	4 (1.7%)
	Missed Visit	0	0	1 (0.4%)	0
	Discontinued	3 (1.3%)	3 (1.3%)	5 (2.2%)	7 (3.0%)

Eye	Accountability	Visit 1 (Day 1-2)	Visit 2 (Day 7-14)	Visit 3 (Day 30-60)	Visit 4 (Day 120-180)
	Lost to Follow-up	0	2 (0.9%)	2 (0.9%)	4 (1.7%)
	% Accountability	229/229 (100%)	227/229 (99.1%)	224/227 (98.7%)	221/225 (98.2%)

Abbreviations: n = number of eyes in the specified accountability category; N = total number of eyes in the respective treatment and eye group. Accountability-category results are presented as n (%). Percentages for the individual accountability categories are calculated as n/N using the applicable N for the respective treatment and eye group. **Available for Analysis (In Window):** Total number of eyes for whom data are available at the visit and within the visit window. **Available for Analysis (Out of Window):** Total number of eyes that were seen at the scheduled visit, but before or after the time window associated with the visit. **Missed Visit:** Total number of eyes that did not attend the scheduled visit. **Discontinued:** Total number of eyes that discontinued study participation prior to the visit for any reason, not including subjects that are lost to follow-up. **Lost to Follow-up:** Total number of eyes that missed the visit and for whom there is no information available. **% Accountability:** Available for Analysis / (N - Discontinued)

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an intraocular lens clinical study performed in the US.

The distributions of age, gender, race and ethnicity of all ITT subjects are presented in **TABLE 14**. Subjects ranged in age from 46 to 81 years in the Multifocal group (Mean: 67.3 ± 7.3 years) and from 34 to 81 years in the Monofocal group (Mean: 67.7 ± 7.4 years). The majority ($> 90\%$; 106/114 and 109/116, respectively) of subjects were White in both study groups. Females comprised 61.2 - 64.0% (73/114 and 71/116) of the subjects enrolled in each group, respectively.

The demographic characteristics were generally similar between the Multifocal and Monofocal treatment groups.

TABLE 15 shows the summary statistics for baseline and screening parameters for the ITT. Summary statistics for First Implanted and Second Implanted eyes were similar within and between lens groups.

TABLE 14 SUBJECT DEMOGRAPHICS (ITT SET)

Demographic Parameter	Outcome	Randomized Lens	
		RAO605G Multifocal IOL (N=114)	RAO600C Monofocal IOL (N=116)
Age (years)	N	114	116
	Mean $\pm$ SD	67.3 ± 7.3	67.7 ± 7.4
	Median	68	69
	Min, Max	46, 81	34, 81
	Q1, Q3	64, 72	63, 73
Age Group: n (%)	< 65 years	30 (26.3%)	36 (31.0%)
	$\geq$ 65 years	84 (73.7%)	80 (69.0%)
Sex: n (%)	Male	41 (36.0%)	45 (38.8%)
	Female	73 (64.0%)	71 (61.2%)
Race: n (%)	American Indian or Alaska Native	0	1 (0.9%)
	Asian	4 (3.5%)	1 (0.9%)
	Black or African American	3 (2.6%)	3 (2.6%)
	Native Hawaiian or Other Pacific Islander	0	1 (0.9%)
	White	106 (93.0%)	109 (94.0%)
	Multiple	1 (0.9%)	1 (0.9%)

		Randomized Lens	
Demographic Parameter	Outcome	RAO605G Multifocal IOL (N=114)	RAO600C Monofocal IOL (N=116)
	Other	0	0
Ethnicity: n (%)	Hispanic or Latino	4 (3.5%)	8 (6.9%)
	Not Hispanic or Latino	110 (96.5%)	108 (93.1%)
First Eye: n (%)	OD	70 (61.4%)	56 (48.3%)
	OS	44 (38.6%)	60 (51.7%)

Abbreviations: n = number of subjects in the specified category; N = total number of subjects in the respective randomized treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective randomized treatment group.

TABLE 15 BASELINE PARAMETERS (ITT SET)

		RAO605G Multifocal IOL			RAO600C Monofocal IOL		
Parameter	Statistic	First Eye ^[1]	Second Eye	All Eyes	First Eye ^[1]	Second Eye	All Eyes
Axial Length (mm)	n	114	114	228	116	116	232
	Mean $\pm$ SD	23.975 $\pm$ 1.219	23.936 $\pm$ 1.215	23.956 $\pm$ 1.215	24.243 $\pm$ 1.226	24.194 $\pm$ 1.181	24.218 $\pm$ 1.201
	Median	23.80	23.71	23.77	24.07	24.07	24.07
	Min, Max	22.01, 28.27	21.91, 28.63	21.91, 28.63	21.57, 27.33	21.68, 26.94	21.57, 27.33
Anterior Chamber Depth (mm)	n	114	114	228	116	116	232
	Mean $\pm$ SD	3.355 $\pm$ 0.395	3.321 $\pm$ 0.378	3.338 $\pm$ 0.386	3.394 $\pm$ 0.403	3.383 $\pm$ 0.398	3.389 $\pm$ 0.399
	Median	3.32	3.32	3.32	3.41	3.39	3.40
	Min, Max	2.27, 4.34	2.30, 4.30	2.27, 4.34	2.50, 4.63	2.53, 4.60	2.50, 4.63
Photopic BCDVA (logMAR)	n	114	114	228	116	116	232
	Mean $\pm$ SD	0.244 $\pm$ 0.180	0.102 $\pm$ 0.112	0.173 $\pm$ 0.166	0.281 $\pm$ 0.236	0.138 $\pm$ 0.188	0.209 $\pm$ 0.224
	Median	0.21	0.10	0.14	0.22	0.10	0.18
	Min, Max	-0.08, 0.92	-0.18, 0.40	-0.18, 0.92	-0.04, 1.10	-0.20, 1.10	-0.20, 1.10
MRSE (D)	n	114	114	228	116	116	232
	Mean $\pm$ SD	-0.9594 $\pm$ 2.5021	-0.6009 $\pm$ 2.4603	-0.7802 $\pm$ 2.4823	-1.6239 $\pm$ 3.1324	-1.1056 $\pm$ 2.8376	-1.3648 $\pm$ 2.9934
	Median	-0.375	0.000	-0.250	-1.000	-0.250	-0.625
	Min, Max	-9.750, 3.250	-10.000, 2.625	-10.000, 3.250	-9.875, 3.500	-9.250, 3.000	-9.875, 3.500

		RAO605G Multifocal IOL			RAO600C Monofocal IOL		
Parameter	Statistic	First Eye ^[1]	Second Eye	All Eyes	First Eye ^[1]	Second Eye	All Eyes
Target Residual Spherical Equivalent (D)	n	114	114	228	116	116	232
	Mean ± SD	-0.007 ± 0.113	-0.000 ± 0.095	-0.003 ± 0.104	-0.006 ± 0.108	-0.002 ± 0.093	-0.004 ± 0.101
	Median	-0.01	0.00	0.00	-0.02	0.00	-0.01
	Min, Max	-0.50, 0.18	-0.17, 0.16	-0.50, 0.18	-0.18, 0.18	-0.17, 0.17	-0.18, 0.18
Keratometric Cylinder (D)	n	114	114	228	116	116	232
	Mean ± SD	0.521 ± 0.255	0.530 ± 0.209	0.525 ± 0.233	0.586 ± 0.244	0.533 ± 0.230	0.559 ± 0.238
	Median	0.50	0.52	0.51	0.58	0.52	0.54
	Min, Max	0.00, 0.99	0.00, 0.98	0.00, 0.99	0.06, 0.99	0.00, 0.99	0.00, 0.99

^[1]For implanted subjects, First Eye is the First-Implanted Eye and Second Eye is the Second-Implanted Eye. For subjects who were not implanted, the First and Second eyes were determined according to the methods described in the study protocol.

D. Safety and Effectiveness Results

1. Overall Study Success Criteria

Overall study success was based on meeting the pre-specified primary effectiveness and safety endpoint success criteria. The primary effectiveness success criteria were: (1) mean photopic monocular BCDVA at 4 meters in First Implanted Multifocal eyes at Visit 4 of ≤ 0.20 logMAR, without rounding; and (2) statistically superior photopic monocular DCNVA at 40 cm in First Implanted Multifocal eyes compared with Monofocal control eyes at Visit 4, based on a one-sided significance level of 0.025. The primary safety success criteria were: (1) the rate of device-related secondary surgical interventions related to the optical properties of the investigational IOL was not statistically significantly higher than the Monofocal control by more than the pre-specified 0.014 margin; (2) the rate of Multifocal eyes achieving BCDVA of 0.30 logMAR or better at Visit 4 was not statistically significantly lower than the applicable ISO 11979-7 (2024) historical control rate in either the Safety Set or Best-Case Set; and (3) the rates of cumulative and persistent IOL adverse events were not statistically significantly higher than the applicable ISO 11979-7 (2024) SPE rates. The two additional primary safety endpoints—rates of other adverse events not included in the ISO 11979-7 (2024) cumulative and persistent adverse event categories and rates of adverse events defined by Masket et al.—were not hypothesis driven and were evaluated descriptively.

2. Safety Results

The analysis of safety was based on the Safety cohort of 227 patients who underwent bilateral cataract surgery and IOL implantation (112 in the Multifocal IOL group and 115 in the Monofocal IOL group) through the 120 to 180 day postoperative evaluation (Visit 4). The key safety outcomes for this study, including adverse effects, are presented below in **TABLE 16** to **TABLE 24**.

Adverse effects that occurred in the PMA clinical study:

The first co-primary safety endpoint was to evaluate rates of device-related secondary surgical interventions related to the optical properties of the investigational lens through 120 to 180 days post-operatively (Visit 4). The results are summarized in **TABLE 16** for the First Implanted eyes and Second Implanted eyes. SSIs were considered to be related to optical properties of IOL if these were associated with subject intolerance of visual symptoms, not adequately improved by spectacle correction. No First Implanted eyes in either lens group required a secondary surgical intervention due to the optical properties of the IOL. And no Second Implanted eyes in either group required a secondary surgical intervention due to the optical properties of the lens. There was no observed difference in rates between the two treatment

groups (0% in both groups); the p-value was not applicable (NA), and this endpoint was considered successful.

The second co-primary safety endpoint was the frequency and percentage of eyes which achieved a BCDVA of 0.30 logMAR or better at 4 meters 120 to 180 days post-operatively (Visit 4). The results are summarized in **TABLE 17** for the First Implanted eyes and Second Implanted eyes. All (110/110, 100% Multifocal; 111/111, 100% Monofocal) First Implanted eyes in both lens groups achieved BCDVA of 0.30 logMAR or better at the final study visit. For Second Implanted eyes 98.2% (108/110) and 99.1% (109/110) of patients achieved a BCDVA of 0.30 logMAR or better at the final visit in the Multifocal and Monofocal groups, respectively, in the Safety Set; corresponding rates were 99.0% (100/101) and 100% (106/106) in the Best-Case Set. Compared with the historical control specified in ISO 11979-7 (2024), no statistically significant difference was observed in either the Safety Set or the Best-Case Set. Similarly, when compared with the SPE rate, differences for both lenses were not statistically significant ($p > 0.05$); therefore, the endpoint was met.

The third co-primary safety endpoint was the rates of adverse events through 120 to 180 days post-operatively (Visit 4) compared to the ISO Safety and Performance Endpoint (SPE) rates as described in ISO 11979-7 (2024). **TABLE 18** and **TABLE 19** present the cumulative and persistent adverse events rates for the Multifocal IOL group in First and Second Implanted eyes, respectively, compared to the ISO grid. The rate of adverse events in the Multifocal First Implanted were not statistically higher than the ISO grid ($p > 0.05$) and this endpoint was successfully met. The supportive analyses using Second Implanted eyes and All Implanted eyes were successful for all AEs listed in the ISO grid, except Secondary Surgical Interventions which were statistically significant compared to the ISO grid.

TABLE 20 and **TABLE 21** present similar analyses performed on the Monofocal control group; there were no cumulative or persistent adverse events (AEs) in First Implanted Monofocal eyes. In Second Implanted Monofocal eyes, the only cumulative adverse event was secondary surgical intervention, occurring in 1 of 114 subjects (0.9%). There were no persistent AEs in Second Implanted Monofocal eyes. No adverse event rates in Monofocal First Implanted or Second Implanted eyes were statistically higher than those specified in the ISO grid ($p > 0.05$).

The fourth co-primary safety endpoint was the rates of all AEs not included in the IOL adverse event list based on ISO 11979-7 (2024) for First and Second Implanted eyes in both lens groups. The results are summarized in **TABLE 22** and **TABLE 23**. The safety profiles of the two lens groups were broadly comparable, with most adverse events occurring at similar frequencies. In the Multifocal group, the most frequent events were anterior chamber cells grade 0.5 or greater at Visit 2 or later, and posterior capsule opacification. In the

Monofocal group, most frequent events were anterior chamber cells grade 0.5 or greater at Visit 2 or later, and corneal oedema.

The fifth co-primary safety endpoint was to evaluate the frequency and percentage of eyes with adverse events meeting the definition(s) put forth by the AAO Task Force (i.e., Masket et al.) through 120 to 180 days post-operatively (Visit 4). The results are summarized in **TABLE 24**. The nature and overall rates of adverse events were similar between the two lens groups.

TABLE 16 RATES OF DEVICE-RELATED SECONDARY SURGICAL INTERVENTIONS RELATED TO THE OPTICAL PROPERTIES OF THE IOL (SAFETY SET)

RAO605G Multifocal IOL n/N (%)	RAO600C Monofocal IOL n/N (%)	Difference (Multifocal - Monofocal)	Z-value	P-value^[1]	95% Confidence Interval^[2]
First-Implanted Eyes					
0/112	0/115	0.0000	NA	NA	NA
Second-Implanted Eyes					
0/111	0/114	0.0000	NA	NA	NA

Abbreviations: n=number of eyes that experienced a device-related secondary surgical intervention related to the optical properties of the IOL; N = total number of eyes in the applicable implanted-eye and treatment group.

Secondary Surgical Interventions with a Relationship to Device of 'Definitely Related', 'Probably Related,' or 'Possibly Related' and associated with subject intolerance of visual symptoms, or in consultation with Medical Monitor, are considered to be SSIs Related to the Optical Properties of the IOL.

^[1] One-sided Farrington-Manning superiority test comparing the difference in proportions to 0.014.

^[2] Two-sided 95% Wald confidence interval for the difference in AE Rates.

TABLE 17 RATE OF BCDVA OF 0.30 LOGMAR OR BETTER IN FIRST-IMPLANTED EYES AND SECOND-IMPLANTED EYES AT VISIT 4

Analysis Set	Implanted Lens	n/N (%)	SPE Rate (%)	P-value^[1]	95% Confidence Interval^[2]
First-Implanted Eyes					
Safety Set	RAO605G Multifocal IOL	110/110 (100.0%)	92.5	>.9999	(96.70%, 100%)
	RAO600C Monofocal IOL	111/111 (100.0%)	92.5	>.9999	(96.73%, 100%)
Best Case Set	RAO605G Multifocal IOL	101/101 (100.0%)	96.7	>.9999	(96.41%, 100%)

Analysis Set	Implanted Lens	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
	RAO600C Monofocal IOL	106/106 (100.0%)	96.7	>.9999	(96.58%, 100%)
Second-Implanted Eyes					
Safety Set	RAO605G Multifocal IOL	108/110 (98.2%)	92.5	0.9981	(93.59%, 99.78%)
	RAO600C Monofocal IOL	109/110 (99.1%)	92.5	0.9998	(95.04%, 99.98%)
Best Case Set	RAO605G Multifocal IOL	100/101 (99.0%)	96.7	0.9663	(94.61%, 99.97%)
	RAO600C Monofocal IOL	106/106 (100.0%)	96.7	>.9999	(96.58%, 100%)

Abbreviations: n = number of eyes achieving BCDVA of 0.30 logMAR or better; N = total number of eyes with evaluable BCDVA data at Visit 4 in the applicable analysis set, implanted-eye group, and treatment group; SPE = Safety and Performance Endpoint. Results are presented as n/N (%). Percentages are calculated as n/N using the applicable N.

^[1]One-sided Exact Binomial Test comparing the proportion of eyes to the SPE

Rate.

^[2]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the AE

Rate.

TABLE 18 RATES OF MULTIFOCAL IOL ADVERSE EVENTS IN FIRST-IMPLANTED EYES COMPARED TO ISO GRID (SAFETY SET)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Cumulative				
Cystoid Macular Edema	0/112	3.0	>.9999	(0%, 3.24%)
Hypopyon	0/112	0.3	>.9999	(0%, 3.24%)
Endophthalmitis	0/112	0.1	>.9999	(0%, 3.24%)
Lens Dislocated from Posterior Chamber	0/112	0.1	>.9999	(0%, 3.24%)
Pupillary Block	0/112	0.1	>.9999	(0%, 3.24%)
Retinal Detachment	1/112 (0.9%)	0.3	0.2857	(0.02%, 4.87%)
Secondary Surgical Intervention ^[3]	2/112 (1.8%)	0.8	0.2259	(0.22%, 6.30%)
Persistent				
Corneal Stroma Edema	0/110	0.3	>.9999	(0%, 3.30%)
Cystoid Macular Edema	0/110	0.5	>.9999	(0%, 3.30%)
Anterior Uveitis (Iritis)	0/110	0.3	>.9999	(0%, 3.30%)
Raised IOP Requiring Treatment	0/110	0.4	>.9999	(0%, 3.30%)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
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Abbreviations: n=number of eyes that experienced the event; SPE=Safety and Performance Endpoints

The denominator (N) for cumulative AEs is the total number of first-implanted Multifocal eyes in the Safety Set.

The denominator (N) for persistent AEs is the total number of first-implanted Multifocal eyes who had a follow-up visit on or after the beginning of the Visit 4 visit window (120 days after implantation).

^[1] One-sided Exact Binomial Test comparing the proportion of Multifocal eyes to the SPE Rate from Table E.2 of ISO 11979-7(2024).

^[2] Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the Multifocal IOL AE Rate.

^[3] Excludes posterior capsulotomies and wound burp.

TABLE 19 RATES OF MULTIFOCAL IOL ADVERSE EVENTS IN SECOND-IMPLANTED EYES COMPARED TO ISO GRID (SAFETY SET)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Cumulative				
Cystoid Macular Edema	0/111	3.0	>.9999	(0%, 3.27%)
Hypopyon	0/111	0.3	>.9999	(0%, 3.27%)
Endophthalmitis	0/111	0.1	>.9999	(0%, 3.27%)
Lens Dislocated from Posterior Chamber	0/111	0.1	>.9999	(0%, 3.27%)
Pupillary Block	0/111	0.1	>.9999	(0%, 3.27%)
Retinal Detachment	0/111	0.3	>.9999	(0%, 3.27%)
Secondary Surgical Intervention ^[3]	4/111 (3.6%)	0.8	0.0125	(0.99%, 8.97%)
Persistent				
Corneal Stroma Edema	0/110	0.3	>.9999	(0%, 3.30%)
Cystoid Macular Edema	0/110	0.5	>.9999	(0%, 3.30%)
Anterior Uveitis (Iritis)	0/110	0.3	>.9999	(0%, 3.30%)
Raised IOP Requiring Treatment	0/110	0.4	>.9999	(0%, 3.30%)

Abbreviations: n=number of eyes that experienced the event; SPE=Safety and Performance Endpoints

The denominator (N) for cumulative AEs is the total number of second-implanted Multifocal eyes in the Safety Set.

The denominator (N) for persistent AEs is the total number of second-implanted Multifocal eyes who had a follow-up visit on or after the beginning of the Visit 4 visit window (120 days after implantation).

^[1] One-sided Exact Binomial Test comparing the proportion of Multifocal eyes to the SPE Rate from Table E.2 of ISO 11979-7(2024).

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
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^[2] Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the Multifocal IOL AE Rate.

^[3] Excludes posterior capsulotomies and wound burp.

TABLE 20 RATES OF MONOFOCAL IOL ADVERSE EVENTS IN FIRST-IMPLANTED EYES COMPARED TO ISO GRID (SAFETY SET)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Cumulative				
Cystoid Macular Edema	0/115	3.0	>.9999	(0%, 3.16%)
Hypopyon	0/115	0.3	>.9999	(0%, 3.16%)
Endophthalmitis	0/115	0.1	>.9999	(0%, 3.16%)
Lens Dislocated from Posterior Chamber	0/115	0.1	>.9999	(0%, 3.16%)
Pupillary Block	0/115	0.1	>.9999	(0%, 3.16%)
Retinal Detachment	0/115	0.3	>.9999	(0%, 3.16%)
Secondary Surgical Intervention ^[3]	0/115	0.8	>.9999	(0%, 3.16%)
Persistent				
Corneal Stroma Edema	0/111	0.3	>.9999	(0%, 3.27%)
Cystoid Macular Edema	0/111	0.5	>.9999	(0%, 3.27%)
Anterior Uveitis (Iritis)	0/111	0.3	>.9999	(0%, 3.27%)
Raised IOP Requiring Treatment	0/111	0.4	>.9999	(0%, 3.27%)

Abbreviations: n=number of eyes that experienced the event; SPE=Safety and Performance Endpoints

The denominator (N) for cumulative AEs is the total number of first-implanted Monofocal eyes in the Safety Set.

The denominator (N) for persistent AEs is the total number of first-implanted Monofocal eyes who had a follow-up visit on or after the beginning of the Visit 4 visit window (120 days after implantation).

^[1] One-sided Exact Binomial Test comparing the proportion of Monofocal eyes to the SPE Rate from Table E.2 of ISO 11979-7(2024).

^[2] Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the Monofocal IOL AE Rate.

^[3] Excludes posterior capsulotomies and wound burp.

TABLE 21 RATES OF MONOFOCAL IOL ADVERSE EVENTS IN SECOND-IMPLANTED EYES COMPARED TO ISO GRID (SAFETY SET)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Cumulative				
Cystoid Macular Edema	0/114	3.0	>.9999	(0%, 3.18%)
Hypopyon	0/114	0.3	>.9999	(0%, 3.18%)
Endophthalmitis	0/114	0.1	>.9999	(0%, 3.18%)
Lens Dislocated from Posterior Chamber	0/114	0.1	>.9999	(0%, 3.18%)
Pupillary Block	0/114	0.1	>.9999	(0%, 3.18%)
Retinal Detachment	0/114	0.3	>.9999	(0%, 3.18%)
Secondary Surgical Intervention ^[3]	1/114 (0.9%)	0.8	0.5998	(0.02%, 4.79%)
Persistent				
Corneal Stroma Edema	0/110	0.3	>.9999	(0%, 3.30%)
Cystoid Macular Edema	0/110	0.5	>.9999	(0%, 3.30%)
Anterior Uveitis (Iritis)	0/110	0.3	>.9999	(0%, 3.30%)
Raised IOP Requiring Treatment	0/110	0.4	>.9999	(0%, 3.30%)

Abbreviations: n=number of eyes that experienced the event; SPE=Safety and Performance Endpoints

The denominator (N) for cumulative AEs is the total number of second-implanted Monofocal eyes in the Safety Set.

The denominator (N) for persistent AEs is the total number of second-implanted Monofocal eyes who had a follow-up visit on or after the beginning of the Visit 4 visit window (120 days after implantation).

^[1]One-sided Exact Binomial Test comparing the proportion of Monofocal eyes to the SPE Rate from Table E.2 of ISO 11979-7(2024).

^[2]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the Monofocal IOL AE Rate.

^[3]Excludes posterior capsulotomies and wound burp.

TABLE 22 RATES OF ALL OTHER ADVERSE EVENTS IN FIRST-IMPLANTED EYES (SAFETY SET)

	RAO605G Multifocal IOL (N=112)		RAO600C Monofocal IOL (N=115)	
Adverse Event	n (%) e	95% Confidence Interval^[1]	n (%) e	95% Confidence Interval^[1]
Anterior Uveitis	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Corneal Edema	10 (8.9%) 10	(4.4%, 15.8%)	17 (14.8%) 17	(8.9%, 22.6%)
Elevated IOP	4 (3.6%) 4	(1.0%, 8.9%)	5 (4.3%) 5	(1.4%, 9.9%)

	RAO605G Multifocal IOL (N=112)		RAO600C Monofocal IOL (N=115)	
Adverse Event	n (%) e	95% Confidence Interval^[1]	n (%) e	95% Confidence Interval^[1]
Best-corrected visual acuity loss of 2 lines (10 letters) or more on the ETDRS chart measured at Visit 4 or later from any prior post-operative visit	2 (1.8%) 2	(0.2%, 6.3%)	0	(0%, 3.2%)
Progression or onset of diabetic retinopathy	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.7%)
Retained lens material	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Secondary Surgical Intervention	24 (21.4%) 24	(14.2%, 30.2%)	9 (7.8%) 9	(3.6%, 14.3%)
Nd:YAG laser capsulotomy	24 (21.4%) 24	(14.2%, 30.2%)	8 (7.0%) 8	(3.1%, 13.2%)
Wound burp (aqueous tap, or paracentesis)	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Other	54 (48.2%) 66	(38.7%, 57.9%)	48 (41.7%) 59	(32.6%, 51.3%)
Anterior chamber cells grade 0.5 or greater at visit 2 or later	31 (27.7%) 31	(19.6%, 36.9%)	37 (32.2%) 37	(23.8%, 41.5%)
Posterior capsule opacification requiring YAG capsulotomy	24 (21.4%) 24	(14.2%, 30.2%)	8 (7.0%) 8	(3.1%, 13.2%)
Posterior vitreous detachment	3 (2.7%) 3	(0.6%, 7.6%)	3 (2.6%) 3	(0.5%, 7.4%)
Subconjunctival hemorrhage	2 (1.8%) 2	(0.2%, 6.3%)	2 (1.7%) 2	(0.2%, 6.1%)
Anterior chamber cells greater than grade 2 at visit 1	2 (1.8%) 2	(0.2%, 6.3%)	1 (0.9%) 1	(0.0%, 4.7%)
Keratoconjunctivitis sicca, not specified as Sjogrens	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.7%)
Worsening of dry eye disease	0	(0%, 3.2%)	2 (1.7%) 2	(0.2%, 6.1%)
Chalazion	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Corneal edema	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Double/Multiple images	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Epithelial defect	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Hypotony	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Meibomian gland dysfunction	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Ocular pain	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Worsening of keratoconjunctivitis sicca	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)

Abbreviations: n=number of eyes that experienced the event; N = total number of first-implanted eyes in the Safety Set for each IOL; e = total number of events.

Excludes Cumulative AEs from Table E.2 of ISO 11979-7 (2024).

	RAO605G Multifocal IOL (N=112)		RAO600C Monofocal IOL (N=115)	
Adverse Event	n (%) e	95% Confidence Interval ^[1]	n (%) e	95% Confidence Interval ^[1]

^[1]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the AE Rate.

TABLE 23 RATES OF ALL OTHER ADVERSE EVENTS IN SECOND-IMPLANTED EYES (SAFETY SET)

	RAO605G Multifocal IOL (N=111)		RAO600C Monofocal IOL (N=114)	
Adverse Event	n (%) e	95% Confidence Interval ^[1]	n (%) e	95% Confidence Interval ^[1]
Anterior Uveitis	0	(0%, 3.3%)	2 (1.8%) 2	(0.2%, 6.2%)
Corneal Edema	7 (6.3%) 7	(2.6%, 12.6%)	12 (10.5%) 12	(5.6%, 17.7%)
Elevated IOP	4 (3.6%) 4	(1.0%, 9.0%)	4 (3.5%) 4	(1.0%, 8.7%)
IOL decentration/malposition resulting in secondary surgical intervention	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Best-corrected visual acuity loss of 2 lines (10 letters) or more on the ETDRS chart measured at Visit 4 or later from any prior post-operative visit	3 (2.7%) 3	(0.6%, 7.7%)	0	(0%, 3.2%)
Secondary Surgical Intervention	27 (24.3%) 27	(16.7%, 33.4%)	10 (8.8%) 10	(4.3%, 15.5%)
Nd:YAG laser capsulotomy	27 (24.3%) 27	(16.7%, 33.4%)	9 (7.9%) 9	(3.7%, 14.5%)
Wound burp (aqueous tap, or paracentesis)	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Other	61 (55.0%) 82	(45.2%, 64.4%)	41 (36.0%) 53	(27.2%, 45.5%)
Anterior chamber cells grade 0.5 or greater at visit 2 or later	31 (27.9%) 31	(19.8%, 37.2%)	28 (24.6%) 28	(17.0%, 33.5%)
Posterior capsule opacification requiring YAG capsulotomy	27 (24.3%) 27	(16.7%, 33.4%)	9 (7.9%) 9	(3.7%, 14.5%)
Anterior chamber cells greater than grade 2 at visit 1	4 (3.6%) 4	(1.0%, 9.0%)	2 (1.8%) 2	(0.2%, 6.2%)
Posterior vitreous detachment	3 (2.7%) 3	(0.6%, 7.7%)	3 (2.6%) 3	(0.5%, 7.5%)
Subconjunctival hemorrhage	2 (1.8%) 2	(0.2%, 6.4%)	2 (1.8%) 2	(0.2%, 6.2%)
Corneal abrasion	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)
Corneal edema	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)
Keratoconjunctivitis sicca, not specified as Sjogrens	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)

	RAO605G Multifocal IOL (N=111)		RAO600C Monofocal IOL (N=114)	
Adverse Event	n (%) e	95% Confidence Interval^[1]	n (%) e	95% Confidence Interval^[1]
Superficial punctate keratitis	2 (1.8%) 2	(0.2%, 6.4%)	0	(0%, 3.2%)
Allergic conjunctivitis	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Anterior chamber debris	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Capsular bag distension syndrome	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Chalazion	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Double vision	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Double/Multiple images	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Dry eye	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Ecchymosis	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Hyphema	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Macular edema	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Meibomian gland dysfunction	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Skin laceration	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Vitreous floaters	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Vitreous syneresis	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Worsening of dry eye disease	0	(0%, 3.3%)	1 (0.9%) 1	(0.0%, 4.8%)
Worsening of keratoconjunctivitis sicca	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)

Abbreviations: n=number of eyes that experienced the event; N = total number of second-implanted eyes in the Safety Set for each IOL; e = total number of events.

Excludes Cumulative AEs from Table E.2 of ISO 11979-7 (2024).

^[1]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the AE Rate.

TABLE 24 RATES OF ADVERSE EVENTS DEFINED IN MASKET ET AL. IN FIRST-IMPLANTED EYES AND SECOND-IMPLANTED EYES (SAFETY SET)

	RAO605G Multifocal IOL		RAO600C Monofocal IOL	
Adverse Event	n (%) e	95% Confidence Interval^[1]	n (%) e	95% Confidence Interval^[1]
First-Implanted Eyes	N=112		N=115	
Anterior Uveitis	0	(0%, 3.2%)	1 (0.9%) 1	(0.0%, 4.7%)
Clinically Significant Cystoid Macular Edema	0	(0%, 3.2%)	0	(0%, 3.2%)
Visually Significant Corneal Edema	0	(0%, 3.2%)	0	(0%, 3.2%)
Endophthalmitis	0	(0%, 3.2%)	0	(0%, 3.2%)
Mechanical Pupillary Block	0	(0%, 3.2%)	0	(0%, 3.2%)
Increased IOP	3 (2.7%) 3	(0.6%, 7.6%)	3 (2.6%) 3	(0.5%, 7.4%)

	RAO605G Multifocal IOL		RAO600C Monofocal IOL	
Adverse Event	n (%) e	95% Confidence Interval^[1]	n (%) e	95% Confidence Interval^[1]
Rhegmatogenous Retinal Detachment	1 (0.9%) 1	(0.0%, 4.9%)	0	(0%, 3.2%)
Toxic Anterior Segment Syndrome	0	(0%, 3.2%)	0	(0%, 3.2%)
IOL Exchange	0	(0%, 3.2%)	0	(0%, 3.2%)
IOL Removal	0	(0%, 3.2%)	0	(0%, 3.2%)
IOL Reposition	0	(0%, 3.2%)	0	(0%, 3.2%)
Second-Implanted Eyes	N=111		N=114	
Anterior Uveitis	0	(0%, 3.3%)	2 (1.8%) 2	(0.2%, 6.2%)
Clinically Significant Cystoid Macular Edema	0	(0%, 3.3%)	0	(0%, 3.2%)
Visually Significant Corneal Edema	0	(0%, 3.3%)	0	(0%, 3.2%)
Endophthalmitis	0	(0%, 3.3%)	0	(0%, 3.2%)
Mechanical Pupillary Block	0	(0%, 3.3%)	0	(0%, 3.2%)
Increased IOP	2 (1.8%) 2	(0.2%, 6.4%)	3 (2.6%) 3	(0.5%, 7.5%)
Rhegmatogenous Retinal Detachment	0	(0%, 3.3%)	0	(0%, 3.2%)
Toxic Anterior Segment Syndrome	0	(0%, 3.3%)	0	(0%, 3.2%)
IOL Exchange	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)
IOL Removal	1 (0.9%) 1	(0.0%, 4.9%)	1 (0.9%) 1	(0.0%, 4.8%)
IOL Reposition	0	(0%, 3.3%)	0	(0%, 3.2%)

Abbreviations: n=number of eyes that experienced the event; N = total number of eyes in the applicable implanted-eye and treatment group in the Safety Set; e = total number of events.

^[1]Two-sided 95% Exact Binomial (Clopper-Pearson) confidence interval for the AE Rate.

	RAO605G Multifocal IOL		RAO600C Monofocal IOL	
Adverse Event	n (%) e	95% Confidence Interval ^[1]	n (%) e	95% Confidence Interval ^[1]

Anterior Uveitis = Anterior segment inflammation characterized by grade 1+ cell or greater (using the Standardization of Uveitis Nomenclature criteria) that is persistent for greater than 3 months after surgery, or relapses in less than 3 months after discontinuation of therapy, or the subject is maintained on therapy for more than 3 months to control inflammation.

Clinically significant cystoid macular edema = Macular edema diagnosed by clinical examination and adjunct testing (e.g., OCT, FA) resulting in BCDVA of $\leq 20/40$ at ≥ 1 month

Visually Significant Corneal edema = Corneal swelling (stromal or epithelial) resulting in CDVA of 20/40 or worse at Form 3 or later.

Endophthalmitis = Intraocular inflammation requiring diagnostic vitreous tap and intraocular antibiotics

Mechanical pupillary block = Shallowing of anterior chamber due to obstruction of aqueous humor flow from the posterior to anterior chamber through the pupil by the crystalline lens, vitreous face, or implanted device

Increased IOP = Elevation of IOP greater than or equal to 10 mmHg above baseline to a minimum of 25mmHg.

Rhegmatogenous RD = Partial or complete RD associated with retinal tear

Toxic anterior segment syndrome = Acute, noninfectious inflammation of the anterior segment that starts within 24 to 48 hrs after surgery, usually resulting in hypopyon and commonly presenting with corneal edema, that improves with steroid treatment

IOL Exchange = The investigational device is replaced with the same lens model.

IOL Removal = The investigational device is removed and replaced with a noninvestigational lens or no lens is implanted.

IOL Reposition = The existing IOL is surgically moved to another location or rotated.

Quality of Vision (QoV) Patient Reported Outcome

Visual disturbances were assessed by the Quality of Vision (QoV) Patient Reported Outcome (PRO) Instrument and Patient Vision Questionnaire. **TABLE 25**, **TABLE 26** and **TABLE 27** present the frequency, severity and bothersomeness, respectively, of visual disturbances at 120-180 days postoperatively (Visit 4). **TABLE 25** presents the frequency of each visual disturbance for subjects who provided a frequency response. **TABLE 26** and **TABLE 27** present the severity and bothersomeness, respectively among subjects who also reported experiencing the applicable visual disturbance. The highest ratings of frequency, severity, and bothersomeness were reported by few subjects in either group, indicating good quality of vision for most subjects. Most symptoms, including glare, starbursts, hazy vision, blurred vision, distortion, double images, fluctuation, focusing difficulty, and difficulty judging distance or depth, occurred at similar rates in both groups. Halos were reported more

frequently in the Multifocal group; among subjects who reported halos, most rated them not at all or only a little bothersome, and this pattern is consistent with the published literature on multifocal lenses. Rasch-modeled analyses of questionnaire data showed comparable Frequency, Severity and Bothersome scores between the Multifocal group and the Monofocal group, with overlapping distributions and confidence intervals.

Patient Vision Questionnaire (PVQ) Patient Reported Outcome

The Patient Vision Questionnaire (PVQ) assessed patient-reported visual experience following intraocular lens implantation. **TABLE 28** presents descriptive summaries of responses for each PVQ item at Visit 4 (120 to 180 days postoperatively) by treatment group.

The PVQ was a secondary exploratory measure. The PVQ was not developed or validated in accordance with current guidance for patient-reported outcome measures. Accordingly, the PVQ results are presented as descriptive item-level results only and should be interpreted with caution. No measure-level statistics or formal comparative statistical analysis are presented. These results should be interpreted alongside objective clinical measures of visual function. Because visual symptoms may affect patient satisfaction and could influence decisions regarding lens exchange, a procedure associated with the risks of secondary intraocular surgery, the findings are presented with this limitation in mind.

Contrast Sensitivity

Monocular contrast sensitivity testing with best correction was measured under photopic and mesopic conditions using the M&S System for sine-wave gratings of 1.5, 3, 6, 12 and/or 18 cycles per degree (CPD) at a test distance of 2.5 meters. The mean monocular distance contrast sensitivity under 3 lighting conditions in First Implanted eyes at 120 to 180 days post-operatively (Visit 4) is presented below in **FIGURE 10** to **FIGURE 12**. Under mesopic conditions without glare, the mean contrast sensitivity of eyes implanted with the multifocal IOL was not more than 0.3 log units below that of the Monofocal control at each tested spatial frequency, thereby meeting the predefined ISO 11979-7:2024 criterion.

Fundus Visualization

Across First and Second Implanted eyes in both the Multifocal and Monofocal groups, dilated fundus examination findings were generally stable over the course of study follow-up.

TABLE 25 QUALITY OF VISION (QOV) CATEGORICAL SUMMARY OF THE FREQUENCY OF EACH VISUAL DISTURBANCE AT VISIT 4 (DAY 120–180), SAFETY SET

Visual Disturbance	RAO605G Multifocal IOL						RAO600C Monofocal IOL					
	N	Never	Occasionally	Quite Often	Very Often	Not Done	N	Never	Occasionally	Quite Often	Very Often	Not Done
Glare	110	38/110 (34.5%)	61/110 (55.5%)	9/110 (8.2%)	2/110 (1.8%)	0	111	57/109 (52.3%)	46/109 (42.2%)	6/109 (5.5%)	0	2
Halos	110	45/110 (40.9%)	40/110 (36.4%)	13/110 (11.8%)	12/110 (10.9%)	0	111	67/109 (61.5%)	37/109 (33.9%)	4/109 (3.7%)	1/109 (0.9%)	2
Starbursts	110	45/110 (40.9%)	44/110 (40.0%)	16/110 (14.5%)	5/110 (4.5%)	0	111	62/109 (56.9%)	39/109 (35.8%)	4/109 (3.7%)	4/109 (3.7%)	2
Hazy Vision	110	83/110 (75.5%)	22/110 (20.0%)	4/110 (3.6%)	1/110 (0.9%)	0	111	80/109 (73.4%)	23/109 (21.1%)	4/109 (3.7%)	2/109 (1.8%)	2
Blurred Vision	110	58/110 (52.7%)	43/110 (39.1%)	7/110 (6.4%)	2/110 (1.8%)	0	111	51/109 (46.8%)	46/109 (42.2%)	8/109 (7.3%)	4/109 (3.7%)	2
Distortion	110	97/110 (88.2%)	10/110 (9.1%)	1/110 (0.9%)	2/110 (1.8%)	0	111	96/109 (88.1%)	12/109 (11.0%)	1/109 (0.9%)	0	2
Double/Multiple Images	110	92/110 (83.6%)	15/110 (13.6%)	2/110 (1.8%)	1/110 (0.9%)	0	111	95/109 (87.2%)	12/109 (11.0%)	1/109 (0.9%)	1/109 (0.9%)	2
Fluctuation	110	49/110 (44.5%)	52/110 (47.3%)	9/110 (8.2%)	0	0	111	59/109 (54.1%)	44/109 (40.4%)	5/109 (4.6%)	1/109 (0.9%)	2
Focusing	110	36/110 (32.7%)	64/110 (58.2%)	9/110 (8.2%)	1/110 (0.9%)	0	111	34/109 (31.2%)	62/109 (56.9%)	9/109 (8.3%)	4/109 (3.7%)	2
Distance/Depth Perception	110	71/110 (64.5%)	32/110 (29.1%)	4/110 (3.6%)	3/110 (2.7%)	0	111	80/109 (73.4%)	20/109 (18.3%)	8/109 (7.3%)	1/109 (0.9%)	2

Note: N represents the number of subjects who completed the QoV frequency assessment for the applicable treatment group at Visit 4. Percentages are based on subjects who provided a frequency response for the applicable visual disturbance. Two Monofocal subjects had “Not Done” responses; therefore, the Monofocal percentage denominator is 109.

TABLE 26 QUALITY OF VISION (QOV) CATEGORICAL SUMMARY OF THE SEVERITY OF EACH VISUAL DISTURBANCE AT VISIT 4 (DAY 120–180), SAFETY SET

Visual Disturbance	RAO605G Multifocal IOL						RAO600C Monofocal IOL					
	N	Not at All	Mild	Moderate	Severe	Not Done	N	Not at All	Mild	Moderate	Severe	Not Done
Glare	72	4/72 (5.6%)	51/72 (70.8%)	14/72 (19.4%)	3/72 (4.2%)	0	52	1/52 (1.9%)	40/52 (76.9%)	10/52 (19.2%)	1/52 (1.9%)	0
Halos	65	2/65 (3.1%)	41/65 (63.1%)	15/65 (23.1%)	7/65 (10.8%)	0	42	2/42 (4.8%)	37/42 (88.1%)	3/42 (7.1%)	0	0
Starbursts	65	4/65 (6.2%)	45/65 (69.2%)	11/65 (16.9%)	5/65 (7.7%)	0	47	4/47 (8.5%)	37/47 (78.7%)	2/47 (4.3%)	4/47 (8.5%)	0
Hazy Vision	27	1/27 (3.7%)	21/27 (77.8%)	4/27 (14.8%)	1/27 (3.7%)	0	29	0	25/29 (86.2%)	3/29 (10.3%)	1/29 (3.4%)	0
Blurred Vision	52	4/52 (7.7%)	35/52 (67.3%)	12/52 (23.1%)	1/52 (1.9%)	0	58	3/58 (5.2%)	42/58 (72.4%)	9/58 (15.5%)	4/58 (6.9%)	0
Distortion	13	2/13 (15.4%)	8/13 (61.5%)	2/13 (15.4%)	1/13 (7.7%)	0	13	0	12/13 (92.3%)	1/13 (7.7%)	0	0
Double/Multiple Images	18	2/18 (11.1%)	11/18 (61.1%)	4/18 (22.2%)	1/18 (5.6%)	0	14	0	13/14 (92.9%)	0	1/14 (7.1%)	0
Fluctuation	61	5/61 (8.2%)	46/61 (75.4%)	10/61 (16.4%)	0	0	50	5/50 (10.0%)	39/50 (78.0%)	6/50 (12.0%)	0	0
Focusing	74	6/74 (8.1%)	57/74 (77.0%)	10/74 (13.5%)	1/74 (1.4%)	0	75	3/75 (4.0%)	58/75 (77.3%)	11/75 (14.7%)	3/75 (4.0%)	0
Distance/Depth Perception	39	1/39 (2.6%)	33/39 (84.6%)	5/39 (12.8%)	0	0	29	3/29 (10.3%)	22/29 (75.9%)	4/29 (13.8%)	0	0

Note: N represents the number of subjects who reported a frequency of “Occasionally,” “Quite often,” or “Very often” for the applicable visual disturbance. Because the number of subjects reporting each visual disturbance varied, N varies by visual disturbance. Percentages are based on these subjects.

TABLE 27 QUALITY OF VISION (QOV) CATEGORICAL SUMMARY OF THE BOTHERSOMENESS OF EACH VISUAL DISTURBANCE AT VISIT 4 (DAY 120–180), SAFETY SET

Visual Disturbance	RAO605G Multifocal IOL						RAO600C Monofocal IOL					
	N	Not at All	A Little	Quite	Very	Not Done	N	Not at All	A Little	Quite	Very	Not Done
Glare	72	10/72 (13.9%)	52/72 (72.2%)	9/72 (12.5%)	1/72 (1.4%)	0	52	14/52 (26.9%)	32/52 (61.5%)	4/52 (7.7%)	2/52 (3.8%)	0
Halos	65	17/65 (26.2%)	36/65 (55.4%)	6/65 (9.2%)	6/65 (9.2%)	0	42	14/42 (33.3%)	25/42 (59.5%)	2/42 (4.8%)	1/42 (2.4%)	0
Starbursts	65	17/65 (26.2%)	36/65 (55.4%)	9/65 (13.8%)	3/65 (4.6%)	0	47	17/47 (36.2%)	26/47 (55.3%)	1/47 (2.1%)	3/47 (6.4%)	0
Hazy Vision	27	5/27 (18.5%)	17/27 (63.0%)	4/27 (14.8%)	1/27 (3.7%)	0	29	3/29 (10.3%)	22/29 (75.9%)	2/29 (6.9%)	2/29 (6.9%)	0
Blurred Vision	52	8/52 (15.4%)	33/52 (63.5%)	9/52 (17.3%)	2/52 (3.8%)	0	58	3/58 (5.2%)	44/58 (75.9%)	7/58 (12.1%)	4/58 (6.9%)	0
Distortion	13	4/13 (30.8%)	6/13 (46.2%)	1/13 (7.7%)	2/13 (15.4%)	0	13	1/13 (7.7%)	11/13 (84.6%)	1/13 (7.7%)	0	0
Double/Multiple Images	18	0	14/18 (77.8%)	3/18 (16.7%)	1/18 (5.6%)	0	14	1/14 (7.1%)	10/14 (71.4%)	2/14 (14.3%)	1/14 (7.1%)	0
Fluctuation	61	15/61 (24.6%)	39/61 (63.9%)	7/61 (11.5%)	0	0	50	9/50 (18.0%)	37/50 (74.0%)	3/50 (6.0%)	1/50 (2.0%)	0
Focusing	74	17/74 (23.0%)	46/74 (62.2%)	10/74 (13.5%)	1/74 (1.4%)	0	75	5/75 (6.7%)	56/75 (74.7%)	10/75 (13.3%)	4/75 (5.3%)	0
Distance/Depth Perception	39	5/39 (12.8%)	29/39 (74.4%)	4/39 (10.3%)	1/39 (2.6%)	0	29	8/29 (27.6%)	17/29 (58.6%)	2/29 (6.9%)	2/29 (6.9%)	0

Note: N represents the number of subjects who reported a frequency of “Occasionally,” “Quite often,” or “Very often” for the applicable visual disturbance. Because the number of subjects reporting each visual disturbance varied, N varies by visual disturbance. Percentages are based on these subjects.

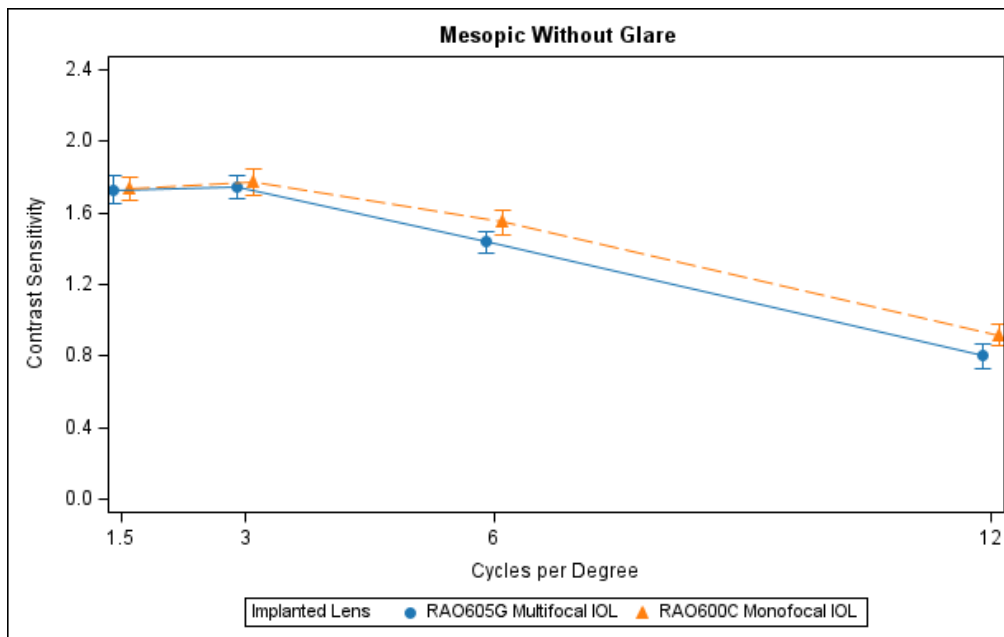
TABLE 28 PATIENT VISION QUESTIONNAIRE RESULTS AT VISIT 4 (DAY 120-180)
(SAFETY SET)

	<u>RAO605G Multifocal IOL n (%)</u>	<u>RAO600C Monofocal IOL n (%)</u>
<u>Question</u>		
<u>1. Do you have trouble with distance vision outdoors in daylight?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>50 (45.5%)</u>	<u>71 (65.1%)</u>
<u>Rarely</u>	<u>45 (40.9%)</u>	<u>29 (26.6%)</u>
<u>Often</u>	<u>9 (8.2%)</u>	<u>7 (6.4%)</u>
<u>Always</u>	<u>6 (5.5%)</u>	<u>2 (1.8%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>2. Do you have trouble with distance vision outdoors at night or in dark situations?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>27 (24.5%)</u>	<u>47 (43.1%)</u>
<u>Rarely</u>	<u>52 (47.3%)</u>	<u>48 (44.0%)</u>
<u>Often</u>	<u>21 (19.1%)</u>	<u>7 (6.4%)</u>
<u>Always</u>	<u>10 (9.1%)</u>	<u>7 (6.4%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>3. Do you have trouble with distance vision when indoors?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>57 (51.8%)</u>	<u>82 (75.2%)</u>
<u>Rarely</u>	<u>42 (38.2%)</u>	<u>23 (21.1%)</u>
<u>Often</u>	<u>9 (8.2%)</u>	<u>2 (1.8%)</u>
<u>Always</u>	<u>2 (1.8%)</u>	<u>2 (1.8%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>4. Do you have trouble with near vision outdoors in daylight?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>65 (59.1%)</u>	<u>34 (31.2%)</u>
<u>Rarely</u>	<u>36 (32.7%)</u>	<u>34 (31.2%)</u>
<u>Often</u>	<u>6 (5.5%)</u>	<u>23 (21.1%)</u>
<u>Always</u>	<u>3 (2.7%)</u>	<u>18 (16.5%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>5. Do you have trouble with near vision outdoors at night or in dark situations?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>41 (37.3%)</u>	<u>24 (22.0%)</u>
<u>Rarely</u>	<u>52 (47.3%)</u>	<u>35 (32.1%)</u>

	<u>RAO605G</u> <u>Multifocal</u> <u>IOL</u> <u>n (%)</u>	<u>RAO600C</u> <u>Monofocal</u> <u>IOL</u> <u>n (%)</u>
<u>Question</u>		
<u>Often</u>	<u>14 (12.7%)</u>	<u>25 (22.9%)</u>
<u>Always</u>	<u>3 (2.7%)</u>	<u>25 (22.9%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>6. Do you have trouble with near vision when indoors?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>57 (51.8%)</u>	<u>23 (21.1%)</u>
<u>Rarely</u>	<u>40 (36.4%)</u>	<u>36 (33.0%)</u>
<u>Often</u>	<u>11 (10.0%)</u>	<u>24 (22.0%)</u>
<u>Always</u>	<u>2 (1.8%)</u>	<u>26 (23.9%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>7. Do you have trouble with blurred vision when looking at things in the distance?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>35 (31.8%)</u>	<u>65 (59.6%)</u>
<u>Rarely</u>	<u>53 (48.2%)</u>	<u>33 (30.3%)</u>
<u>Often</u>	<u>13 (11.8%)</u>	<u>10 (9.2%)</u>
<u>Always</u>	<u>9 (8.2%)</u>	<u>1 (0.9%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>8. Do you have trouble with blurred vision when looking at things that are near?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>49 (44.5%)</u>	<u>33 (30.3%)</u>
<u>Rarely</u>	<u>48 (43.6%)</u>	<u>23 (21.1%)</u>
<u>Often</u>	<u>10 (9.1%)</u>	<u>37 (33.9%)</u>
<u>Always</u>	<u>3 (2.7%)</u>	<u>16 (14.7%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>9. Do you have trouble with night vision?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>24 (21.8%)</u>	<u>41 (37.6%)</u>
<u>Rarely</u>	<u>58 (52.7%)</u>	<u>47 (43.1%)</u>
<u>Often</u>	<u>18 (16.4%)</u>	<u>16 (14.7%)</u>
<u>Always</u>	<u>10 (9.1%)</u>	<u>5 (4.6%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>10. Do you have trouble with night driving because of your vision?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>33 (30.0%)</u>	<u>49 (45.0%)</u>

	<u>RAO605G</u> <u>Multifocal</u> <u>IOL</u> <u>n (%)</u>	<u>RAO600C</u> <u>Monofocal</u> <u>IOL</u> <u>n (%)</u>
<u>Question</u>		
<u>Rarely</u>	<u>42 (38.2%)</u>	<u>33 (30.3%)</u>
<u>Often</u>	<u>19 (17.3%)</u>	<u>13 (11.9%)</u>
<u>Always</u>	<u>10 (9.1%)</u>	<u>4 (3.7%)</u>
<u>N/A</u>	<u>6 (5.5%)</u>	<u>10 (9.2%)</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>11. Do you have trouble with color disturbances in your vision?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Never</u>	<u>90 (81.8%)</u>	<u>84 (77.1%)</u>
<u>Rarely</u>	<u>19 (17.3%)</u>	<u>21 (19.3%)</u>
<u>Often</u>	<u>0</u>	<u>4 (3.7%)</u>
<u>Always</u>	<u>1 (0.9%)</u>	<u>0</u>
<u>Not Done</u>	<u>0</u>	<u>2</u>
<u>12. If given the opportunity, would you again elect to be implanted with the IOL?</u>		
<u>N</u>	<u>110</u>	<u>111</u>
<u>Yes</u>	<u>100 (90.9%)</u>	<u>97 (89.8%)</u>
<u>No</u>	<u>10 (9.1%)</u>	<u>11 (10.2%)</u>
<u>Not Done</u>	<u>0</u>	<u>3</u>

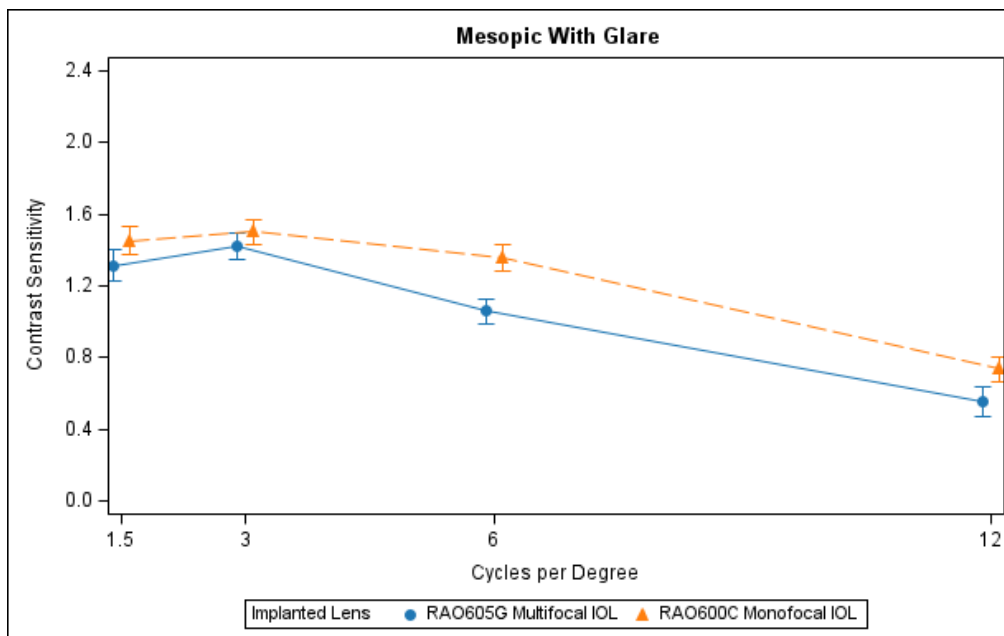
FIGURE 10 - MONOCULAR BEST CORRECTED CONTRAST SENSITIVITY (MESOPIC WITHOUT GLARE) IN FIRST-IMPLANTED EYES (BEST CASE SET)



Error bars represent ± 1 standard error about the mean.

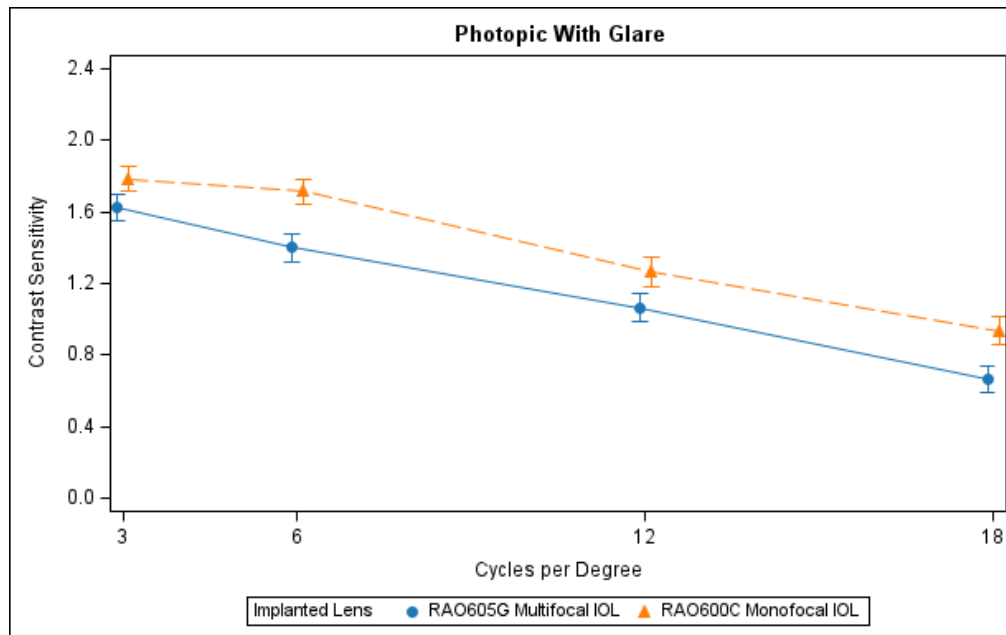
Contrast Sensitivity is presented in log units ranging from 0.00 (100% contrast) to 2.4 (0.4% contrast).

FIGURE 11 - MONOCULAR BEST CORRECTED CONTRAST SENSITIVITY (MESOPIC WITH GLARE) IN FIRST-IMPLANTED EYES (BEST CASE SET)



Error bars represent ± 1 standard error about the mean.
 Contrast Sensitivity is presented in log units ranging from 0.00 (100% contrast) to 2.4 (0.4% contrast).

FIGURE 12 - MONOCULAR BEST CORRECTED CONTRAST SENSITIVITY (PHOTOPIC WITH GLARE) IN FIRST-IMPLANTED EYES (BEST CASE SET)



Error bars represent ± 1 standard error about the mean.

Contrast Sensitivity is presented in log units ranging from 0.00 (100% contrast) to 2.4 (0.4% contrast).

3. Effectiveness Results

The analysis of effectiveness was based on the intent to treat (ITT) cohort of 230 patients who were randomized (114 in the Multifocal IOL group and 116 in the Monofocal IOL group) and available for the 6-month (120 to 180) evaluation. Key effectiveness outcomes are presented in **TABLE 29** to **TABLE 37**.

Co-primary effectiveness outcomes are presented in **TABLE 29** and **TABLE 30**.

All co-primary effectiveness endpoints for this study were met.

The first co-primary effectiveness endpoint was the mean photopic monocular BCDVA at 4 meters in First Implanted eyes at 120 to 180 days postoperatively (Visit 4). The success criterion was that the mean photopic monocular BCDVA at 4 meters in First Implanted eyes in the Multifocal group would be better than or equal to 0.20 logMAR (i.e., mean logMAR ≤ 0.20 without rounding). At Visit 4, the estimated mean (SE) monocular BCDVA in First Implanted Multifocal eyes

was 0.031 (0.0076) logMAR (n = 114), and this co-primary effectiveness endpoint was successful. For First Implanted Monofocal eyes in the ITT set, the mean (SE) monocular BCDVA was -0.035 (0.0078) logMAR (n = 116).

The second co-primary effectiveness endpoint was the difference in mean photopic monocular DCNVA at 40 cm between IOL groups (Multifocal – Monofocal) in First Implanted eyes at 120 to 180 days post-operatively (Visit 4). The endpoint was considered successful if the mean monocular DCNVA in Multifocal group was statistically superior to the Monofocal group. At Visit 4, the estimated mean [95% CI] difference between groups was -0.275 [-0.309, -0.241] logMAR in favor of the Multifocal group in the ITT set. The one-sided t-test was statistically significant (p < 0.0001). Therefore, the Multifocal IOL was successful in this co-primary endpoint, with an improvement of 0.275 logMAR or 2.75 lines over the Monofocal group at a near distance of 40 cm.

Monocular BCDVA and DCNVA outcomes in first-implanted eyes were generally consistent across study site, sex, age group, race, and ethnicity, with poolability analyses showing no statistically significant heterogeneity in treatment effect; although a numerically larger DCNVA treatment difference was observed in the Hispanic/Latino subgroup, this finding was limited by small sample size and was considered statistically fragile and not clinically meaningful.

TABLE 29 PHOTOPIC MONOCULAR BCDVA (LOGMAR) AT 4M IN FIRST-IMPLANTED EYES AT VISIT 4 (ITT SET)

Statistic	RAO605G Multifocal IOL (N=114)	RAO600C Monofocal IOL (N=116)	Multifocal - Monofocal
Available for Analysis (In Window) at Visit 4	110/114 (96.5%)	109/116 (94.0%)	
Imputed at Visit 4	4/114 (3.5%)	7/116 (6.0%)	
Estimated Mean ± SE ^[1]	0.031 ± 0.0076	-0.035 ± 0.0078	0.066 ± 0.0109
95% Confidence Interval	(0.0161, 0.0460)	(-0.0502, -0.0195)	(0.0445, 0.0873)
Min, Max	0.028, 0.034	-0.038, -0.031	0.060, 0.070
t Value			-3.13
P-value ^[2]			0.0018

Missing values were imputed using 50 imputed datasets. The Markov chain Monte Carlo method was used to compute monotone imputations using treatment and the corresponding visual acuity assessment(s) at all scheduled visits prior to Visit 4. As Visit 4 is the final assessment of visual acuity (excluding potential unscheduled visits following Visit 4), data was imputed using a monotone regression method.

^[1]The Primary Effectiveness Endpoint of mean photopic monocular best corrected distance visual acuity (BCDVA) at 4 meters in first implanted eyes is successful if the mean meets or exceeds 0.20 logMAR (i.e. mean logMAR $\leq$ 0.20 without rounding).

^[2]A non-inferiority t-test with a non-inferiority margin of 0.10 is used to evaluate the Secondary Effectiveness Endpoint of photopic monocular best corrected distance visual acuity (BCDVA) at 4 meters.

TABLE 30. PHOTOPIC MONOCULAR DCNVA (LOGMAR) AT 40CM IN FIRST-IMPLANTED EYES AT VISIT 4 (ITT SET)

Statistic	RAO605G Multifocal IOL (N=114)	RAO600C Monofocal IOL (N=116)	Multifocal - Monofocal
Available for Analysis (In Window) at Visit 4	110/114 (96.5%)	109/116 (94.0%)	
Imputed at Visit 4	4/114 (3.5%)	7/116 (6.0%)	
Estimated Mean $\pm$ SE ^[1]	0.252 $\pm$ 0.0101	0.527 $\pm$ 0.0139	-0.275 $\pm$ 0.0172
95% Confidence Interval	(0.2324, 0.2718)	(0.4999, 0.5545)	(-0.3089, -0.2414)
Min, Max	0.248, 0.255	0.518, 0.533	-0.285, -0.267
t Value			-15.98
P-value ^[2]			<0.0001

Missing values were imputed using 50 imputed datasets. The Markov chain Monte Carlo method was used to compute monotone imputations using treatment and the corresponding visual acuity assessment(s) at all scheduled visits prior to Visit 4. As Visit 4 is the final assessment of visual acuity (excluding potential unscheduled visits following Visit 4), data was imputed using a monotone regression method.

^[1]The Secondary Effectiveness Endpoint of mean photopic monocular distance-corrected near visual acuity (DCNVA) at 40 cm is successful if the mean meets or exceeds 0.20 logMAR (i.e. mean logMAR $\leq$ 0.20 without rounding).

^[2]The Primary Effectiveness Endpoint of difference in mean photopic monocular distance-corrected near visual acuity (DCNVA) at 40 cm is successful if the mean DCNVA of Multifocal group is significantly better than that of Monofocal group using a one-sided t-test at alpha of 0.025.

Secondary Effectiveness Endpoints

The mean difference [95% CI] between groups in mean photopic monocular BCDVA at 4 meters in First Implanted eyes was 0.066 [0.045, 0.087] logMAR, for a statistically significant difference demonstrating non-inferiority of the Multifocal IOL over the Monofocal IOL p= 0.0018. Refer to **TABLE 29**.

The mean difference [95% CI] between groups in mean photopic monocular DCIVA at 66 cm in First Implanted eyes (Multifocal – Monofocal) at 120 to 180 days post-operatively (Visit 4) was -0.206 [-0.238, -0.173] logMAR, for a statistically significant difference p < 0.0001) in favor of the Multifocal group,

corresponding to an improvement of 0.2 logMAR over the Monofocal group at intermediate distance of 66 cm. Refer to **TABLE 31**.

The mean (SE) photopic monocular DCIVA at 66 cm in First Implanted eyes at 120 to 180 days post-operatively (Visit 4) was 0.129 (0.0112) logMAR in Multifocal eyes, which exceeded the threshold of 0.20 logMAR; therefore, the endpoint was met. Refer to **TABLE 31**.

The mean $\pm$ SD photopic monocular DCVA in First Implanted eyes at 120 to 180 days post-operatively (Visit 4) in the Multifocal IOL group was 0.141 ± 0.129 logMAR at 1.0 m, and 0.194 ± 0.171 logMAR at 50 cm, which exceeded the threshold of 0.20 logMAR; therefore, the endpoint was met. For comparison, in the Monofocal group, the mean $\pm$ SD DCVA was 0.198 ± 0.123 logMAR at 1.0 m and 0.452 ± 0.194 logMAR at 50 cm, corresponding to differences in means [95% CI] of -0.057 [-0.091, -0.023] at 1.0 m and -0.258 [-0.307, -0.209] at 50 cm in favor of the Multifocal group. Refer to **TABLE 32**.

The mean photopic monocular DCNVA at 40 cm in First Implanted eyes at 120 to 180 days post-operatively (Visit 4) was 0.252 (0.0101) logMAR in the Multifocal eyes and 0.527 (0.0139) logMAR in the Monofocal eyes with a difference in means of -0.275 (0.0172). A one-sided t-test demonstrated that the difference in means was statistically significant ($t = -15.98$, $P < .0001$). Refer to **TABLE 30**.

The binocular best-corrected distance defocus curve at 120 to 180 days post-operatively (Visit 4) is shown **FIGURE 13**. Each subject was defocused using spherical lenses from -4.00 D to +2.00 D, applied in randomized order over each subject's manifest distance correction. Lens power was adjusted in 0.50 D increments, except between -0.50 D and +0.50 D, where 0.25 D steps were used. In both lens groups, the defocus curves peaked at 0.00 D, with a mean acuity of 0.0 logMAR or better. In the Multifocal group, visual acuity better than 0.20 logMAR was maintained through -2.50 D of defocus, corresponding to approximately 40 cm. In contrast, visual acuity in the Monofocal group declined below the 0.20 logMAR threshold between -1.00 and -1.50 D. Subjects were also subdivided by photopic pupil size. Those with the smallest pupil sizes ≤ 3.0 mm (Multifocal IOL group, $n=6$; Monofocal IOL group, $n=4$), those with medium pupil > 3.0 mm and < 4 mm (Multifocal IOL group, $n=25$; Monofocal IOL group, $n=30$) and those with large pupil size > 4 mm (Multifocal IOL group, $n=78$; Monofocal IOL group, $n=76$). The global poolability statistic demonstrated no effect of preoperative pupil size on the difference between IOL groups in binocular defocus outcomes ($p = 0.7019$).

TABLE 31 PHOTOPIC MONOCULAR DCIVA (LOGMAR) AT 66CM IN FIRST-IMPLANTED EYES AT VISIT 4 (ITT SET)

Statistic	RAO605G Multifocal IOL (N=114)	RAO600C Monofocal IOL (N=116)	Multifocal - Monofocal
Available for Analysis (In Window) at Visit 4	110/114 (96.5%)	109/116 (94.0%)	
Imputed at Visit 4	4/114 (3.5%)	7/116 (6.0%)	
Estimated Mean $\pm$ SE ^[1]	0.129 $\pm$ 0.0112	0.335 $\pm$ 0.0119	-0.206 $\pm$ 0.0164
95% Confidence Interval	(0.1073, 0.1510)	(0.3113, 0.3581)	(-0.2377, -0.1735)
Min, Max	0.124, 0.134	0.330, 0.340	-0.212, -0.200
t Value			-12.56
P-value ^[2]			<.0001

Missing values were imputed using 50 imputed datasets. The Markov chain Monte Carlo method was used to compute monotone imputations using treatment and the corresponding visual acuity assessment(s) at all scheduled visits prior to Visit 4. As Visit 4 is the final assessment of visual acuity (excluding potential unscheduled visits following Visit 4), data was imputed using a monotone regression method.

^[1]The Secondary Effectiveness Endpoint of mean photopic monocular distance-corrected intermediate visual acuity (DCIVA) at 66cm is successful if the mean meets or exceeds 0.20 logMAR (i.e. mean logMAR $\leq$ 0.20 without rounding).

^[2]A one-sided t-test is used to evaluate the Secondary Effectiveness Endpoint of photopic monocular distance-corrected intermediate visual acuity (DCIVA) at 66 cm.

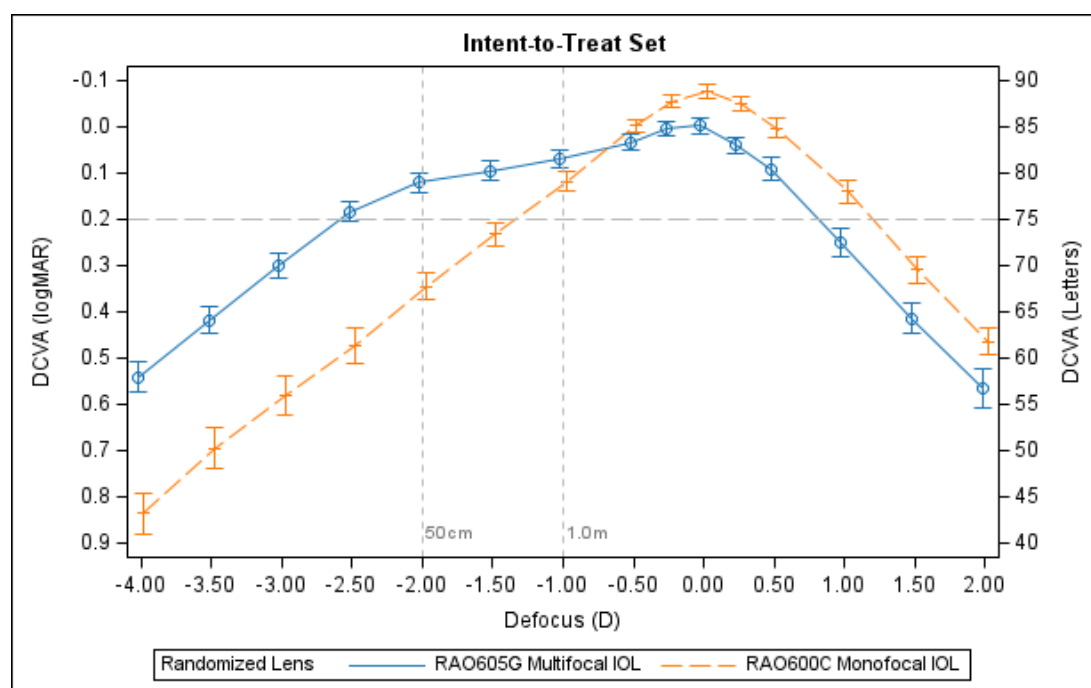
TABLE 32 PHOTOPIC MONOCULAR DCVA (LOGMAR) IN FIRST-IMPLANTED EYES AT VISIT 4 (ITT SET)

		Focal Length	
Randomized Lens	Statistic	1.0 m	50 cm
RAO605G Multifocal IOL	n	110	110
	Mean $\pm$ SD	0.141 $\pm$ 0.129	0.194 $\pm$ 0.171
	Median	0.12	0.16
	Min, Max	-0.12, 0.48	-0.04, 0.94
	Q1, Q3	0.04, 0.24	0.10, 0.24
RAO600C Monofocal IOL	n	109	109
	Mean $\pm$ SD	0.198 $\pm$ 0.123	0.452 $\pm$ 0.194
	Median	0.20	0.44
	Min, Max	-0.14, 0.50	0.04, 1.10
	Q1, Q3	0.12, 0.30	0.32, 0.58
	Difference in Means $\pm$ SE	-0.057 $\pm$ 0.0171	-0.258 $\pm$ 0.0247
	95% CI for Diff in Means	(-0.0905, -0.0233)	(-0.3067, -0.2092)

Abbreviations: n = number of First Implanted Eyes with non-missing photopic monocular distance-corrected visual acuity data at the applicable focal length. Note: Focal Length (m) = 1/D, where D is the defocus step in negative power.

The Secondary Effectiveness Endpoint of Photopic monocular distance-corrected visual acuity (DCVA) at 1.0 m and 50 cm is successful if both the mean DCVA at 1.0 m, and the mean DCVA at 50 cm, of Multifocal group first-implanted eyes at Visit 4 are ≤ 0.20 logMAR

FIGURE 13. PHOTOPIC BINOCULAR DEFOCUS CURVES AT VISIT 4 (ITT SET)



Error bars represent a 95% confidence interval about the mean.

Additional Effectiveness Endpoints

Additional effectiveness endpoints were descriptive in nature, and no formal statistical inference was conducted. Each analysis was summarized by treatment group using the ITT set. Supportive effectiveness analyses included categorical summaries of visual acuity outcomes.

TABLE 33 shows photopic monocular distance-corrected visual acuity at distance (BCDVA), intermediate (DCIVA) and near (DCNVA) in first implanted eyes (ITT Set) at Visit 4 (Day 120-180). All First Implanted eyes in both groups achieved BCDVA of 0.30 logMAR or better. The majority of Multifocal eyes achieved DCIVA of 0.30 logMAR or better at Visit 4 (104/110, 94.5% First Implanted eyes and 107/109); for Monofocal eyes these corresponded to 44/111 (39.6%). Similarly, most Multifocal eyes had DCNVA of 0.30 logMAR or better (83/110, 75.5%) while only 8/111 (7.2%) of First Implanted Monofocal eyes achieved monocular DCNVA of 0.30 logMAR or better.

TABLE 34 shows the mean photopic binocular distance-corrected visual acuity (logMAR) (ITT Set) at distance (BCDVA), intermediate (DCIVA) and near (DCNVA) at Visit 4 (Day 120-180)

TABLE 35 shows mesopic monocular distance-corrected visual acuity at distance (BCDVA), intermediate (DCIVA) and near (DCNVA) in first implanted eyes (ITT Set) at Visit 4 (Day 120-180). In both lens groups, most eyes had mesopic BCDVA of 0.30 logMAR or better (94/110, 85.5% of First Multifocal eyes and 104/111, 93.7% of First Monofocal eyes). Approximately half of Multifocal eyes achieved mesopic DCIVA of 0.30 logMAR or better (57/110, 51.8%), while very few Monofocal eyes had mesopic DCIVA 0.30 logMAR or better at Visit 4 (7/111, 6.3%). In the Multifocal group, 15/110 (13.6%) maintained DCNVA 0.30 logMAR or better under mesopic lighting compared to no (0%) eyes in the Monofocal group.

TABLE 36 shows mesopic binocular distance-corrected visual acuity (ITT Set) at distance (BCDVA), intermediate (DCIVA) and near (DCNVA) at Visit 4 (Day 120-180). Nearly all subjects in both groups achieved mesopic binocular BCDVA of 0.30 logMAR or better (104/109, 95.4% Multifocal and 108/109, 99.1% Monofocal) at Visit 4. A majority of Multifocal subjects achieved mesopic binocular DCIVA of 0.30 logMAR or better (87/109, 79.8%) compared to 23/109 (21.1%) of Monofocal subjects. And approximately a third of Multifocal subjects had 0.30 logMAR or better binocular mesopic near vision (40/109, 36.7%) compared to no (0%) Monofocal subjects.

TABLE 37 shows photopic binocular uncorrected visual acuity (ITT Set) at Visit 4 (Day 120-180).

TABLE 33 PHOTOPIC MONOCULAR DISTANCE-CORRECTED VISUAL ACUITY IN FIRST IMPLANTED EYES (ITT SET) AT VISIT 4 (DAY 120-180)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
4 m	N (eyes)	110	111
	0.00 (20/20) logMAR or better	48 (43.6%)	88 (79.3%)
	0.10 (20/25) logMAR or better	94 (85.5%)	107 (96.4%)
	0.20 (20/32) logMAR or better	107 (97.3%)	109 (98.2%)
	0.30 (20/40) logMAR or better	110 (100%)	111 (100%)
	Worse than 0.30 logMAR	0	0
66 cm	N (eyes)	110	111
	0.00 (20/20) logMAR or better	12 (10.9%)	0
	0.10 (20/25) logMAR or better	54 (49.1%)	5 (4.5%)
	0.20 (20/32) logMAR or better	91 (82.7%)	22 (19.8%)
	0.30 (20/40) logMAR or better	104 (94.5%)	44 (39.6%)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
	Worse than 0.30 logMAR	6 (5.5%)	67 (60.4%)
40 cm	N (eyes)	110	111
	0.00 (20/20) logMAR or better	2 (1.8%)	0
	0.10 (20/25) logMAR or better	7 (6.4%)	0
	0.20 (20/32) logMAR or better	39 (35.5%)	2 (1.8%)
	0.30 (20/40) logMAR or better	83 (75.5%)	8 (7.2%)
	Worse than 0.30 logMAR	27 (24.5%)	103 (92.8%)

TABLE 34 MEAN PHOTOPIC BINOCULAR DISTANCE-CORRECTED VISUAL ACUITY (LOGMAR) (ITT SET) AT VISIT 4 (DAY 120-180)

Lens	Statistics	Mean Photopic Binocular Distance-Corrected Visual Acuity (logMAR)		
		4 m	66 cm	40 cm
RAO605G Multifocal IOL	Mean (SE)	-0.020 (0.083)	0.059 (0.074)	0.172 (0.081)
RAO600C Monofocal IOL	Mean (SE)	-0.081 (0.072)	0.234 (0.115)	0.425 (0.137)
Difference	Mean ± SD	0.061 ± 0.0105	-0.175 ± 0.0131	-0.253 ± 0.0153
	95% CI	0.0403; 0.0819	-0.2012; -0.1496	-0.2832; -0.2229

TABLE 35 MESOPIC MONOCULAR DISTANCE-CORRECTED VISUAL ACUITY IN FIRST IMPLANTED EYES (ITT SET) AT VISIT 4 (DAY 120-180)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
4 m	N (eyes)	110	111
	0.00 (20/20) logMAR or better	2 (1.8%)	11 (9.9%)
	0.10 (20/25) logMAR or better	23 (20.9%)	50 (45.0%)
	0.20 (20/32) logMAR or better	55 (50.0%)	89 (80.2%)
	0.30 (20/40) logMAR or better	94 (85.5%)	104 (93.7%)
	Worse than 0.30 logMAR	16 (14.5%)	7 (6.3%)
66 cm	N (eyes)	110	111
	0.00 (20/20) logMAR or better	2 (1.8%)	0
	0.10 (20/25) logMAR or better	4 (3.6%)	0
	0.20 (20/32) logMAR or better	19 (17.3%)	1 (0.9%)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
	0.30 (20/40) logMAR or better	57 (51.8%)	7 (6.3%)
	Worse than 0.30 logMAR	53 (48.2%)	104 (93.7%)
40 cm	N (eyes)	110	110
	0.00 (20/20) logMAR or better	0	0
	0.10 (20/25) logMAR or better	1 (0.9%)	0
	0.20 (20/32) logMAR or better	4 (3.6%)	0
	0.30 (20/40) logMAR or better	15 (13.6%)	0
	Worse than 0.30 logMAR	95 (86.4%)	110 (100%)

Abbreviations: n = number of eyes meeting the specified visual acuity criterion; N = total number of First Implanted Eyes with non-missing mesopic distance-corrected visual acuity data at the respective testing distance in each treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective testing distance and treatment group.

TABLE 36 MESOPIC BINOCULAR DISTANCE-CORRECTED VISUAL ACUITY (ITT SET) AT VISIT 4 (DAY 120-180)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
4 m	N (subjects)	109	109
	0.00 (20/20) logMAR or better	6 (5.5%)	26 (23.9%)
	0.10 (20/25) logMAR or better	36 (33.0%)	80 (73.4%)
	0.20 (20/32) logMAR or better	80 (73.4%)	98 (89.9%)
	0.30 (20/40) logMAR or better	104 (95.4%)	108 (99.1%)
	Worse than 0.30 logMAR	5 (4.6%)	1 (0.9%)
66 cm	N (subjects)	109	109
	0.00 (20/20) logMAR or better	1 (0.9%)	0
	0.10 (20/25) logMAR or better	7 (6.4%)	1 (0.9%)
	0.20 (20/32) logMAR or better	42 (38.5%)	6 (5.5%)
	0.30 (20/40) logMAR or better	87 (79.8%)	23 (21.1%)
	Worse than 0.30 logMAR	22 (20.2%)	86 (78.9%)
40 cm	N (subjects)	109	109
	0.00 (20/20) logMAR or better	0	0
	0.10 (20/25) logMAR or better	1 (0.9%)	0
	0.20 (20/32) logMAR or better	10 (9.2%)	0
	0.30 (20/40) logMAR or better	40 (36.7%)	0
	Worse than 0.30 logMAR	69 (63.3%)	109 (100%)

Abbreviations: n = number of subjects meeting the specified visual acuity criterion; N = total number of subjects with non-missing mesopic binocular distance-corrected visual acuity data at

the respective testing distance in each treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective testing distance and treatment group.

TABLE 37 -PHOTOPIC BINOCULAR UNCORRECTED VISUAL ACUITY (ITT SET) AT VISIT 4 (DAY 120-180)

Distance	Statistic	RAO605G Multifocal IOL n (%)	RAO600C Monofocal IOL n (%)
4 m	N (subjects)	109	109
	0.00 (20/20) logMAR or better	32 (29.4%)	75 (68.8%)
	0.10 (20/25) logMAR or better	74 (67.9%)	98 (89.9%)
	0.20 (20/32) logMAR or better	101 (92.7%)	109 (100%)
	0.30 (20/40) logMAR or better	107 (98.2%)	109 (100%)
	Worse than 0.30 logMAR	2 (1.8%)	0
66 cm	N (subjects)	109	109
	0.00 (20/20) logMAR or better	35 (32.1%)	12 (11.0%)
	0.10 (20/25) logMAR or better	87 (79.8%)	35 (32.1%)
	0.20 (20/32) logMAR or better	105 (96.3%)	69 (63.3%)
	0.30 (20/40) logMAR or better	109 (100%)	95 (87.2%)
	Worse than 0.30 logMAR	0	14 (12.8%)
40 cm	N (subjects)	109	109
	0.00 (20/20) logMAR or better	7 (6.4%)	1 (0.9%)
	0.10 (20/25) logMAR or better	48 (44.0%)	4 (3.7%)
	0.20 (20/32) logMAR or better	94 (86.2%)	13 (11.9%)
	0.30 (20/40) logMAR or better	109 (100%)	42 (38.5%)
	Worse than 0.30 logMAR	0	67 (61.5%)

Abbreviations: n = number of subjects meeting the specified visual acuity criterion; N = total number of subjects with non-missing photopic binocular uncorrected visual acuity data at the respective testing distance in each treatment group. Categorical results are presented as n (%). Percentages are calculated as n/N using the applicable N for the respective testing distance and treatment group.

4. Subgroup Analyses

The following baseline characteristics were evaluated for potential association with safety and effectiveness outcomes: study site, sex, age group, race, and ethnicity.

Monocular BCDVA and DCNVA outcomes in first-implanted eyes were generally consistent across study site, sex, age group, race, and ethnicity, with poolability analyses showing no statistically significant heterogeneity in treatment

effect; although a numerically larger DCNVA treatment difference was observed in the Hispanic/Latino subgroup, this finding was limited by small sample size and was considered statistically fragile and not clinically meaningful.

For safety, variables and time points used for the primary safety endpoints were summarized descriptively for each treatment group by sex, age group, race, and ethnicity. Cumulative and persistent adverse events were also summarized separately by age group and investigator.

The study was not specifically powered for study site-, sex-, age-, race-, or ethnicity-specific subgroup analyses.

4. Pediatric Extrapolation

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

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 10 investigators of which none were full-time or part-time employees of the sponsor and 1 had disclosable financial interests/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: None
- Significant payment of other sorts: None
- Proprietary interest in the product tested held by the investigator: None
- Significant equity interest held by investigator in sponsor of covered study: 1

The applicant 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

There have been no prospective randomized controlled clinical trials conducted OUS on the RayOne Galaxy (Model RAO605G) or RayOne Galaxy Toric (Model RAO615X). Since commercialization outside of the United States, there have been several post-market studies conducted and presented at various ophthalmic society meetings.

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

A. Panel Meeting Recommendation

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 Ophthalmics Devices 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 PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The effectiveness results from the sequentially conducted RayOne EMV Toric IOL (Model RAO210T) (IDE#G230072) and RayOne Galaxy (Model RAO605G) IOL clinical studies (IDE#G210105) demonstrate that the RayOne Galaxy and RayOne Galaxy Toric (Model RAO615X) are effective for primary implantation in the capsular bag for the visual correction of aphakia, in adult patients in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity while maintaining comparable distance visual acuity to an aspheric monofocal IOL.

In addition, the studies demonstrated that RayOne Galaxy Toric is effective to provide reduction of residual refractive astigmatism of the eye in patients with corneal astigmatism greater than or equal to 1.00 diopter.

All primary effectiveness endpoints in the RayOne Galaxy (Model RAO605G) IOL clinical trial were met. Mean photopic monocular BCDVA in First Implanted Multifocal eyes at Visit 4 was 0.031 logMAR, which exceeded the threshold of 0.20 logMAR. The second co-primary effectiveness endpoint of photopic monocular DCNVA was also met, with a mean difference between groups of -0.275, in favor of the Multifocal. This difference was statistically and clinically significant ($p < 0.0001$).

B. Safety Conclusions

The risks of the RayOne Galaxy and RayOne Galaxy Toric devices are based on non-clinical laboratory and animal testing as well as data cumulatively collected in RayOne EMV Toric IOL (Model RAO210T) (IDE# G230072) and RayOne Galaxy (Model RAO605G) IOL IDE clinical studies conducted to support PMA approval as described above. The results of the non-clinical laboratory testing including biocompatibility testing, dimensional, optical and mechanical testing, sterility testing, and chemical testing on the Rayacryl material support safety conclusions.

All primary clinical safety endpoints of the clinical trial were met. No First Implanted Multifocal eye required secondary surgical intervention due to the optical properties of the IOL, and all First Implanted Multifocal eyes had BCDVA of 0.30 logMAR or better at Visit 4. No Second Implanted Multifocal eye required secondary surgical intervention due to the optical properties of the IOL, and 108/110 (98.2%) Second Implanted Multifocal eyes achieved BCDVA of 0.30 logMAR or better at Visit 4, which exceeded the ISO SPE rate of 92.5%. Rates of adverse events in First Implanted Multifocal eyes were not statistically higher than the ISO grid ($p > 0.05$), and the safety endpoint was therefore successfully met. Rates and types of other adverse events were consistent with those expected with cataract surgery. In the supportive analyses, the rates of cumulative and persistent adverse events observed in Second Implanted and All Implanted eyes were not statistically higher than the ISO grid (all p -values > 0.05), except for SSI, the majority of which were unrelated to the IOL. Rates and types of other adverse events were consistent with those expected with cataract surgery.

Ocular adverse events were reported in 60/112 (53.6%) First Implanted Multifocal eyes and 66/111 (59.5%) Second Implanted Multifocal eyes. The most common ocular adverse events included anterior chamber cells grade 0.5 or greater at Visit 2 or later, posterior capsule opacification requiring Nd:YAG capsulotomy, corneal edema, and elevated IOP. Anterior chamber cell events were predominantly mild in severity and resolved without sequelae and per the study protocol, anterior chamber cell or flare of any grade at Week 1 (Visit 2) or later was reported as an adverse event, regardless of whether a change in the standard postoperative medication regimen was required. Corneal edema was early onset and resolved during study follow-up, and elevated IOP events were mild or moderate in severity and resolved without sequelae. Secondary surgical interventions in Multifocal eyes were predominantly Nd:YAG laser capsulotomies for posterior capsule opacification.

Postoperative ocular SAE rates were low. In First Implanted eyes, 3 SAEs occurred in 2/112 (1.8%) Multifocal eyes compared with no SAEs in Monofocal eyes. The events in the Multifocal group were deemed not related to the study device. In Second Implanted eyes, 3 SAEs occurred in 3/111 (2.7%) Multifocal eyes compared with 3 SAEs in 1/114 (0.9%) Monofocal eye. In the Multifocal group, one IOL exchange was determined to be related to the study device. A small number of subjects also experienced non-ocular SAEs: 2/112 (1.8%) subjects in the Multifocal group and 4/115 (3.5%) subjects in the Monofocal group. No non-ocular in either group was determined to be related to the study device or study procedure.

The study successfully met the ISO 11979-7:2024 predefined criterion for contrast sensitivity: under mesopic conditions without glare, the mean contrast sensitivity for the Multifocal group was not more than 0.3 log units below that of the Monofocal control at each tested spatial frequency.

Patient-reported visual disturbances were assessed using the Quality of Vision (QoV) Patient Reported Outcome Instrument and Patient Vision Questionnaire, as further described in the Patient Perspective below.

Potential heterogeneity in treatment safety was evaluated by summarizing the variables and time points used for the primary safety endpoints descriptively for each treatment group by sex, age, race, and ethnicity.

Overall results confirm the safety and effectiveness of the RayOne Galaxy IOL are as expected and fulfill ISO 11979-7 for a Multifocal IOL with improved near and intermediate vision and comparable distance vision to a monofocal IOL.

C. Benefit-Risk Determination

The probable benefits of the devices are based on data collected in clinical studies conducted to support PMA approval as described above.

The clinical benefits of the RayOne Galaxy and RayOne Galaxy Toric are based on the data collected in this clinical study (IDE# G210105) and on the data previously collected in the RayOne EMV Toric clinical study (IDE# G230072).

IDE# G210105 clinical trial demonstrated the safety and effectiveness of the RayOne Galaxy IOL following bilateral (sequential) implantation for the correction of aphakia in adults in whom the cataractous lens has been removed by phacoemulsification extraction. Visual acuity outcomes across distance, intermediate, and near ranges, combined with a safety profile comparable to an approved intraocular lens, support the effectiveness and safety of the RayOne Galaxy IOL for cataract surgery. Overall, the RayOne Galaxy performed as intended and fulfilled the requirements of ISO 11979-7:2024. The clinical benefit of the RayOne Galaxy includes improved intermediate and near visual acuity while maintaining distance visual acuity. At Visit 4, the mean difference in photopic monocular DCNVA between the Multifocal and Monofocal groups was 0.275 logMAR in favor of the Multifocal group, and 94.5% (104/110) of First Implanted Multifocal eyes achieved photopic monocular DCIVA of 0.30 logMAR or better. These benefits were demonstrated through the 120 to 180 day post-operative evaluation.

IDE# G230072 demonstrated that the RayOne EMV Toric is safe and effective when used as intended and according to the instructions for use. The study has demonstrated statistically significant and clinically meaningful results in favor of RayOne EMV Toric regarding visual correction of aphakia and reduction of residual refractive astigmatism in adult subjects with greater than or equal to 1.00 diopter (D) of preoperative corneal astigmatism.

The probable risks of the devices are also based on data collected in the IDE# G210105 clinical study conducted to support PMA approval as described above. Adverse events were comparable to those associated with a Monofocal lens. Observed adverse events included device- and procedure-related ocular events of varying severity, as described in the clinical safety results above. Rates and types of other adverse events were consistent

with those expected with cataract surgery, and subjects with ocular adverse events or complications were followed until the event resolved or stabilized.

Additional factors considered in determining the probable risks and benefits of the RayOne Galaxy and RayOne Galaxy Toric included:

- the prospective, multicenter, randomized, active-controlled, masked study design;
- protocol-standardized clinical assessments;
- the availability of alternative intraocular lenses; and
- patient-reported visual outcomes.

Potential heterogeneity in treatment safety and effectiveness was evaluated by sex, age, race, and ethnicity, as described above.

1. Patient Perspective

Patient perspectives considered during the review included patient-reported visual disturbances assessed using the Quality of Vision (QoV) Patient Reported Outcome Instrument and Patient Vision Questionnaire. At Visit 4, the number of subjects reporting the highest ratings of severity, bothersomeness, or frequency was low for both lens groups, indicating good quality of vision for most subjects. Rasch-modeled analyses showed comparable Frequency, Severity, and Bothersomeness scores between the Multifocal and Monofocal groups. The highest frequency of visual disturbance at 6 months, reported as “very often” in 10.9% (12/110 responses), was for halos in the Multifocal group. Halos were also reported as severe and very bothersome at higher rates in the Multifocal group compared with the Monofocal group; however, a vast majority of subjects in the Multifocal group (53/65 responses, 82%) did not report these as bothersome (“Not at all” or “a little”). The frequency, severity, and bothersomeness of the remaining categories of visual symptoms were similar between the two groups.

In conclusion, the data provided support that the probable benefits outweigh the probable risks for the primary implantation of the RayOne Galaxy and RayOne Galaxy Toric in the capsular bag of the eye in adult subjects in whom a cataractous lens has been removed by phacoemulsification. The lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity while maintaining comparable distance visual acuity to an aspheric monofocal IOL. In addition, the toric variant provides reduction of residual refractive astigmatism in adult patients with greater than or equal to 1.00 diopter (D) of corneal astigmatism, compared to a monofocal IOL.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the RayOne Galaxy and RayOne Galaxy Toric when used in accordance with the indications for use. The above-described clinical study was a prospective, multicenter, randomized, active controlled, masked pivotal study design based on ISO 11979-7:2024 to support a simultaneous vision IOL. It compared the RayOne Galaxy (Model

RAO605G) multifocal IOL (investigational device) to the RayOne Aspheric (Model RAO600C) monofocal IOL (control device) in 230 subjects at 10 US sites.

The study was conducted consistent with recognized ISO standard and typical enrollment criteria for an IOL study. Bias was minimized by inclusion and exclusion criteria, protocol-standardized clinical assessments (including masked testing) and surgical procedure, a randomized, controlled study design, and safety and effectiveness performance criteria endpoints in accordance with the ISO standard. Success was based on protocol-specified safety and effectiveness endpoints. Safety and effectiveness findings from the clinical study, summarized in Sections A and B above, support that a significant portion of the patient population will achieve clinically significant results. The benefits of using the device outweigh the risks, as summarized in Section C, above.

XV. CDRH DECISION

CDRH issued an approval order on September 24, 2026.

The applicant's manufacturing facility was inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820), which was in effect at the time of the inspection. As of February 2, 2026, the revised part 820, referred to as the Quality Management System Regulation (QMSR), is effective.

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

ANSI Z80.30 – Ophthalmics – Toric Intraocular Lenses

ISO 10993-1 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process

ISO 10993-3 – Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity

ISO 10993-5 – Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity

ISO 10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization

ISO 10993-11 – Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity

ISO 11979-2 – Ophthalmic Implants – Intraocular Lenses – Part 2: Optical Properties and Test Methods

ISO 11979-3 – Ophthalmic Implants – Intraocular Lenses – Part 3: Mechanical Properties and Test Methods

ISO 11979-5 – Ophthalmic Implants – Intraocular Lenses – Part 5: Biocompatibility

Masket S, Rorer E, Stark W, Holladay JT, MacRae S, Tarver ME, Glasser A, Calogero D, Hilmantel G, Nguyen T, Eydelman M. Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with Intraocular Lenses. *Ophthalmology*. 2017 Jan;124(1):142-144. doi: 10.1016/j.ophtha.2016.09.031