SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Intraocular Lens
Device Trade Name:	FINEVISION HP Trifocal IOL
Device Procode:	Intraocular Lens (HQL) Multifocal Intraocular (MFK)
Applicant's Name and Address:	Beaver-Visitec International, Inc. 500 Totten Pond Rd, 10 CityPoint, Waltham, MA 02451
Date(s) of Panel Recommendation:	None

Premarket Approval Application (PMA) Number: P240038

Date of FDA Notice of Approval: 9/10/2025

II. INDICATIONS FOR USE

The FlNEVISION HP Trifocal IOL is indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, 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 compared to a monofocal IOL.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the FINEVISION HP Trifocal IOL labeling.

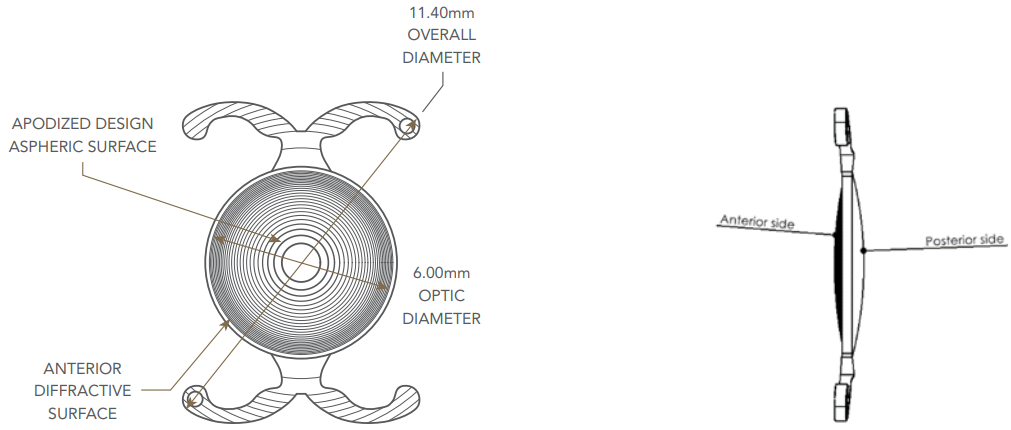
V. DEVICE DESCRIPTION

The FINEVISION HP Trifocal IOL is an ultraviolet absorbing and blue light filtering foldable multifocal IOL. Each IOL is a single-piece design with a central optic and 4 open-loop haptics (Double C-loop) (Figure 1). The optic consists of a proprietary high refractive index hydrophobic acrylic material with a UV absorbing filter (< 24% transmittance at 400 nm for a +20.0 D IOL) and a blue light filtering chromophore (< 64% at 450 nm for a +20.0 D IOL). The optic is biconvex and consists of a soft acrylic material capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. The optic is 6.0 mm in diameter and the lens has an overall diameter of 11.4 mm. After surgical insertion into the eye, the lens unfolds to its intended shape. The optic diffractive structure is apodized on the entire front portion of the optic and divides the incoming light to create a +1.75 D intermediate and a +3.50 D near add power at the IOL plane. The anterior surface is designed with negative spherical aberration to partially compensate for the positive spherical aberration of the cornea. The physical properties of this lens are described in **Table 1** and **Figures 1, 2,** and **3**.

Table 1: Physical Characteristics of FINEVISION HP Trifocal IOLs

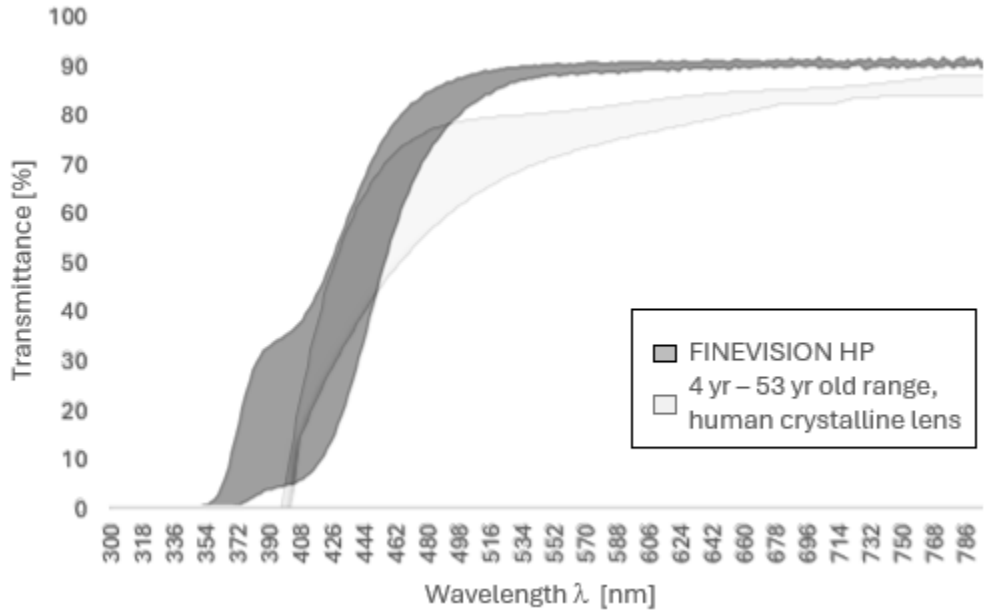
Physical Characteristic	Description
Optic Type	Single-piece IOL with aspheric biconvex apodized non-toric diffractive optic
UV cutoff at 24% T	400 nm for +20.0 D
Index Of Refraction	1.53
Spherical power	+6 D to +35 D (0.5D steps)
Add powers	+1.75D intermediate and +3.50D near add power at the IOL plane (representing +1.20 D and +2.40 D at the corneal plane after implantation, respectively, for the average human eye)
Haptic configuration	Double C-loop (POD) quadripode
Lens Material	Ultraviolet light absorbing and blue light filtering Acrylate/Methacrylate Copolymer
Optic diameter	6.00mm
Overall diameter	11.40mm
Haptic angle	5°
Sterilization	Moist steam

Figure 1: Physical Characteristics of FINEVISION HP Trifocal IOL. (A) Front view. (B) Side view.



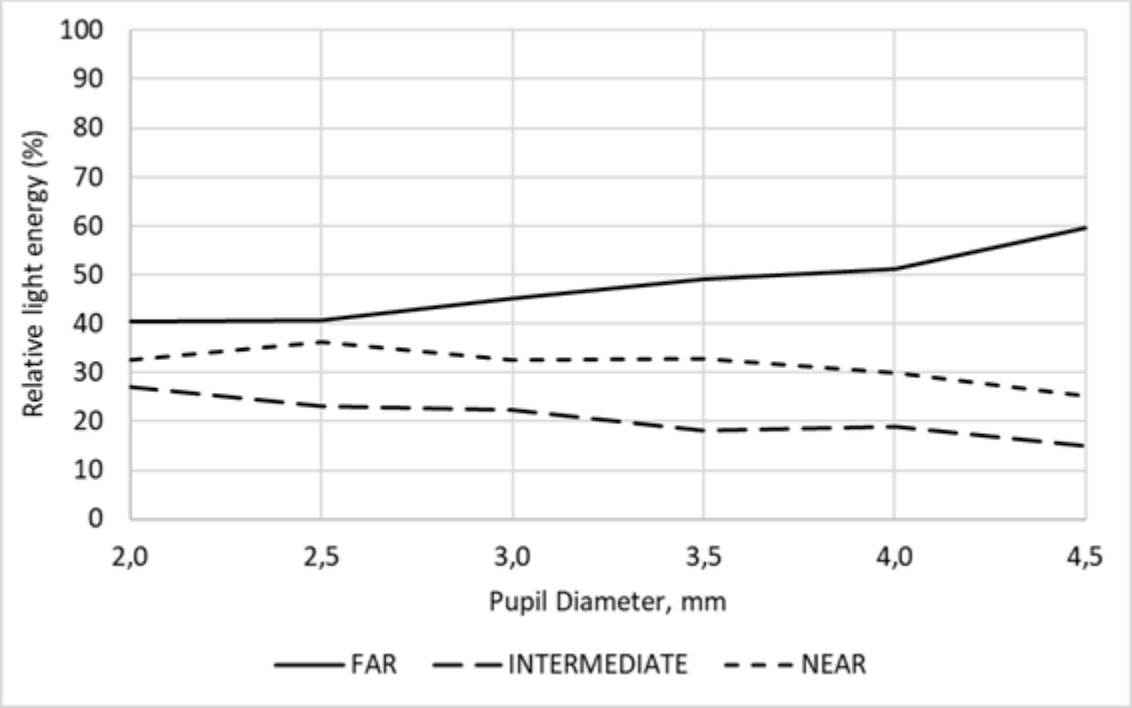
(A) Front view (B) Side view

Figure 2: Spectral Transmittance of FINEVISION HP Trifocal IOL for the entire marketed power range as well as data from human crystalline lenses of ages 4 to 53 years.



Hammond, B. R., Jr., Renzi, L. M., Sachak, S., & Brint, S. F. (2010). Contralateral comparison of blue-filtering and non-blue-filtering intraocular lenses: glare disability, heterochromatic contrast, and photostress recovery. *Clinical Ophthalmology*, 4, 1465–1473.

Figure 3: Graph of theoretical light energy repartition between the 3 foci between 2.0- and 4.5-mm pupillary aperture by increments of 0.5mm at 546 nm.



Mode of Action

The FINEVISION HP Trifocal IOLs are intended to be positioned in the lens capsule in the posterior chamber of the eye, replacing the human crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. This IOL has a biconvex optic containing an aspheric design and a diffractive structure on the anterior surface. The diffractive structure divides incoming light to provide a range of vision from distance to intermediate to near. This IOL provides an option for clinicians to provide patients an intermediate add power of +1.75 D and a near add power of +3.50 D (in the IOL plane).

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of cataracts. These include special cataract glasses or contact lenses. Surgical options such as monofocal, multifocal, extended depth of focus 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

The FINEVISION HP Trifocal IOLs are currently commercially available in the European Union, Albania, Australia, New Zealand, Azerbaijan, Bahrain, Bangladesh, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, Egypt, Hong Kong, India, Iran, Iraq, Israel, Ivory Coast, Japan, Jordan, South Korea, Kuwait, Lebanon, Libya, Malaysia, Morocco, Oman, Peru, Philippines, Saudi Arabia, Singapore, South Africa, Switzerland, Syria, Taiwan, Thailand, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Kingdom, and Vietnam. The lenses have not been withdrawn from any country for any reason including for any reason related to safety and effectiveness.

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.

- Ocular infection (endophthalmitis, microbial keratitis)
- Inflammatory reaction (e.g. uveitis, Toxic anterior segment syndrome (TASS), hypopyon)
- Anterior capsule contraction syndrome (ACCS) (Phimosis)
- Corneal edema
- Corneal endothelial damage
- Cystoid macular edema (CME)
- Secondary surgical intervention (include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration, iridectomy for pupillary block, wound leak repair, and retinal detachment repair)
- IOL dislocation, tilt, decentration, luxation, rotation
- Elevated intraocular pressure
- Pupillary block
- Posterior capsular opacification (PCO)
- Chromatic aberrations
- Dysphotopsia
- Loss of visual acuity
- Deviation from target refraction
- Hyphema
- Retinal detachment
- Iris or pupil damage
- Posterior capsular rupture
- Vitreous loss
- Wound leak (positive Seidel)

Additional complications that may occur following implantation of a multifocal intraocular lens include objectionable visual quality under certain lighting conditions (e g, chromatic aberrations, halos, night glare, decreased contrast), hazy/filmy images, "ghost" imaging of near and/or distant objects, diplopia and poor stereopsis. Some of these optical effects may be mitigated upon patient's adaptation to the multifocal optic. However, some of the above listed complications may require secondary surgical intervention for intraocular lens exchange or explantation.

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

IX. SUMMARY OF NON-CLINICAL STUDIES

Biocompatibility Testing

The studies listed in **Table 2** below were conducted to meet ISO 11979-5:2006 and ISO 10993 requirements and were 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 the biocompatibility were conducted in accordance with provisions of 21 CFR 58, Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies.

Table 2: Biocompatibility Testing

Test	Purpose	Acceptance Criteria	Results
Cytotoxicity Testing – Agar Overlay	Evaluate the potential for cellular toxicity	Non-cytotoxic	Pass
Cytotoxicity – Agar Diffusion	Evaluate the potential for cellular toxicity	Non-cytotoxic	Pass
Cytotoxicity – MEM Elution Assay	Evaluate the potential for cellular toxicity	Non-cytotoxic	Pass
Genotoxicity – Bacterial Reverse Mutation	Evaluate the potential for mutagenic activity	Non-mutagenic	Pass
Genotoxicity – In vitro Micronucleus Test	Evaluate the potential for genotoxic activity	Non-genotoxic	Pass
Sensitization	Evaluate the potential for sensitization	Non-sensitizer	Pass
Primary Ocular Irritation	Determine if extracts of IOL caused irritation in the eyes of rabbits	Non-irritant to the ocular tissues of the model animal.	Pass
Intracutaneous Injection	See the potential to produce irritation after injection	Test article meets the requirements of ISO 10993-10	Pass
Systemic Toxicity	Evaluate biological reaction to extracts	Test article meets the requirements of ISO 10993-11	Pass
Material Mediated Pyrogenicity	Potential to produce a pyrogenic response	Test article is considered non-pyrogenic and meets the requirements of ISO 10993-11	Pass
Intramuscular Implantation	Evaluate muscle reaction after implantation	Test article meets the requirements of ISO 10993-6	Pass

Test	Purpose	Acceptance Criteria	Results
Complement Activation	potential for activation of the complement system.	Test article meets the requirements of ISO 10993-4	Pass
Hemolysis (Extract Method)	Potential to cause hemolysis in human blood	Test article meets the requirements of ISO 10993-4	Pass
Hemolysis (Direct Contact Method)	Potential to cause hemolysis in human blood	Test article meets the requirements of ISO 10993-4	Pass
Biocompatibility and Capsular Bag Opacification	Assessment of capsular bag opacification	Test article meets the requirements of ISO 11979-5:2006	Pass

Physiochemical Tests

The material used for FINEVISION HP Trifocal IOL has been tested to meet the recommendations in ISO 11979-5 Ophthalmic implants- intraocular Lenses Part 5- Biocompatibility and has Pass the tests listed in **Table 3** below.

Table 3: Chemical Testing

Test	Purpose	Acceptance Criteria	Results
Exhaustive Extraction	Soxhlet extraction to recover polymerization residuals, impurities, and additives, quantitative analysis of extracts	ISO 11979-5:2020 Section 5.3 and Annex A	Pass
Hydrolytic Stability	Test to verify material does not degrade by hydrolysis	ISO 11979-5:2020 Section 5.5 and Annex C	Pass
Leachable Extraction	Extraction procedure to simulate leachable components that are expected to be released in-vivo	ISO 11979-5:2020 Section 5.4 and Annex B	Pass
Photostability	Test to evaluate photostability over 20 years at 300-400 nm	ISO 11979-5:2020 Section 5.6 and Annex D	Pass
Nd-YAG Laser Exposure	Test to evaluate material stability when exposed to Nd-YAG laser treatment, and no leakage of toxic components	ISO 11979-5:2020 Section 5.7 and Annex E	Pass
Insoluble Inorganics	Test to verify removal of residual inorganics residues from the manufacturing process.	ISO 11979-5:2020 Section 5.8	Pass

Optical/Mechanical Testing

The mechanical and optical properties of the FINEVISION HP Trifocal IOLs (POD F GF IOLs) were assessed in compliance with ISO 11979-2 Ophthalmic Implants – Intraocular Lenses – Part 2: Optical Properties and Test Methods and ISO 11979-3 Ophthalmic Implants – Intraocular Lenses – Part 3: Mechanical Properties and Test Methods

Table 4a lists all the tests performed.

Table 4a: Mechanical and Optical Testing

Test	Purpose	Acceptance Criteria	Results
Dimensions	To assess conformance to dimensional tolerances	ISO 11979-3:2012 Section 4.2	Pass
Surface and Bulk Homogeneity	To ensure IOL is free of surface and bulk defects	ISO 11979-3:2012 Section 4.12	Pass
Mechanical Characterization (Compression Force, Force Decay, Angle of Contact, Axial Displacement)	To characterize the mechanical properties of the IOL	ISO 11979-3:2012 Sections 4.4, 4.5, 4.8, 4.9	Pass
Optic Decentration	To assess optic decentration under compression	ISO 11979-3:2012 Section 4.6	Pass
Optic Tilt	To assess optic tilt under compression	ISO 11979-3:2012 Section 4.7	Pass
Dynamic Fatigue	To assess the ability of the haptics to withstand cyclic compressive loading	ISO 11979-3:2012 Section 4.10	Pass
Surgical Manipulation (Haptic Pull Test)	To assess the force required to separate the haptic from the optic	ISO 11979-3:2012 Section 4.11	Pass
Dioptric Power and Image Quality	To assess conformance to optical power and image quality tolerances	ISO 11979-2:2014 Sections 4.2.1, 4.2.3, 4.3	Pass
Image Quality with Tilt and Decentration	To assess image quality under off-axis conditions	ISO 11979-2:2014 Section 4.3	Pass
Spectral Transmittance	To characterize the spectral transmittance of the IOL	ISO 11979-2:2014 Section 4.4.2	Pass
Glistening Testing	To characterize glistening performance of the IOL	Average Grade 0 according to Miyata Scale	Pass

The optical properties of the FINEVISION HP Trifocal IOL are also illustrated in the Modulation Transfer (MTF) through focus response at 50 lp/mm for a 2.0, 3.0-, and 4.5-mm aperture, as shown in **Figure 4.**

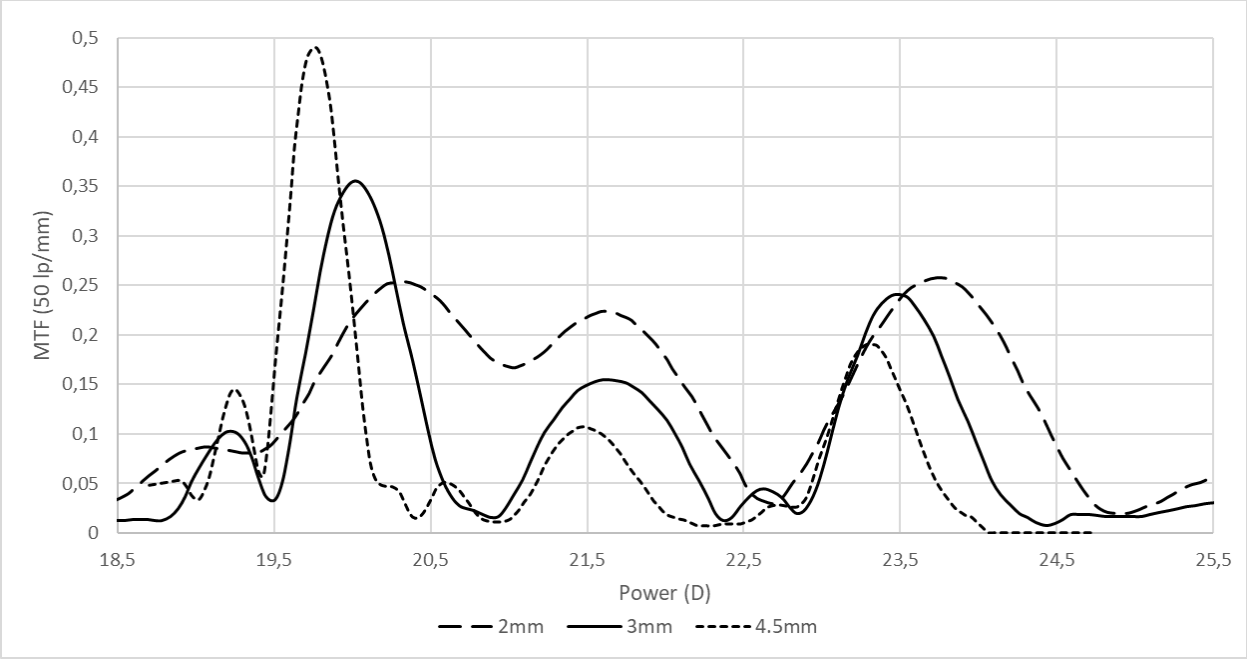


Figure 4: Illustrative FINEVISION HP Trifocal IOL MTF through focus response at 50 lp/mm for a 2.0, 3.0-, and 4.5-mm aperture, in green light with ISO1 cornea.

Simulated Surgical Manipulation Testing

Recovery of mechanical and optical properties of the FINEVISION HP Trifocal IOLs (POD F GF IOLs) after simulated surgical manipulation was assessed in compliance with ISO 11979-3: 2012 and ISO 11979-2: 2014. The objective was to document that the FINEVISION HP Trifocal IOLs can be successfully delivered using Medicel Accuject 2.1 inserter. Testing was performed with the INJ100 inserter and NuVisc Pro viscoelastic (OVD).

Table 4b lists all the tests performed.

Table 4b: Recovery of mechanical and optical properties testing

Test	Purpose	Acceptance Criteria	Results
IOL Dimensions (Pre- and Post-Delivery)	To assess conformance to dimensional tolerances	ISO 11979-3:2012 Section 5 > ISO 11979-3:2012 Section 4.2	Pass
Surface and Bulk Homogeneity (Pre- and Post-Delivery)	To ensure IOL is free of surface and bulk defects	ISO 11979-3:2012 Section 5 > ISO 11979-3:2012 Section 4.12	Pass
Dioptric Power and Image Quality (Post-Delivery)	To assess conformance to optical power and image quality tolerances	ISO 11979-3:2012 Section 5 > ISO 11979-2:2014	Pass

Delivery Outcome	To assess the ability of the insertion device to deliver the IOL	IOL cannot flip over upon delivery, IOL must exit inserter upon completion of delivery (no IOL stuck).	Pass

Sterilization and Stability Evaluation

Sterilization evaluation, shelf-life and transport stability testing, and bacterial endotoxin testing were performed to support the FINEVISION HP Trifocal IOL. The results are summarized in **Table 5**.

Table 5: Sterilization Evaluation Results

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 10^{-6}, based upon inactivation of control biological indicators (BIs, *G. stearothermophilus*) in process challenge devices (PCDs).	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 $\leq 10^{-6}$.	Pass

Test	Purpose	Acceptance Criteria	Results
Transport stability (ISO 11979-6, ISO 11607-1, ASTM F88, ASTM F1929, & ASTM D3078)	Confirm that the sterile barrier packaging can maintain device sterility throughout anticipated transport conditions. Testing includes visual inspection, whole package integrity (bubble emission testing), and seal integrity assessments (seal peel and dye penetration testing) after transport conditioning.	Meets lens cosmetics and functional delivery requirements. 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 whole package integrity assessed by bubble emission testing of the primary vial sterile barrier, no leaks are observed. For seal integrity, assessed by seal peel and dye penetration testing of the secondary blister tray packaging, average peel strength and no penetration of dye into seal area are observed, respectively.	Pass
Shelf-life stability (ISO 11979-6 & ISO 11607-1)	Confirm that device performance is maintained throughout claimed shelf-life.	Meets optical, mechanical, chemical and biological testing requirements	Pass
Package Integrity (ISO 11979-6, ISO 11607-1, ASTM F88, ASTM F1929, & ASTM D3078)	Confirm that the primary sterile barrier packaging can maintain device sterility throughout claimed shelf life. Testing includes visual inspection, whole package integrity (bubble emission testing), and seal integrity assessments (seal peel and dye penetration testing) 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 whole package integrity assessed by bubble emission testing of the primary vial sterile barrier, no leaks are observed. For seal integrity, assessed by seal peel and dye penetration testing of the secondary blister tray packaging, average peel strength and no penetration of dye into seal area are observed, respectively.	Pass
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	Pass
Bioburden Estimation Testing (ISO 11737-1)	Confirm that naturally occurring Bioburden is controlled on product and in manufacturing environment.	Less than the Action Limit of < 50 Colony Forming Units (CFU)/device	Pass

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of implantation with the FINEVISION HP Trifocal IOLs for the visual correction of aphakia in adult subjects with less than 1 D of pre-existing corneal astigmatism, following removal of a cataractous lens to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to a monofocal IOL, in the US under IDE G210165. Data from this clinical study was the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Subjects were treated between April 2022 and April 2023. The database for this PMA reflected data collected through 15 Aug 2024 and included 539 subjects. There were 20 US investigational sites.

The study was a prospective, multicenter, randomized, active controlled, double masked pivotal study. This study was designed to evaluate the effectiveness and safety of FINEVISION HP Trifocal IOL in providing a range of vision (distance, intermediate, and near) as compared to a standard monofocal IOL, the AcrySof Monofocal IOL Model SN60AT. Adult subjects with operable cataracts in both eyes who were eligible for phacoemulsification cataract surgery followed by IOL implantation were randomized at a 2:1 ratio to receive either the FINEVISION HP Trifocal IOL (test) or the AcrySof SN60AT Monofocal IOL (control) in both eyes. Subjects underwent cataract surgery/IOL implantation in the second eye 7 to 30 days after the first eye surgery. Subjects attended 5 post-operative evaluation visits for each eye where they underwent ophthalmic examinations over a period of approximately 12 months.

The control IOL is a legally marketed monofocal lens.

A total of 501 subjects were planned for bilateral implantation in a 2:1 ratio, in order to ensure that at least 300 eligible subjects in the test arm and 150 subjects in the control arm completed the study. This sample size assumed a dropout rate of 10% and was based on the following assumptions (Table 6). Subjects were randomly assigned to receive either the investigational FINEVISION HP Trifocal IOL or the AcrySof monofocal IOL in both eyes according to the randomization schedule (2:1 ratio) provided following the completion of informed consent and screening procedures. Randomization was stratified by site. 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.

Table 6: Sample Size Calculations

	Margin	Expected Difference	SD	Type I error sided	Power
Non-Inferiority					
BCDVA (4 m)	0.1	0.0	0.10	5%	>99%
Superiority					
DCNVA (40 cm)		-0.10	0.14	2.5%	>99%
DCIVA (66 cm)		-0.10	0.14	2.5%	>99%

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

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the FINEVISION HP Trifocal IOL study was limited to subjects who met the following inclusion criteria in both eyes:

1) Male or female adults, age 22 years or older at the Preoperative Visit.
2) Visually significant cataracts in both eyes that are eligible for phacoemulsification cataract surgery.
3) Willing to undergo cataract surgery in the second operative eye within 7 – 30 days after surgery in the first eye.
4) Projected BCDVA of 0.2 logMAR (20/32 Snellen) or better in each eye after cataract surgery/IOL implantation, as determined by the medical judgement of the Investigator
5) Eligible for receipt of an IOL power within the range of the investigational IOL (+10.0 D to +30.0 D, in 0.50 D increments) in each eye
6) Contact lens users must be willing to discontinue wear of their lenses in accordance with the following requirements:
    - Rigid gas permeable lenses for ≥ 7 days prior to the Preoperative Visit
    - Soft contact lenses for ≥ 3 days prior to the Preoperative Visit

   Contact lens wearers must demonstrate a stable refraction (within ±0.50 D for both sphere and cylinder) in each eye, as determined by manifest refraction on two consecutive examination dates at least one week apart after discontinuation of contact lens wear.
7) Provide signed written consent prior to participation in any study-related procedures.
8) Ability, comprehension, and willingness to follow study instructions, and likely to complete all study visits.
9) Female subjects must be 1-year postmenopausal, surgically sterilized, or, if of childbearing potential, have a negative urine pregnancy test at the Preoperative 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.

Subjects were not permitted to enroll in the FINEVISION HP Trifocal IOL study if they met any of the following exclusion criteria:

1) History or presence of, or predisposition to, degenerative visual disorders (e.g., macular degeneration, retinal detachment, proliferative diabetic retinopathy, or other retinal disorders) predicted to result in BCDVA worse than 0.2 LogMAR (20/32 Snellen) in either eye during the study participation period.
2) Significant anterior segment pathology in either eye that might increase intraoperative risk or compromise IOL stability (e.g., pseudoexfoliation syndrome)
3) Reasonably expected to require secondary ocular surgical intervention or laser treatment other than YAG capsulotomy in either eye during the study participation period.
4) Presence of one or more clinically significant corneal abnormalities in either eye, including corneal dystrophy, irregularity, or edema per the Investigator's medical opinion.
5) Previous intraocular, corneal, or retinal detachment surgery, including corneal transplant, LASIK, astigmatic keratotomy and limbal relaxing incisions in either eye
6) Rubella, congenital, traumatic or complicated cataract in either eye
7) Preoperative keratometric astigmatism > 1.0 D or irregular corneal astigmatism in either eye (Note: corneal incisions intended to reduce astigmatism are not permitted)
8) Clinically significant ocular inflammation or infection present ≤ 30 days in either eye prior to the Preoperative Visit.
9) Presence or history of one or more severe/serious ocular conditions (e.g., glaucoma, uveitis, ocular infection, severe dry eye) in either eye, or any other unstable medical condition (e.g., uncontrolled diabetes) that in the opinion of the Investigator would put the subject's health at risk, confound the results of the study and/or prevent the subject from completing all study visits.
10) Use of medications known to interfere with visual performance, pupil dilation, or iris structure ≤ 30 days prior to the Preoperative Visit.
11) Participation in any study of an investigational, interventional product within 30 days prior to the Preoperative Visit or at any time during the study period.
12) Pregnant or nursing females.

The following were intraoperative criteria for not implanting the device:

1) Intraoperative complications during the phacoemulsification and IOL implant that require any other additional procedures or further intervention

2) Significant detachment of Descemet's membrane

3) Significant corneal endothelial damage

4) Wound burn

5) Capsular tear, iris incarceration or damage, posterior capsular rupture, vitreous loss or prolapse, or zonular weakness, dehiscence or rupture

6) Significant anterior chamber bleeding

7) Excessive iris mobility or need for iris manipulation

8) Mechanical or surgical manipulation required to enlarge the pupil prior to or at IOL implantation

9) Other ocular conditions or complications that could compromise IOL stability

10) Bag sulcus, sulcus-sulcus or unknown placement of haptics

11) Any method of anterior capsulotomy other than circular continuous capsulorhexis (e.g., anterior capsular tears or any areas of 'can-opener' capsulotomy or FLACS)

12) Capsular fibrosis or other opacity

13) Optic and/or haptic damage/amputation

14) Inability to fixate IOL in desired position

2. Follow-up schedule

All subjects were scheduled to return for follow-up examinations postoperatively as mentioned in **Table 7**.

Table 7: Study Design

Scheduled Visit	Eyes Evaluated	Visit Window
Pre-Operative Visit 0	Both Eyes	Day -90 to -1
Operative Visit 00A	1st Operative Eye	Day 0
Post-Operative Visit 1A	1st Operative Eye	Day 1 to 2 post Operative Visit 00A
Post-Operative Visit 2A	1st Operative Eye	Day 7 to 14 post Operative Visit 00A
Post-Operative Visit 3A	1st Operative Eye	Day 30 to 60 post Operative Visit 00A
Operative Visit 00B	2nd Operative Eye	Day 7 to 30 post Operative Visit 00A
Post-Operative Visit 1B	2nd Operative Eye	Day 1 to 2 post Operative Visit 00B
Post-Operative Visit 2B	2nd Operative Eye	Day 7 to 14 post Operative Visit 00B
Post-Operative Visit 3B	2nd Operative Eye	Day 30 to 60 post Operative Visit 00B
Post-Operative Visit 4	Both Eyes	Day 150 to 180 post Operative Visit 00A
Post-Operative Visit 5	Both Eyes	Day 360 to 420 post Operative Visit 00A

Note: IOL implantation in the second eye was intended to occur between 7 and 30 days after IOL implantation in the first eye.

Preoperatively, several examinations and clinical assessments were performed, as listed in **Table 8**. Postoperatively, objective parameters were measured during the study and are listed below, in Table 8. Specific examinations and scheduled clinical assessments are presented in **Table 8**. Adverse events and complications were recorded at all visits.

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

Table 8: Schedule of Assessments

			Visit 0	**Visit 00 A**	**Visit 00 B**	**Visit 1 A/B**	**Visit 2 A/B**	**Visit 3 A/B**	**Visit 4**	**Visit 5**	**USV[2]**
Examination	**Light Condition**	**Monocular / Binocular**	**Pre-Op / Screen D -90 to -1**	**Implant A[1] D 0**	**Implant B[1] (D 7 to D 30 after Visit 00 A)**	**Post-Op D 1-2**	**Post-Op D 7-14**	**Post-Op D 30-60**	**Post-Op D 150-180 (from 1st eye)**	**Post-Op D 360-420 (from 1st eye)**	**N/A**
Informed Consent and HIPAA			X								
Demographics			X								
Inclusion & Exclusion Criteria Evaluation			X								
Inclusion & Exclusion Criteria Review				X							
Ocular and non-ocular Medical History			X	X	X	X	X	X	X	X	X
Urine Pregnancy Test (if applicable)			X								
Projected Visual Acuity			X								
Target Refraction			X								
IOL Power Calculation			X								
Axial Length and Anterior Chamber Depth			X								
Keratometry Measurement			X					X	X	X	X
Corneal Topography			X								
Manifest Refraction (ETDRS) – 4 meters			X				X	X	X	X	X
Randomization			X								
Operative Procedures				X	X						
Patient Reported Outcome Questionnaires[3]			X						X	X	X

				Visit 0	Visit 00 A	Visit 00 B	Visit 1 A/B	Visit 2 A/B	Visit 3 A/B	Visit 4	Visit 5	USV[2]
Examination		**Light Condition**	**Monocular / Binocular**	**Pre-Op / Screen D -90 to -1**	**Implant A[1] D 0**	**Implant B[1] (D 7 to D 30 after Visit 00 A)**	**Post-Op D 1-2**	**Post-Op D 7-14**	**Post-Op D 30-60**	**Post-Op D 150-180 (from 1st eye)**	**Post-Op D 360-420 (from 1st eye)**	**N/A**
Pupil Size[4]		Photopic	Monocular	X						X	X	
		Mesopic		X						X	X	
Intraocular Pressure				X			X	X	X	X	X	X
Slit Lamp Examination				X			X	X	X	X	X	X
IOL Tilt and Decentration Grading							X	X	X	X	X	X
IOL Axis Orientation (selected sites only)[5]					X	X	X	X	X	X	X	X
Dilated Fundus Examination				X					X	X	X	X
Posterior Capsule Assessment (PCO grade assessment)							X	X	X	X	X	X
IOL Observations							X	X	X	X	X	X
Adverse Events				X	X	X	X	X	X	X	X	X
Device Deficiencies					X	X	X	X	X	X	X	X
Concomitant Medications				X	X	X	X	X	X	X	X	X
Exit from Study											X	
Visual Acuity	UCDVA (4 meters)	Photopic	Monocular	X			X	X	X	X	X	X
			Binocular					X	X	X	X	X
	(4 meters)	Photopic	Monocular	X				X	X	X	X	X
			Binocular					X	X	X	X	X
	UCNVA (40 cm)	Photopic	Monocular						X	X	X	
			Binocular						X	X	X	
	BCNVA (40 cm)	Photopic	Monocular						X	X	X	
			Binocular						X	X	X	
	DCNVA (40 cm)	Photopic	Monocular						X	X	X	
			Binocular						X	X	X	

Examination		Light Condition	Monocular / Binocular	Visit 0 Pre-Op / Screen D -90 to -1	Visit 00 A Implant A[1] D 0	Visit 00 B Implant B[1] (D 7 to D 30 after Visit 00 A)	Visit 1 A/B Post-Op D 1-2	Visit 2 A/B Post-Op D 7-14	Visit 3 A/B Post-Op D 30-60	Visit 4 Post-Op D 150-180 (from 1st eye)	Visit 5 Post-Op D 360-420 (from 1st eye)	USV[2] N/A
		Mesopic	Monocular						X	X	X	
			Binocular						X	X	X	
	BCIVA (80 cm)	Photopic	Monocular						X	X	X	
			Binocular						X	X	X	
	UCIVA (66 cm)	Photopic	Monocular						X	X	X	
			Binocular							X	X	
	DCIVA (66 cm)	Photopic	Monocular						X	X	X	
			Binocular							X	X	
		Mesopic	Monocular						X	X	X	
			Binocular							X	X	
	DCIVA (80 cm)	Photopic	Monocular						X	X	X	
			Binocular							X	X	
		Mesopic	Monocular						X	X	X	
			Binocular							X	X	
	UCIVA (80 cm)	Photopic	Monocular						X	X	X	
			Binocular							X	X	
Contrast Sensitivity with Glare – 2.5 meters		Photopic	Monocular							X	X	
Contrast Sensitivity without Glare – 2.5 meters										X	X	
Contrast Sensitivity with Glare – 2.5 meters		Mesopic	Monocular							X	X	
Contrast Sensitivity without Glare – 2.5 meters										X	X	

Examination	Light Condition	Monocular / Binocular	Visit 0 Pre-Op / Screen D -90 to -1	Visit 00 A Implant A[1] D 0	Visit 00 B Implant B[1] (D 7 to D 30 after Visit 00 A)	Visit 1 A/B Post-Op D 1-2	Visit 2 A/B Post-Op D 7-14	Visit 3 A/B Post-Op D 30-60	Visit 4 Post-Op D 150-180 (from 1st eye)	Visit 5 Post-Op D 360-420 (from 1st eye)	USV[2] N/A
Defocus Curve (Best Distance Corrected) – 4 meters[6]		Monocular							X	X	
		Binocular							X	X	

Abbreviations: ETDRS = Early Treatment Diabetic Retinopathy Study, UCDVA = Uncorrected Distance Visual Acuity, UCNVA = Uncorrected Near Visual Acuity, BCNVA = Best Corrected Near Visual Acuity, BCIVA = Best Corrected Intermediate Visual Acuity, UCIVA = Uncorrected Intermediate Visual Acuity

[1] A – First Operative Eye, B – Second Operative Eye

[2] USV – Unscheduled Visit; for unscheduled visits, mandatory assessments to be completed are defined in the table. Additional assessments may be performed as appropriate, based on the subject's condition.

[3] Patient Reported Outcome Questionnaires include the PRSIQ, QoV and QoV Supplemental Questions

[4] Pupil size measurements in mesopic and photopic lighting conditions must be taken right before contrast sensitivity testing (see instructions for Pupil Size Measurements in Manual of Procedures)

[5] Subjects must be dilated for IOL axis of orientation assessment

[6] Sites that are conducting rotational stability assessments will only perform monocular defocus curve testing on the first operative eye. Sites not conducting rotational stability assessments will perform binocular defocus curve testing

3. Clinical Endpoints

With regards to safety:

- Co-primary safety objectives
    - Estimate the cumulative rate of Secondary Surgical Interventions (SSIs) related to the optical properties of the IOL for the first operative eye up to Month 12 (Visit 5). Success was defined as the upper limit of the confidence interval being less than 0.014 (1.4%)
    - Evaluate the mean monocular contrast sensitivity for the first operative eye, with and without glare for mesopic conditions and photopic conditions, at Month 12 (Visit 5). (No specific success criteria were pre-specified.)
- Secondary safety objectives
    - Estimate rates of cumulative and persistent adverse events in first operative eyes at Month 12 (Visit 5) in comparison to the ISO Safety and Performance Endpoint (SPE) rates as described in ISO 11979-7. Success criteria for each type of event was a rate not statistically greater than the ISO SPE rate.
    - Estimate visual disturbances using the Quality of Vision (QoV) questionnaire and QoV Supplemental Questions at Month 12 (Visit 5). (No specific success criteria were pre-specified.)
- Other Safety Endpoints
    - All other AEs not specified by ISO SPE grid (which includes the Modified AAO Task Force AEs).
    - Binocular defocus curve sub study at Visit 4 (6-months) and 5 (12-months)
    - Manifest refraction at Visit 2 (1-2 weeks), 3 (1-month), 4, and 5
    - Slit lamp examination findings at all study visits
    - Device deficiencies
    - Intraocular Pressure (IOP) at all study visits
    - Dilated Fundus examination at Visit 3, 4, and 5
    - Fundus visualization through multifocal IOL at Visit 3, 4, and 5

With regards to effectiveness:

- Co-primary effectiveness objectives:
    - Demonstrate non-inferiority of FINEVISION HP Trifocal IOL to the control in mean photopic monocular Best Corrected Distance Visual Acuity (BCDVA) for the first operative eye at Month 6 (Visit 4). The success criterion was statistical non-inferiority of BCDVA compared to the control. The non-inferiority margin was set at 0.10 logMAR.

- Demonstrate superiority of FINEVISION HP Trifocal IOL to the control in mean photopic monocular Distance Corrected Near Visual Acuity (DCNVA) for the first operative eye at Month 6 (Visit 4). The success criterion was statistical superiority of DCNVA compared to the control. The superiority margin was set at 0.0 logMAR.

- The secondary effectiveness objective:
  - Demonstrate superiority of FINEVISION HP Trifocal IOL to the control in mean photopic monocular DCVA at intermediate (66 cm) for the first operative eye at Month 6 (Visit 4). The success criterion was statistical superiority of DCNVA compared to the control. The superiority margin was set at 0.0 logMAR.

- Additional effectiveness objectives (no specific success criteria were pre-specified):
  - Photopic monocular logMAR BCDVA, DCIVA (80 cm), DCIVA (66 cm), and DCNVA in first operative eyes at Month 6 (Visit 4) and Month 12 (Visit 5)
  - Mesopic monocular logMAR DCIVA (80 cm), DCIVA (66 cm), and DCNVA in first operative eyes at Month 6 (Visit 4) and Month 12 (Visit 5)
  - Photopic binocular logMAR BCDVA, DCIVA (80 cm), DCIVA (66 cm), and DCNVA at Month 6 (Visit 4) and Month 12 (Visit 5)
  - Mesopic binocular logMAR DCIVA (80 cm), DCIVA (66 cm), and DCNVA at Month 6 (Visit 4) and Month 12 (Visit 5)
  - Photopic monocular logMAR UCDVA, UCIVA (80 cm), UCIVA (66 cm), and UCNVA in first operative eyes at Month 6 (Visit 4) and Month 12 (Visit 5)
  - Photopic binocular logMAR UCDVA, UCIVA (80 cm), UCIVA (66 cm), and UCNVA at Month 6 (Visit 4) and Month 12 (Visit 5)
  - Photopic monocular logMAR BCIVA (80 cm) and BCNVA in first operative eyes at Month 6 (Visit 4) and Month 12 (Visit 5)
  - Photopic binocular logMAR BCIVA (80 cm) and BCNVA at Month 6 (Visit 4) and Month 12 (Visit 5)
  - Monocular and binocular defocus curves at Month 6 (Visit 4)
  - Spectacle Independence using the Patient-Reported Spectacle Independence Questionnaire (PRSIQ) at Month 6 (Visit 4).

With regard to success/failure criteria, all primary safety and effectiveness endpoints with success criteria were required to demonstrate statistical study success. Individual subject success was not defined.

The following analyses sets were utilized in the study:

AAS (All Implanted analyses Set)- Includes all eyes with successful IOL implantation and at least one post-operative visit.

Best Case Set- Includes all eyes successfully implanted that had at least one postoperative visit and had no preoperative ocular pathology or macular degeneration at any time, and no major protocol deviations.

Intent-to-Treat (ITT) Set- Includes all randomized subjects (eyes).

Safety Analysis Set- Includes all subjects with at least one eye implanted with a study lens.

B. Accountability of PMA Cohort

At the time of database lock, of 539 subjects enrolled in the PMA study, 92.6% (474/512) subjects s were available for analysis at the completion of the study, the 12–14-month post-operative visit. The disposition of 512 all randomized subjects is summarized in **Table 9**.

Table 9: Subject Disposition (All Enrolled Subjects)

	FINEVISION HP n (%)	AcrySof SN60AT n (%)	All Subjects n (%)
Screened			539
Screen Failures Prior to Randomization			27
Randomized (N)	341	171	512
Implanted	332 (97.4%)	164 (95.9%)	496 (96.9%)
Randomized But Not Implanted	9 (2.6%)	7 (4.1%)	16 (3.1%)
Analysis Populations [1]			
Intent-to-Treat Set	341 (100.0%)	171 (100.0%)	512 (100.0%)
All-Implanted Analysis Set	332 (97.4%)	164 (95.9%)	496 (96.9%)
Best Case Set	312 (91.5%)	152 (88.9%)	464 (90.6%)
Safety Set	332 (97.4%)	164 (95.9%)	496 (96.9%)
Rotational Analysis Set	148 (43.4%)	0	148 (28.9%)
Completed Study	315 (92.4%)	159 (93.0%)	474 (92.6%)
Discontinued	26 (7.6%)	10 (5.8%)	36 (7.0%)
Reason for Discontinuation [2]			
Adverse Event	0	0	0
Death	1 (3.8%)	2 (20.0%)	3 (8.3%)
Lost to Follow-up	10 (38.5%)	2 (20.0%)	12 (33.3%)
Physician Decision	0	0	0
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	9 (34.6%)	1 (10.0%)	10 (27.8%)
Other	6 (23.1%)	5 (50.0%)	11 (30.6%)
Protocol Deviations [3,4]			

	FINEVISION HP n (%)	AcrySof SN60AT n (%)	All Subjects n (%)
Any Deviation	148 (43.4%)	60 (35.1%)	208 (40.6%)
Major Deviation	21 (6.2%)	13 (7.6%)	34 (6.6%)
Minor Deviation	140 (41.6%)	54 (31.6%)	196 (38.3%)

Abbreviations: IOL = Intraocular Lens; ITT = Intent-to-Treat.

Rotational Analysis Set (RAS)- Includes all subjects with successful FINEVISION HP Trifocal IOL implantation from a sub-set of clinical sites that examined subjects for rotational stability.

Note: Percentages are based on the number of randomized subjects in the respective treatment group unless otherwise stated. Two subjects (07-0730, 07-0735) who were randomized to the AcrySof SN60AT group and were not implanted with an IOL were recorded as screen failures per the protocol but were not recorded as discontinuations because they did not complete end of study case report forms.

[1] For the treatment assignments, ITT includes subjects as randomized, while all other populations include subjects as treated.

[2] Percentages are based on the number of subjects who discontinued for the respective treatment group.

[3] Classifications for all but eight deviations were assigned by the sponsor prior to database lock and unmasking. Of the eight deviations classified after unmasking, five deviations were inadvertently omitted from the deviation classification meetings prior to database lock, and three deviations were added to the database after lock. Of these eight deviations, three were classified as Major, which resulted in the exclusion of the respective three subjects, 05-0510, 06-0616, and 07-0718, from the Best-Case Set. The remaining five deviations were classified as Minor and had no impact on the Best-Case Set.

[4] Subjects with multiple deviations are only counted once in each category.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a randomized, prospective, multicenter clinical study of intraocular lenses performed in the US.

The study population demographics and baseline parameters are reported in **Tables 10** and **11**. The demographic and baseline characteristics were similar between the two groups.

Table 10: Demographics (All implanted Analysis Set)

Variable	FINEVISION HP (N=332)	AcrySof SN60AT (N=164)	All Subjects (N=496)
Age (years)			
Mean (SD)	67.1 (7.41)	67.8 (6.78)	67.3 (7.21)
Median	68.0	68.0	68.0

Variable	FINEVISION HP (N=332)	AcrySof SN60AT (N=164)	All Subjects (N=496)
Min, Max	41, 84	44, 90	41, 90
Age Category: n (%)			
<65 years	99 (29.8%)	38 (23.2%)	137 (27.6%)
>=65 years	233 (70.2%)	126 (76.8%)	359 (72.4%)
Sex: n (%)			
Male	121 (36.4%)	62 (37.8%)	183 (36.9%)
Female	211 (63.6%)	102 (62.2%)	313 (63.1%)
Ethnicity: n (%)			
Hispanic or Latino	27 (8.1%)	7 (4.3%)	34 (6.9%)
Not Hispanic or Latino	305 (91.9%)	157 (95.7%)	462 (93.1%)
Race: n (%)			
American Indian or Alaska Native	1 (0.3%)	0	1 (0.2%)
Asian	13 (3.9%)	3 (1.8%)	16 (3.2%)
Black or African American	19 (5.7%)	11 (6.7%)	30 (6.0%)
Native Hawaiian or Other Pacific Islander	1 (0.3%)	1 (0.6%)	2 (0.4%)
White	294 (88.6%)	148 (90.2%)	442 (89.1%)
Other	4 (1.2%)	1 (0.6%)	5 (1.0%)
Multi-Racial	0	0	0

Note: N in the headers represents the number of subjects in the respective treatment group for the population being analyzed. Percentages are based on the number of subjects (N) in each respective treatment group. Subjects who selected more than one race are summarized in the Multi-Racial group. Age is calculated using the following equation: Age = (Informed Consent Date – Date of Birth) / 365.25, truncated as an integer.

Table 11: Baseline Characteristics (All implanted Analysis Set)

	FINEVISION HP (N=332)		AcrySof SN60AT (N=164)		All Subjects (N=496)	
Variable	Right Eye (OD)	Left Eye (OS)	Right Eye (OD)	Left Eye (OS)	Right Eye (OD)	Left Eye (OS)
Potential Visual Acuity (logMAR)						
n	332	332	164	164	496	496
Mean (SD)	0.03 (0.056)	0.03 (0.056)	0.02 (0.047)	0.02 (0.047)	0.03 (0.053)	0.03 (0.053)
Median	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	0.0, 0.2	0.0, 0.2	0.0, 0.2	0.0, 0.2	0.0, 0.2	0.0, 0.2
Target Refraction Sphere (D)						
n	332	332	164	164	496	496
Mean (SD)	-0.044 (0.1095)	-0.059 (0.1201)	-0.072 (0.1144)	-0.070 (0.1289)	-0.053 (0.1118)	-0.063 (0.1230)
Median	0.000	-0.020	-0.040	-0.030	-0.020	-0.030
Min, Max	-0.34, 0.20	-0.83, 0.17	-0.44, 0.24	-0.50, 0.20	-0.44, 0.24	-0.83, 0.20
Target Refraction Cylinder (D)						
n	215	215	107	107	322	322
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Median	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0	0, 0
Target Refraction Axis (deg)						
n	215	215	107	107	322	322
Mean (SD)	138.8 (75.08)	138.7 (75.15)	139.6 (75.43)	139.6 (75.43)	139.1 (75.08)	139.0 (75.13)
Median	180.0	180.0	180.0	180.0	180.0	180.0
Min, Max	0, 180	0, 180	0, 180	0, 180	0, 180	0, 180
IOL Power Calculation (D)						
n	332	332	164	164	496	496
Mean (SD)	20.53 (3.092)	20.55 (3.136)	19.52 (2.671)	19.63 (2.652)	20.20 (2.995)	20.24 (3.013)
Median	21.00	21.00	20.00	20.00	20.50	20.50
Min, Max	11.0, 28.0	10.0, 27.5	11.0, 25.0	12.0, 25.0	11.0, 28.0	10.0, 27.5

Abbreviations: D = Diopters; deg = Degrees; IOL = Intraocular Lens; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: N in the headers represents the number of subjects in the respective treatment group for the population being analyzed. Baseline refers to assessments performed during the Pre-Operative Visit.

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the safety cohort of 496 implanted subjects: 332 FINEVISION HP Trifocal IOL subjects and 164 control subjects available for the 12–14-

month evaluation. The key safety outcomes for this study are presented below in **Tables 12 to16** and **Figures 5 to 8**. Adverse events are reported in **Tables 17** to **20.**

The first co-primary safety endpoints were to estimate the cumulative rate of Secondary Surgical Interventions (SSIs) related to the optical properties of the IOL for the first operative eye up to Month 12 (Visit 5). (**Table 12**)

The second co-primary safety endpoint was to evaluate the mean monocular contrast sensitivity for the first operative eye, with and without glare for mesopic conditions and photopic conditions, at Month 12 (Visit 5). (**Figures 5 to 8**)

There were two secondary co-primary endpoints. The first was to estimate rates of cumulative and persistent adverse events in first operative eyes at Month 12 (Visit 5) in comparison to the ISO Safety and Performance Endpoint (SPE) rates as described in ISO 11979-7 (**Table13**). The second was to estimate visual disturbances using the Quality of Vision (QoV) questionnaire and QoV Supplemental Questions at Month 12 (Visit 5). (**Tables 17 to 1**9).

SSI related to the optical properties of the IOLs

The first co-primary safety objective was to estimate the cumulative rate of secondary surgical interventions (SSIs) related to the optical properties of the IOL for the first operative eyes through Month 12 (Visit 5). Noninferiority of FINEVISION HP Trifocal IOL compared to AcrySof SN60AT IOL in the proportions of first operative eyes with secondary surgical interventions related to the optical properties of the IOL was evaluated using two-sided 90% Farrington method confidence intervals around the difference in proportions between the FINEVISION HP Trifocal IOL and AcrySof SN60AT IOL. Success was defined as the upper limit of the confidence interval being less than 0.014 (1.4%). Results of the cumulative rate of SSIs related to the optical properties of the IOL in first operative eyes through Month 12 (Visit 5) are shown in **Table 12**. Only one SSI related to the optical properties of the IOLs was reported in the clinical study. In the first operative eye for a FINEVISION HP Trifocal IOL subject, there was an explant of the IOL due to subjective complaints of dissatisfaction with the level of vision. The analysis demonstrates that the FINEVISION HP Trifocal IOL is considered statistically non-inferior to the AcrySof SN60AT IOL in rate of SSIs related to the optical properties of the IOL.

Table 12: Cumulative Secondary Surgical Interventions Related to the Optical Properties of the IOL, Safety Set – First Operative Eyes up to Month 12 (Visit 5)

	FINEVISION HP (N=332)	AcrySof SN60AT (N=164)
Any Secondary Surgical Interventions Related to the Optical Properties of the IOL: n (%)	1 (0.3)	0
Difference in Percentages	0.3	
90% CI for Difference in Percentages [1]	(-0.76, 1.36)	

Abbreviations: IOL = Intraocular Lens.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed. Percentages are based on the number of eyes (N) in each respective treatment group for the population being analyzed.

[1] Confidence interval (CI) computed using the Farrington-Manning method.

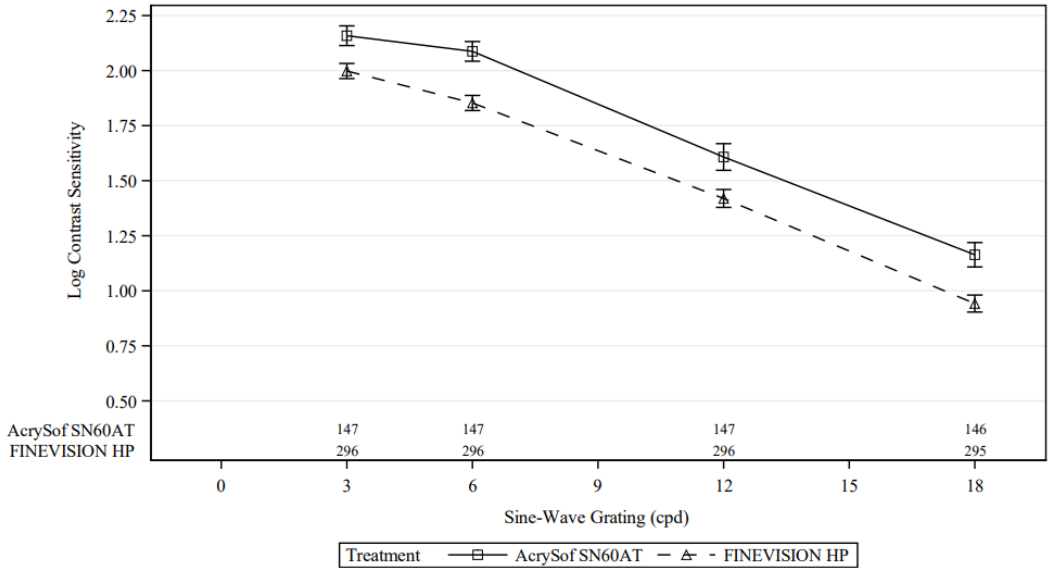
Contrast Sensitivity

The second co-primary safety objective was to evaluate the mean monocular contrast sensitivity for the first operative eye with and without glare for photopic and mesopic conditions at Month 12 (Visit 5).

Contrast sensitivity was measured monocularly at Month 12 (Visit 5) under four conditions: photopic without glare, photopic with glare, mesopic without glare, and mesopic with glare, using the M&S System (Clinical Trial Suite, M&S Technologies, Niles, IL, USA) for sine-wave gratings 1.5, 3, 6, 12 and/or 18 cycles per degree (CPD) at a test distance of 2.5 meters. The luminance for photopic testing was 85 cd/m^2. For mesopic testing, a neutral density filter was placed in front of the screen to reduce lighting to 3 +/- 0.5 cd/m^2. In all testing conditions, mean monocular distance contrast sensitivity (mesopic with and without glare at 1.5, 3, 6, and 12 cycles per degree (cpd) measured at 2.5 m, and photopic with and without glare at 3, 6, 12, and 18 cpd, measured at 2.5 m) was slightly better for eyes in the monofocal IOL group than in the FINEVISION HP Trifocal IOL group in first operative eyes at Month 12 (Visit 5), however, the difference in means was not clinically significant. The results are shown for the best-case set in Figures 5-8. More positive outcomes are indicative of better performance.

Figure 5: Mean Monocular Log Contrast Sensitivity at Month 12 with 95% CIs for Means, Best Case Set – First Operative Eyes

Light Condition: Photopic Without Glare

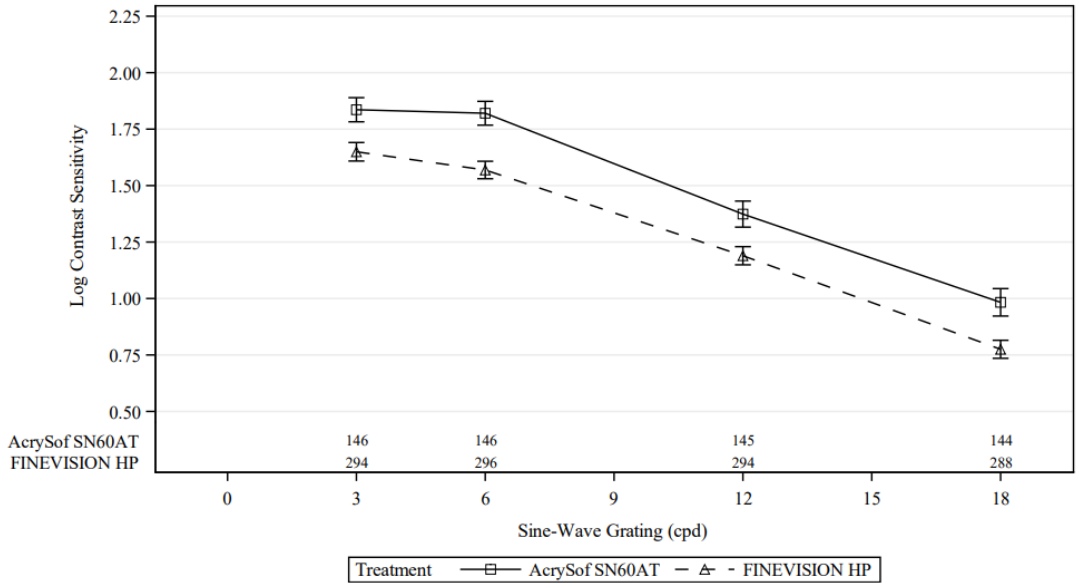


Abbreviations: cpd = Cycles per Degree.

Note: Numbers at bottom of figure are the number of subjects with non-missing data for the respective treatment group and sine-wave grating level. Raw data were collected as log10(contrast threshold) which were converted to log contrast sensitivities representing -log10(contrast threshold). 95% confidence intervals for means are based on the t-distribution.

Figure 6: Mean Monocular Log Contrast Sensitivity at Month 12 with 95% CIs for Means, Best Case Set – First Operative Eyes

Light Condition: Photopic with Glare

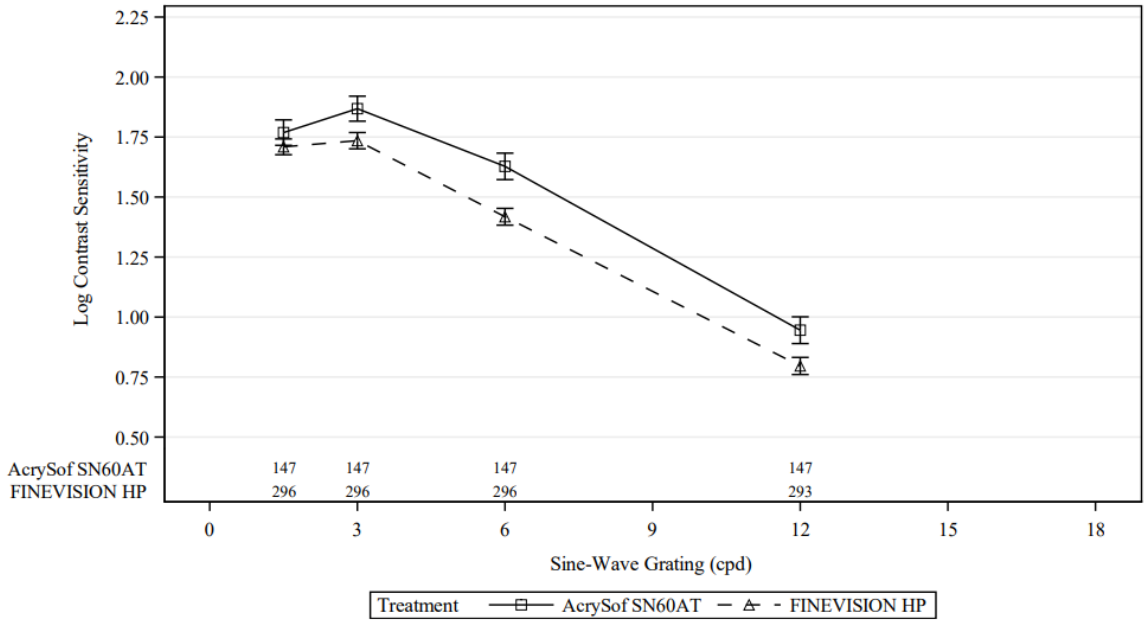


Abbreviations: cpd = Cycles per Degree.

Note: Numbers at bottom of figure are the number of subjects with non-missing data for the respective treatment group and sine-wave grating level. Raw data were collected as log10(contrast threshold) which were converted to log contrast sensitivities representing -log10(contrast threshold). 95% confidence intervals for means are based on the t-distribution.

Figure 7: Mean Monocular Log Contrast Sensitivity at Month 12 with 95% CIs for Means, Best Case Set – First Operative Eyes

Light Condition: Mesopic without Glare

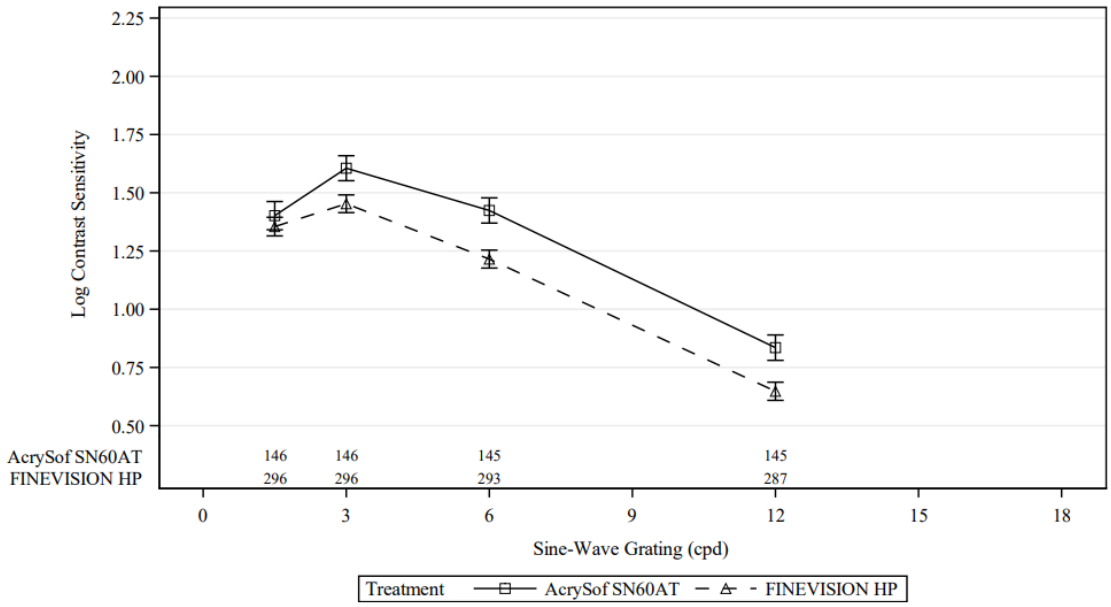


Abbreviations: cpd = Cycles per Degree.

Note: Numbers at bottom of figure are the number of subjects with non-missing data for the respective treatment group and sine-wave grating level. Raw data were collected as log10(contrast threshold) which were converted to log contrast sensitivities representing -log10(contrast threshold). 95% confidence intervals for means are based on the t-distribution.

Figure 8: Mean Monocular Log Contrast Sensitivity at Month 12 with 95% CIs for Means, Best Case Set – First Operative Eyes

Light Condition: Mesopic with Glare



Abbreviations: cpd = Cycles per Degree.

Note: Numbers at bottom of figure are the number of subjects with non-missing data for the respective treatment group and sine-wave grating level. Raw data were collected as log10(contrast threshold) which were converted to log contrast sensitivities representing -log10(contrast threshold). 95% confidence intervals for means are based on the t-distribution.

Cumulative and Persistent Adverse events rate

The first secondary safety objective was to evaluate rates of cumulative and persistent adverse events in first operative eyes at Month 12 (Visit 5) in comparison to the ISO Safety and Performance Endpoint (SPE) rates as described in ISO 11979-7.

The results are provided in **Tables 13-14**. If the same event occurred multiple times in an eye, only the first occurrence is counted in the table below. All SPE rates for FINEVISION HP Trifocal IOL or the control group were below the SPE threshold as set forth by ISO 11979-7.

Table 13: Cumulative and Persistent Adverse Events, Safety Set – First Implanted Eyes

Adverse Event	SPE Rate (%) [3]	FINEVISION HP (N=332) (m=315)		
		n (%)	2-sided 95% CI [4]	1-sided 95% Lower CL [4]
Cumulative				
Cystoid macular edema	3.0	1	(0.01, 1.67)	0.02

		(0.3% [1/332])		
Hypopyon	0.3	0	(0.00, 1.10)	0.00
Endophthalmitis [1]	0.1	0	(0.00, 1.10)	0.00
Lens dislocated from posterior chamber	0.1	0	(0.00, 1.10)	0.00
Pupillary block	0.1	0	(0.00, 1.10)	0.00
Retinal detachment	0.3	3 (0.9% [3/332])	(0.19, 2.62)	0.25
Secondary surgical intervention [2]	0.8	6 (1.8% [6/332])	(0.67, 3.89)	0.79
Persistent				
Corneal stroma edema	0.3	0	(0.00, 1.16)	0.00
Cystoid macular edema	0.5	0	(0.00, 1.16)	0.00
Iritis	0.3	0	(0.00, 1.16)	0.00
Raised IOP requiring treatment	0.4	0	(0.00, 1.16)	0.00

Abbreviations: CL = Confidence Limit; IOL = Intraocular Lens; IOP = Intraocular Pressure; SPE = Safety and Performance Endpoints.

Note: At each level of summarization, n represents the number of unique subjects with at least one specific event. Cumulative AEs are AEs which occur at any time during the study. If a subject experiences a specific cumulative AE more than once during the study, it is counted once for that specific cumulative AE. Percentages for cumulative AEs are based on the number of subjects (N) in each respective treatment group for the population being analyzed. Persistent AEs are AEs which are classified as ongoing at the time of study exit for subjects seen at Visit 5 (Day 360 to 420). A subject is counted once for a specific persistent AE. Percentages for persistent AEs are based on the number of subjects (m) seen at Visit 5 (Day 360 to 420) in each respective treatment group for the population being analyzed.

[1] Endophthalmitis is defined as inflammatory reaction (sterile or infectious) involving the vitreous body.

[2] Excludes posterior capsulotomies.

[3] The SPE rate is from Table E.2 (Posterior chamber IOL adverse event rates) of ISO 11979-7:2018(E).

[4] Confidence intervals and confidence limits for adverse event rates are computed using the Clopper-Pearson method.

Table 14: Cumulative and Persistent Adverse Events, Safety Set – Second Implanted Eyes

Adverse Event	SPE Rate (%) [3]	FINEVISION HP (N=329) (m=314)		
		n (%)	2-sided 95% CI [4]	1-sided 95% Lower CL [4]
Cumulative				
Cystoid macular edema	3.0	5 (1.5% [5/329])	(0.50, 3.51)	0.60
Hypopyon	0.3	0	(0.00, 1.11)	0.00
Endophthalmitis [1]	0.1	0	(0.00, 1.11)	0.00
Lens dislocated from posterior chamber	0.1	0	(0.00, 1.11)	0.00
Pupillary block	0.1	0	(0.00, 1.11)	0.00
Retinal detachment	0.3	2	(0.07, 2.18)	0.11

		(0.6% [2/329])		
Secondary surgical intervention [2]	0.8	3 (0.9% [3/329])	(0.19, 2.64)	0.25
Persistent				
Corneal stroma edema	0.3	0	(0.00, 1.17)	0.00
Cystoid macular edema	0.5	2 (0.6% [2/314])	(0.08, 2.28)	0.11
Iritis	0.3	0	(0.00, 1.17)	0.00
Raised IOP requiring treatment	0.4	1 (0.3% [1/314])	(0.01, 1.76)	0.02

Abbreviations: CL = Confidence Limit; IOL = Intraocular Lens; IOP = Intraocular Pressure; SPE = Safety and Performance Endpoints.

Note: At each level of summarization, n represents the number of unique subjects with at least one specific event. Cumulative AEs are AEs which occur at any time during the study. If a subject experiences a specific cumulative AE more than once during the study, it is counted once for that specific cumulative AE. Percentages for cumulative AEs are based on the number of subjects (N) in each respective treatment group for the population being analyzed. Persistent AEs are AEs which are classified as ongoing at the time of study exit for subjects seen at Visit 5 (Day 360 to 420). A subject is counted once for a specific persistent AE. Percentages for persistent AEs are based on the number of subjects (m) seen at Visit 5 (Day 360 to 420) in each respective treatment group for the population being analyzed.

[1] Endophthalmitis is defined as inflammatory reaction (sterile or infectious) involving the vitreous body.

[2] Excludes posterior capsulotomies.

[3] The SPE rate is from Table E.2 (Posterior chamber IOL adverse event rates) of ISO 11979-7:2018(E).

[4] Confidence intervals and confidence limits for adverse event rates are computed using the Clopper-Pearson method.

Table 15: Secondary Surgical Interventions by Category – Safety Set – First Operative Eyes

SSI Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Any SSI	8 (2.4)	4 (2.4)
Anterior chamber reinflation	0	1 (0.6)
IOL removal	1 (0.3)	0
Lens material removal	1 (0.3)	0
Paracentesis	2 (0.6)	1 (0.6)
Re-suturing of main incision	0	1 (0.6)
Retinal laser	0	0

SSI Category	FINEVISION HP (N=332) n (%)	AcrySof® SN60AT (N=164) n (%)
Vitrectomy	4 (1.2)	1 (0.6)

Abbreviations: IOL=Intraocular Lens; SSI = Secondary Surgical Intervention

Note: Percentages are based on the number of eyes (N) in the respective treatment group for the population being analyzed.

Table 16: Secondary Surgical Interventions by Category – Safety Set – Second Operative Eyes

SSI Category	FINEVISION HP (N=329) n (%)	AcrySof® SN60AT (N=164) n(%)
Any SSI	6 (1.8)	2 (1.2)
Anterior chamber reinflation	0	0
IOL removal	0	0
Lens material removal	0	0
Paracentesis	3 (0.9)	2 (1.2)
Re-suturing of main incision	0	0
Retinal laser	1 (0.3)	0
Vitrectomy	2 (0.6)	0

Abbreviations: IOL=Intraocular Lens; SSI = Secondary Surgical Intervention.

Note: At each level of summarization, n represents the number of unique eyes with at least one specific SSI. Percentages are based on the number of eyes (N) in the respective treatment group for the population being analyzed.

Visual Disturbances

The second secondary safety objective was to estimate the rates of Visual disturbances using the Quality of Vision (QoV) questionnaire and QoV Supplemental Questions at Month 12 (Visit 5). **Table 17-19** report rates of visual disturbances in FINEVISION HP Trifocal IOL and Control groups. Most visual symptoms—such as glare, hazy or blurred vision, image distortion, double or multiple images, trouble focusing, difficulty judging distance or depth, and vision fluctuations—occurred at similar or slightly lower rates in the FINEVISION HP Trifocal IOL group compared to the control group. However, two symptoms—starbursts and halos—were reported more frequently by participants with the FINEVISION HP Trifocal IOL than those with the monofocal control lens.

Outcomes of the QoV Supplemental Questions at Month 12 (Visit 5) overall showed that subjects favored the trifocal IOL for near vision and slightly favored the monofocal IOL for distance vision. Perceived trouble with night driving was lower in the monofocal IOL group by a moderate margin, and trouble with color disturbances was comparable between the study groups. A larger proportion

of participants reported they would have this device implanted again in the FINEVISION HP Trifocal IOL group as compared to the control group.

Table 17: Quality of Vision (QoV) categorical summary of the frequency of each visual disturbance at Visit 5 (Day 360 to 420), Safety Set

	FINEVISION HP (%)					Monofocal (%)				
Visual Disturbance	**N**	**Never**	**Occasionally**	**Quite Often**	**Very Often**	**N**	**Never**	**Occasionally**	**Quite Often**	**Very Often**
Glare	315	38.4% [121/315]	47.3% [149/315]	11.1% [35/315]	3.2% [10/315]	159	38.4% [61/159]	51.6% [82/159]	8.2% [13/159]	1.9% [3/159]
Haloes	315	22.2% [70/315]	39.0% [123/315]	21.0% [66/315]	17.8% [56/315]	159	70.4% [112/159]	23.3% [37/159]	3.8% [6/159]	2.5% [4/159]
Starbursts	315	50.2% [158/315]	31.4% [99/315]	11.7% [37/315]	6.7% [21/315]	159	61.6% [98/159]	30.8% [49/159]	5.7% [9/159]	1.9% [3/159]
Hazy Vision	315	67.9% [214/315]	24.4% [77/315]	5.1% [16/315]	2.5% [8/315]	159	67.3% [107/159]	24.5% [39/159]	5.7% [9/159]	2.5% [4/159]
Blurred Vision	315	61.3% [193/315]	32.7% [103/315]	4.8% [15/315]	1.3% [4/315]	159	50.9% [81/159]	38.4% [61/159]	8.2% [13/159]	2.5% [4/159]
Distortion	315	90.5% [285/315]	8.6% [27/315]	1.0% [3/315]	0.0 %	159	91.8% [146/159]	5.7% [9/159]	2.5% [4/159]	0.0%
Double or multiple images	315	88.6% [279/315]	10.5% [33/315]	0.6% [2/315]	0.3% [1/315]	159	88.7% [141/159]	9.4% [15/159]	1.3% [2/159]	0.6% [1/159]
Fluctuation in Vision	315	48.3% [152/315]	42.5% [134/315]	7.3% [23/315]	1.9% [6/315]	159	50.3% [80/159]	44.0% [70/159]	3.8% [6/159]	1.9% [3/159]
Focusing Difficulties	315	44.1% [139/315]	47.9% [151/315]	5.4% [17/315]	2.5% [8/315]	159	39.6% [63/159]	46.5% [74/159]	9.4% [15/159]	4.4% [7/159]
Difficulty Judging Distance or Depth Perception	315	73.7% [232/315]	19.0% [60/315]	4.4% [14/315]	2.9% [9/315]	159	66.0% [105/159]	25.8% [41/159]	6.3% [10/159]	1.9% [3/159]

Note: Percentages are based on the number of subjects (N) seen at Visit 5 (Day 360 to 420) for the respective treatment group for the population being analyzed.

Table 18: Quality of Vision (QoV) categorical summary of the severity of each visual disturbance at Visit 5 (Day 360 to 420) excluding subjects who reported frequency of "Never", Safety Set

	FINEVISION HP (%)						Monofocal (%)					
Visual Disturbance	**N**	**Not at all**	**Mild**	**Moderate**	**Severe**	**Missing**	**N**	**Not at all**	**Mild**	**Moderate**	**Severe**	**Missing**
Glare	194	4.1 % [8/194]	67.0 % [130/194]	24.7 % [48/194]	3.6 % [7/194]	0.5 % [1/194]	98	6.1 % [6/98]	59.2% [58/98]	31.6% [31/98]	3.1% [3/98]	0.0%
Haloes	245	3.3 % [8/245]	52.7% [129/245]	33.9% [83/245]	9.8% [24/245]	0.4% [1/245]	47	6.4% [3/47]	70.2% [33/47]	21.3% [10/47]	2.1% [1/47]	0.0%
Starbursts	157	8.3% [13/157]	54.8% [86/157]	31.2% [49/157]	5.7% [9/157]	0.0%	61	8.2% [5/61]	65.6% [40/61]	23.0% [14/61]	3.3% [2/61]	0.0%
Hazy Vision	101	7.9% [8/101]	65.3% [66/101]	24.8% [25/101]	1.0% [1/101]	1.0% [1/101]	52	7.7% [4/52]	71.2% [37/52]	15.4% [8/52]	5.8% [3/52]	0.0%
Blurred Vision	122	7.4% [9/122]	73.0% [89/122]	17.2% [21/122]	2.5% [3/122]	0.0%	78	3.8% [3/78]	66.7% [52/78]	24.4% [19/78]	5.1% [4/78]	0.0%
Distortion	30	13.3% [4/30]	73.3% [22/30]	13.3% [4/30]	0.0%	0.0%	13	7.7% [1/13]	69.2% [9/13]	23.1% [3/13]	0.0%	0.0%
Double or multiple images	36	8.3% [3/36]	83.3% [30/36]	8.3% [3/36]	0.0%	0.0%	18	11.1% [2/18]	61.1% [11/18]	16.7% [3/18]	11.1% [2/18]	0.0%
Fluctuation in Vision	163	9.2% [15/163]	69.9% [114/163]	17.8% [29/163]	2.5% [4/163]	0.6% [1/163]	79	8.9% [7/79]	75.9% [60/79]	12.7% [10/79]	2.5% [2/79]	0.0%
Focusing Difficulties	176	12.5% [22/176]	69.9% [123/176]	14.8% [26/176]	2.8% [5/176]	0.0%	96	2.1% [2/96]	71.9% [69/96]	21.9% [21/96]	4.2% [4/96]	0.0%
Difficulty Judging Distance or Depth Perception	83	8.4% [7/83]	68.7% [57/83]	19.3% [16/83]	3.6% [3/83]	0.0%	54	1.9% [1/54]	68.5% [37/54]	27.8% [15/54]	1.9% [1/54]	0.0%

Note: Percentages are based on the number of subjects (N) seen at Visit 5 (Day 360 to 420) who did not report a frequency of "Never" for the visual disturbance and treatment group for the population being analyzed.

Table 19: Quality of Vision (QoV) categorical summary of the bothersomeness of each visual disturbance at Visit 5 (Day 360 to 420) excluding subjects who reported frequency of "Never", Safety Set

	FINEVISION HP (%)						Monofocal (%)					
Visual Disturbance	**N**	**Not at all**	**A little**	**Quite**	**Very**	**Missing**	**N**	**Not at all**	**A little**	**Quite**	**Very**	**Missing**
Glare	194	15.5% [30/194]	67.5% [131/194]	10.8% [21/194]	5.7% [11/194]	0.5% [1/194]	98	17.3% [17/98]	62.2% [61/98]	15.3% [15/98]	5.1% [5/98]	0.0%
Haloes	245	23.7% [58/245]	47.3% [116/245]	18.0% [44/245]	10.6% [26/245]	0.4% [1/245]	47	25.5% [12/47]	59.6% [28/47]	12.8% [6/47]	2.1% [1/47]	0.0%
Starbursts	157	24.2% [38/157]	46.5% [73/157]	21.7% [34/157]	7.6% [12/157]	0.0%	61	21.3% [13/61]	65.6% [40/61]	9.8% [6/61]	3.3% [2/61]	0.0%
Hazy Vision	101	15.8% [16/101]	63.4% [64/101]	16.8% [17/101]	4.0% [4/101]	0.0%	52	21.2% [11/52]	57.7% [30/52]	13.5% [7/52]	7.7% [4/52]	0.0%
Blurred Vision	122	12.3% [15/122]	68.0% [83/122]	16.4% [20/122]	3.3% [4/122]	0.0%	78	12.8% [10/78]	57.7% [45/78]	20.5% [16/78]	9.0% [7/78]	0.0%
Distortion	30	23.3% [7/30]	60.0% [18/30]	16.7% [5/30]	0.0%	0.0%	13	15.4% [2/13]	53.8% [7/13]	30.8% [4/13]	0.0%	0.0%
Double or multiple images	36	22.2% [8/36]	66.7% [24/36]	8.3% [3/36]	2.8% [1/36]	0.0%	18	11.1% [2/18]	61.1% [11/18]	16.7% [3/18]	11.1% [2/18]	0.0%
Fluctuation in Vision	163	23.9% [39/163]	63.8% [104/163]	8.6% [14/163]	3.1% [5/163]	0.6% [1/163]	79	16.5% [13/79]	63.3% [50/79]	13.9% [11/79]	6.3% [5/79]	0.0%
Focusing Difficulties	176	21.0% [37/176]	61.9% [109/176]	11.9% [21/176]	4.5% [8/176]	0.6% [1/176]	96	12.5% [12/96]	66.7% [64/96]	15.6% [15/96]	5.2% [5/96]	0.0%
Difficulty Judging Distance or Depth Perception	83	10.8% [9/83]	68.7% [57/83]	14.5% [12/83]	6.0% [5/83]	0.0%	54	5.6% [3/54]	74.1% [40/54]	13.0% [7/54]	7.4% [4/54]	0.0%

Note: Percentages are based on the number of subjects (N) seen at Visit 5 (Day 360 to 420) who did not report a frequency of "Never" for the visual disturbance and treatment group for the population being analyzed.

Adverse events that occurred in the PMA clinical study:

The ocular treatment-emergent adverse events (TEAEs; serious and non-serious) for both the study and control lens, first eye, are presented in **Table 20.** The most common ocular TEAEs overall were vitreous detachment and increased IOP, which were observed at comparable rates between study and treatments groups (6.1% [40/661] vs 7.6% [25/328] and 3.9% [26/661] vs 4.3% [14/328], respectively). Other TEAEs observed at rates from 1-2% in the study group were corneal dystrophy, iritis, punctate keratitis, meibomian gland dysfunction, and dry eye. In the AcrySof SN60AT IOL group, punctate keratitis was reported in 2.7% [9/328] of eyes. There were no non-ocular TEAEs reported in more than 1% of subjects. Results for the second eyes were similar to the first eyes (**Table 21**).

Table 20: Ocular Treatment-Emergent Adverse Events by Preferred Term, Safety Set – First Operative Eyes

Preferred Term (PT)	FINEVISION HP (N=332) n (%)	AcrySof SN60AT (N=164) n (%)
Any Ocular TEAE	86 (25.9)	33 (20.1)
Vitreous detachment	17 (5.1)	13 (7.9)
Intraocular pressure increased	12 (3.6)	7 (4.3)
Iritis	6 (1.8)	1 (0.6)
Punctate keratitis	6 (1.8)	5 (3.0)
Conjunctival hemorrhage	4 (1.2)	0
Dry eye	4 (1.2)	1 (0.6)
Meibomian gland dysfunction	4 (1.2)	0
Corneal dystrophy	3 (0.9)	1 (0.6)
Blepharitis	3 (0.9)	0
Conjunctivitis allergic	3 (0.9)	0
Retinal detachment	3 (0.9)	0
Punctal plug insertion	3 (0.9)	0
Vitrectomy	3 (0.9)	0
Conjunctivitis	2 (0.6)	0
Conjunctivitis viral	2 (0.6)	0
Diabetic retinopathy	2 (0.6)	1 (0.6)

Preferred Term (PT)	FINEVISION HP (N=332) n (%)	AcrySof SN60AT (N=164) n (%)
Eye pain	2 (0.6)	0
Macular hole	2 (0.6)	1 (0.6)
Retinal degeneration	2 (0.6)	0
Retinal depigmentation	2 (0.6)	2 (1.2)
Vitreous floaters	2 (0.6)	1 (0.6)
Tilted disc syndrome	1 (0.3)	0
Conjunctival hyperemia	1 (0.3)	0
Conjunctival edema	1 (0.3)	0
Conjunctivochalasis	1 (0.3)	0
Corneal deposits	1 (0.3)	0
Corneal epithelium defect	1 (0.3)	0
Cystoid macular edema	1 (0.3)	1 (0.6)
Dermatochalasis	1 (0.3)	0
Eye irritation	1 (0.3)	0
Eye pruritus	1 (0.3)	0
Eyelid ptosis	1 (0.3)	0
Glare	1 (0.3)	0
Halo vision	1 (0.3)	0
Iris transillumination defect	1 (0.3)	0
Keratic precipitates	1 (0.3)	0
Herpes ophthalmic	1 (0.3)	0
Hordeolum	1 (0.3)	0
Cataract operation complication	1 (0.3)	1 (0.6)
Foreign body in eye	1 (0.3)	0
Periorbital hemorrhage	1 (0.3)	0
Basal cell carcinoma	1 (0.3)	0
Lens extraction	1 (0.3)	0

Preferred Term (PT)	FINEVISION HP (N=332) n (%)	AcrySof SN60AT (N=164) n (%)
Scleral buckling surgery	1 (0.3)	0
Lacrimation disorder	1 (0.3)	0
Optic disc hemorrhage	1 (0.3)	0
Retinal drusen	1 (0.3)	0
Retinal hemorrhage	1 (0.3)	0
Visual acuity reduced	1 (0.3)	0
Vitreous prolapse	1 (0.3)	0
Vitritis	1 (0.3)	0
Anterior capsule contraction	0	1 (0.6)
Diplopia	0	1 (0.6)
Epiretinal membrane	0	1 (0.6)
Exposure keratitis	0	1 (0.6)
Flat anterior chamber of eye	0	1 (0.6)
Vitreous degeneration	0	1 (0.6)
Ophthalmic herpes simplex	0	1 (0.6)
Corneal abrasion	0	1 (0.6)
Retinal operation	0	1 (0.6)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; PT = Preferred Term; TEAE = Treatment-Emergent Adverse Event.

Note: At each level of summarization, n represents the number of unique eyes with at least one specific event. Percentages are based on the number of eyes (N) in the respective treatment group for the population being analyzed. Ocular TEAEs for a respective eye include all AEs occurring or worsening during or after the operation for the respective eye. Adverse events are coded using MedDRA Version 24.1. PTs are listed in order of descending frequency for the FINEVISION HP Trifocal IOL group.

Table 21: Ocular Treatment-Emergent Adverse Events by Preferred Term, Safety Set – Second Operative Eyes

Preferred Term (PT)	FINEVISION HP (N=329) n (%)	AcrySof SN60AT (N=164) n (%)
Any Ocular TEAE	81 (24.6)	31 (18.9)
Vitreous detachment	23 (7.0)	12 (7.3)
Intraocular pressure increased	14 (4.3)	7 (4.3)
Cystoid macular edema	5 (1.5)	2 (1.2)
Iritis	5 (1.5)	1 (0.6)
Meibomian gland dysfunction	5 (1.5)	0
Corneal dystrophy	4 (1.2)	1 (0.6)
Punctate keratitis	4 (1.2)	4 (2.4)
Punctal plug insertion	3 (0.9)	0
Blepharitis	3 (0.9)	0
Dry eye	3 (0.9)	2 (1.2)
Conjunctivitis allergic	2 (0.6)	0
Eye irritation	2 (0.6)	0
Retinal degeneration	2 (0.6)	1 (0.6)
Retinal detachment	2 (0.6)	0
Vitreous floaters	2 (0.6)	1 (0.6)
Hordeolum	2 (0.6)	0
Conjunctivitis viral	1 (0.3)	0
Anterior capsular rupture	1 (0.3)	0
Eye injury	1 (0.3)	0
Pupil dilation procedure	1 (0.3)	0
Vitrectomy	1 (0.3)	0
Retinal anomaly congenital	1 (0.3)	0
Blepharitis allergic	1 (0.3)	0
Conjunctival hyperemia	1 (0.3)	0

Preferred Term (PT)	FINEVISION HP (N=329) n (%)	AcrySof SN60AT (N=164) n (%)
Corneal epithelium defect	1 (0.3)	0
Corneal opacity	1 (0.3)	0
Dermatochalasis	1 (0.3)	0
Diabetic retinopathy	1 (0.3)	0
Epiretinal membrane	1 (0.3)	2 (1.2)
Eye pruritus	1 (0.3)	0
Glare	1 (0.3)	0
Halo vision	1 (0.3)	0
Lacrimation disorder	1 (0.3)	0
Macular hole	1 (0.3)	1 (0.6)
Posterior capsule opacification	1 (0.3)	0
Retinal artery embolism	1 (0.3)	0
Retinal depigmentation	1 (0.3)	1 (0.6)
Retinal drusen	1 (0.3)	0
Retinal tear	1 (0.3)	0
Vision blurred	1 (0.3)	0
Vitreoretinal traction syndrome	1 (0.3)	0
Vitreous degeneration	1 (0.3)	1 (0.6)
Vitritis	1 (0.3)	0
Anterior capsule contraction	0	1 (0.6)
Diplopia	0	1 (0.6)
Eyelid cyst	0	1 (0.6)
Macular cyst	0	1 (0.6)
Corneal abrasion	0	1 (0.6)
Malignant melanoma	0	1 (0.6)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; PT = Preferred Term; TEAE = Treatment-Emergent Adverse Event.

Note: At each level of summarization, n represents the number of unique eyes with at least one specific event. Percentages are based on the number of eyes (N) in the respective treatment group for the population being analyzed. Ocular TEAEs for a respective eye include all AEs occurring or worsening during or after the operation for the respective eye. Adverse events are coded using MedDRA Version 24.1. PTs are listed in order of descending frequency for the FINEVISION HP Trifocal IOL group.

The results of adverse events analyses based on the consensus definitions as set forth by American Academy of Ophthalmology's Task Force (Masket et al. Ophthalmology 2017) are shown in **Tables 22** and **23**.

Table 22: Ocular Treatment-Emergent Adverse Events based on a Modified Version of the AAO Task Force Consensus (Masket et al, 2017), Safety Set – First Implanted Eyes

	FINEVISION HP (N=332)			Monofocal IOL (N=164)		
Adverse Event	**n (%)**	**[95% CI]**	**E**	**n (%)**	**[95% CI]**	**E**
Chronic anterior uveitis	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Clinically significant cystoid macular edema	0	[0.00, 1.10]	0	1 (0.6)	[0.02, 3.35]	1
Visually Significant Corneal edema	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Endophthalmitis	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Mechanical pupillary block	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Increased IOP	12 (3.6)	[1.88, 6.23]	12	7 (4.3)	[1.73, 8.60]	7
Rhegmatogenous retinal detachment	3 (0.9)	[0.19, 2.62]	3	0	[0.00, 2.22]	0
Toxic anterior segment syndrome	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Secondary IOL intervention - Exchange	0	[0.00, 1.10]	0	0	[0.00, 2.22]	0
Secondary IOL intervention – Removal	1 (0.3)	[0.01, 1.67]	1	0	[0.00, 2.22]	0
Secondary IOL intervention - Reposition	0	[0.00, 1.10]	0	1 (0.6)	[0.02, 3.35]	1

Abbreviations: AAO = American Academy of Ophthalmology; E = Events; IOL = Intraocular Lens; IOP = Intraocular Pressure; TEAE = Treatment-Emergent Adverse Event.

Note: At each level of summarization, n represents the number of unique subjects with at least one specific event and E represents the total number of the specific events. Percentages are based on the number of subjects (N) in each respective treatment group for the population being analyzed. Adverse events from "Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with intraocular Lenses" by Masket, et al 2017. Ocular TEAEs for a respective eye include all AEs occurring or worsening during or after the operation for the respective eye. Confidence intervals for adverse event rates are computed using the Clopper-Pearson method.

Table 23: Ocular Treatment-Emergent Adverse Events based on a Modified Version of the AAO Task Force Consensus (Masket et al., 2017), Safety Set – Second Implanted Eyes

	FINEVISION HP (N=329)			Monofocal IOL (N=164)		
Adverse Event	**n (%)**	**[95% CI]**	**E**	**n (%)**	**[95% CI]**	**E**
Chronic anterior uveitis	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Clinically significant cystoid macular edema	1 (0.3)	[0.01, 1.68]	1	2 (1.2)	[0.15, 4.34]	2
Visually Significant Corneal edema	1 (0.3)	[0.01, 1.68]	1	0	[0.00, 2.22]	0
Endophthalmitis	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Mechanical pupillary block	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Increased IOP	13 (4.0)	[2.12, 6.66]	17	7 (4.3)	[1.73, 8.60]	7
Rhegmatogenous retinal detachment	2 (0.6)	[0.07, 2.18]	2	0	[0.00, 2.22]	0
Toxic anterior segment syndrome	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Secondary IOL intervention - Exchange	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Secondary IOL intervention – Removal	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0
Secondary IOL intervention - Reposition	0	[0.00, 1.11]	0	0	[0.00, 2.22]	0

Abbreviations: AAO = American Academy of Ophthalmology; E = Events; IOL = Intraocular Lens; IOP = Intraocular Pressure; TEAE = Treatment-Emergent Adverse Event.

Note: At each level of summarization, n represents the number of unique subjects with at least one specific event and E represents the total number of the specific events. Percentages are based on the number of subjects (N) in each respective treatment group for the population being analyzed. Adverse events from "Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with intraocular Lenses" by Masket, et al 2017. Ocular TEAEs for a respective eye include all AEs occurring or worsening during or after the operation for the respective eye. Confidence intervals for adverse event rates are computed using the Clopper-Pearson method.

Fundus Visualization

There was no reported difficulty in fundus visualization at any postoperative visits for the first or second eyes in the study. Clarity of the retinal image was graded 4 (excellent clarity) in >87% [204/233] of eyes in the FINEVISION HP Trifocal IOL group.

Device Failures

There were 16 reported deficiencies for the FINEVISION HP Trifocal IOL (2.4% [16/661] of devices) and 3 for AcrySof SN60AT IOL (0.9% [3/328] of devices). The most common deficiency was for device failure (7) [Torn haptic during loading/injection process], device malfunction (5) [Haptics severed from the optic during injector loading], and device misuse (2) [Broken haptic during injection process]. There were 5 "Other" device deficiencies [IOL Damaged upon loading into the injector, dropping of IOL before implantation].

Out of 661 total FINEVISION HP Trifocal IOL implants, 10 IOLs (1.5% [10/661]) experienced a device deficiency related to the haptic being torn off during the IOL injection process. In 5 of these cases, the initial IOL was already inserted into the eye when the broken haptic was identified, requiring surgical removal of the initial IOL and implantation of the back-up FINEVISION HP Trifocal IOL. A CAPA and root cause analysis was performed. Haptic breakage force testing did not find any manufacturing, haptic design or raw material cause. Simulated surgical testing was performed according to Section 5 of ISO 11979-2, which did not find a root cause. Additional testing which intentionally violated the directions for use (DFU) determined the root cause was likely related to improper loading of the IOL into the injector. Based on the CAPA findings, the DFU and warnings/precautions have been updated to mitigate future haptic breakage events. In addition, training will be available and provided as necessary to surgeons and support staff.

2. Effectiveness Results

The analysis of effectiveness was based on 483 evaluable subjects at the 6-month time point. Key effectiveness outcomes are presented in **Table 24-42** and Figures **9 to 11**.

All the co-primary effectiveness endpoints for this study were met, with the trifocal IOL showing statistical noninferiority to the monofocal IOL in photopic monocular BCDVA, satisfactory BCDVA performance compared to the International Organization for Standardization (ISO) grid performance standards, and statistical superiority to the monofocal IOL in photopic monocular DCNVA and DCIVA (both $P<0.0001$.)

Visual Acuity was assessed using a computerized test system (CTS, M&S Technologies, Niles, IL, USA). The co-primary effectiveness objectives were to demonstrate statistical non-inferiority in mean photopic monocular BCDVA (non-inferiority margin of 0.10 logMAR) and to demonstrate statistical superiority of mean photopic monocular DCNVA for the first operative eyes at Month 6. Non-inferiority of FINEVISION HP Trifocal IOL to Monofocal IOL was demonstrated as the 90% upper confidence limit of the difference of the means (0.059 logMAR) was less than the margin of 0.10 logMAR. The second co-primary effectiveness objective was also met because results demonstrated a statistically significant difference in population means for DCNVA of 0.388 logMAR in favor of FINEVISION HP Trifocal IOL. The secondary effectiveness objective was to demonstrate statistical superiority of mean

photopic monocular DCIVA at 66 cm for first operative eyes at Month 6. A statistically significant difference in population means for DCIVA of 0.182 logMAR was observed in favor of FINEVISION HP Trifocal IOL.

Table 24: Comparison of Photopic Monocular Distance Corrected Visual Acuity (logMAR) in First operative eyes, Intent-to-Treat Set, Primary imputation at Visit 4 (Day 150-180)

		FINEVISION HP (N=332)	AcrySof SN60T (N=164)
BCDVA 4 m	Mean (SE)[1]	0.018 (0.0050)	-0.028 (0.0065)
	Mean Difference (SE)[1]	0.046 (0.0084)	
	90% CI for Mean Difference[1]	(0.0317, 0.0593)	
	p-value[1]	<0.0001	
DCIVA 66 cm	Mean (SE)[1]	0.161 (0.0062)	0.342 (0.0102)
	Mean Difference (SE)[1]	-0.182 (0.0114)	
	95% CI for Mean Difference[1]	(-0.2040, -0.1591)	
	p-value[1]	<0.0001	
DCNVA 40 cm	Mean (SE)[1]	0.162 (0.0076)	0.550 (0.0110)
	Mean Difference (SE)[1]	-0.388 (0.0132)	
	95% CI for Mean Difference[1]	(-0.4137, -0.3618)	
	p-value[1]	<0.0001	

BCDVA = Best Corrected Distance Visual Acuity; DCNVA=Distance Corrected Near Visual Acuity; DCIVA= Distance corrected Intermediate Visual Acuity; CI = Confidence Interval; logMAR = Logarithm of the Minimum Angle of Resolution; SE = Standard Error.

Note: N in the headers represents the number of eyes in the respective treatment group for the population being analyzed·

[1] Difference is computed as FINEVISION HP Trifocal IOL minus AcrySof SN60AT. Combined inference statistics are from multiple imputation methodology. Each imputed dataset is analyzed using a two-sample t-test.

Tables 25 and **26** provide details on the percentage of subjects achieving a Photopic Monocular BCDVA of 0.30 logMAR or better by visit for the first operative eyes.

Tables 27 to 32 provide descriptive statistics on photopic monocular visual acuity (BCDVA, UCDVA, DCIVA (66 cm), UCIVA (66 cm), DCNVA, and UCNVA.

Tables 33 to 38 provide descriptive statistics on photopic binocular visual acuity (BCDVA, UCDVA, DCIVA (66 cm), UCIVA (66 cm), DCNVA, and UCNVA.

Tables 39 to 42 provide descriptive statistics on mesopic monocular and binocular visual acuity (DCIVA (66 cm) and DCNVA).

Table 25: Percentage of Subjects Achieving a Photopic Monocular BCDVA of 0.30 logMAR or Better by Visit – All-Implanted Analysis Set – First Operative Eyes

			FINEVISION HP		AcrySof® SN60AT
Visit	**SPE Rate (%) [1]**	**N**	**n (%)**	**N**	**n (%)**
Visit 4 (Day 150 to 180)	92.5	320	319 (99.7)	159	159 (100.0)
Visit 5 (Day 360 to 420)	92.5	314	311 (99.0)	159	159 (100.0)

Abbreviations: BCDVA= Best Corrected Distance Visual Acuity; logMAR= logarithm of the Minimum Angle of Resolution; SPE = Safety and Performance Endpoints for posterior chamber IOL from ISO 11979-7:2018; n = number of unique eyes meeting the criterion for each respective treatment group and visit; N= the number of eyes for each respective treatment group and visit with non-missing data for the population being analyzed. Percentages are based on "N".
[1] The SPE rate is from Table E.3 (Overall post-operative BCVA 0,3 logMAR or better) of ISO 11979-7:2018(E).

Table 26: Percentage of Subjects Achieving a Photopic Monocular BCDVA of 0.30 logMAR or Better by Visit – Best Case Set – First Operative Eyes

			FINEVISION HP		AcrySof® SN60AT
Visit	**SPE Rate (%) [1]**	**N**	**n (%)**	**N**	**n (%)**
Visit 4 (Day 150 to 180)	96.7	303	302 (99.7)	148	148 (100.0)
Visit 5 (Day 360 to 420)	96.7	296	293 (99.0)	147	147 (100.0)

Abbreviations: BCDVA= Best Corrected Distance Visual Acuity; logMAR= Logarithm of the Minimum Angle of Resolution; SPE = Safety and Performance Endpoints for posterior chamber IOL from ISO 11979-7:2018; n = Number of unique eyes meeting the criterion for each respective treatment group and visit; N= Number of eyes (N) for each respective treatment group and visit with non-missing data for the population being analyzed. Percentages are based on "N".
[1] The SPE rate is from Table E.3 (Overall post-operative BCVA 0,3 logMAR or better) of ISO 11979-7:2018(E).

Table 27: Photopic Monocular logMAR BCDVA at Month 6 (Visit 4) - All-Implanted Analysis Set – First Operative Eyes

Visit **Category**	**FINEVISION HP** **n (%)**	**AcrySof® SN60AT** **n (%)**
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	320	159
0.00 logMAR or Better	166 (51.9)	112 (70.4)
0.10 logMAR or Better	280 (87.5)	152 (95.6)

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
0.20 logMAR or Better	310 (96.9)	157 (98.7)
0.30 logMAR or Better	319 (99.7)	159 (100.0)
Worse than 0.30 logMAR	1 (0.3)	0
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	320	159
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	230 (71.9)	140 (88.1)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	296 (92.5)	155 (97.5)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	315 (98.4)	158 (99.4)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	320 (100.0)	159 (100.0)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	0	0
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	320	159
Mean (SD)	0.017 (0.0897)	-0.028 (0.0832)
Median	0.000	-0.020
Min, Max	-0.18, 0.34	-0.22, 0.26

Abbreviations: BCDVA = Best Corrected Distance Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 28. Photopic Monocular logMAR UCDVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	73 (22.6)	65 (40.6)
0.10 logMAR or Better	190 (58.8)	115 (71.9)
0.20 logMAR or Better	262 (81.1)	141 (88.1)
0.30 logMAR or Better	303 (93.8)	153 (95.6)
Worse than 0.30 logMAR	20 (6.2)	7 (4.4)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	115 (35.6)	89 (55.6)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	223 (69.0)	134 (83.8)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	284 (87.9)	149 (93.1)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	309 (95.7)	153 (95.6)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	14 (4.3)	7 (4.4)

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
n	323	160
Mean (SD)	0.107 (0.1255)	0.056 (0.1339)
Median	0.100	0.040
Min, Max	-0.18, 0.64	-0.24, 0.62

Abbreviations: UCDVA = Uncorrected Distance Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 29: Photopic Monocular logMAR DCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	20 (6.2)	2 (1.3)
0.10 logMAR or Better	120 (37.2)	3 (1.9)
0.20 logMAR or Better	241 (74.6)	27 (16.9)
0.30 logMAR or Better	289 (89.5)	69 (43.1)
Worse than 0.30 logMAR	34 (10.5)	91 (56.9)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	55 (17.0)	2 (1.3)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	162 (50.2)	9 (5.6)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	271 (83.9)	42 (26.3)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	298 (92.3)	87 (54.4)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	25 (7.7)	73 (45.6)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.160 (0.1127)	0.343 (0.1291)
Median	0.140	0.330
Min, Max	-0.08, 0.68	-0.10, 0.62

Abbreviations: DCIVA = Distance Corrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 30. Photopic Monocular logMAR UCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	26 (8.0)	8 (5.0)
0.10 logMAR or Better	145 (44.9)	22 (13.8)
0.20 logMAR or Better	248 (76.8)	55 (34.4)
0.30 logMAR or Better	298 (92.3)	105 (65.6)
Worse than 0.30 logMAR	25 (7.7)	55 (34.4)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	74 (22.9)	12 (7.5)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	191 (59.1)	36 (22.5)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	279 (86.4)	74 (46.3)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	305 (94.4)	122 (76.3)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	18 (5.6)	38 (23.8)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.144 (0.1111)	0.264 (0.1440)
Median	0.120	0.270
Min, Max	-0.08, 0.54	-0.08, 0.68

Abbreviations: UCIVA = Uncorrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 31: Photopic Monocular logMAR DCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	43 (13.3)	0
0.10 logMAR or Better	133 (41.2)	0
0.20 logMAR or Better	217 (67.2)	0
0.30 logMAR or Better	280 (86.7)	3 (1.9)
Worse than 0.30 logMAR	43 (13.3)	157 (98.1)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	70 (21.7)	0
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	166 (51.4)	0
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	248 (76.8)	1 (0.6)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	297 (92.0)	11 (6.9)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	26 (8.0)	149 (93.1)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.159 (0.1376)	0.551 (0.1413)
Median	0.140	0.530
Min, Max	-0.16, 0.70	0.24, 1.00

Abbreviations: DCNVA = Distance Corrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 32. Photopic Monocular logMAR UCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	23 (7.1)	0
0.10 logMAR or Better	95 (29.4)	1 (0.6)
0.20 logMAR or Better	201 (62.2)	8 (5.0)
0.30 logMAR or Better	273 (84.5)	20 (12.5)
Worse than 0.30 logMAR	50 (15.5)	140 (87.5)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	44 (13.6)	0
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	145 (44.9)	2 (1.3)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	238 (73.7)	10 (6.3)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	288 (89.2)	29 (18.1)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	35 (10.8)	131 (81.9)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.186 (0.1342)	0.494 (0.1622)
Median	0.160	0.500
Min, Max	-0.12, 0.60	0.10, 0.90

Abbreviations: UCNVA = Uncorrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 33. Photopic Binocular logMAR BCDVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	248 (76.8)	145 (90.6)
0.10 logMAR or Better	308 (95.4)	158 (98.8)
0.20 logMAR or Better	322 (99.7)	160 (100.0)
0.30 logMAR or Better	323 (100.0)	160 (100.0)
Worse than 0.30 logMAR	0	0
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	284 (87.9)	153 (95.6)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	315 (97.5)	159 (99.4)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	323 (100.0)	160 (100.0)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	323 (100.0)	160 (100.0)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	0	0
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	-0.032 (0.0757)	-0.077 (0.0705)
Median	-0.040	-0.090
Min, Max	-0.20, 0.22	-0.26, 0.20

Abbreviations: BCDVA = Best Corrected Distance Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 34. Photopic Binocular logMAR UCDVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	160 (49.5)	114 (71.3)
0.10 logMAR or Better	274 (84.8)	148 (92.5)
0.20 logMAR or Better	312 (96.6)	154 (96.3)
0.30 logMAR or Better	322 (99.7)	159 (99.4)
Worse than 0.30 logMAR	1 (0.3)	1 (0.6)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	214 (66.3)	135 (84.4)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	297 (92.0)	152 (95.0)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	318 (98.5)	154 (96.3)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	322 (99.7)	160 (100.0)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	1 (0.3)	0
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.022 (0.0950)	-0.022 (0.1005)
Median	0.020	-0.020
Min, Max	-0.20, 0.50	-0.26, 0.32

Abbreviations: UCDVA = Uncorrected Distance Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed

Table 35. Photopic Binocular logMAR DCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	72 (22.3)	2 (1.3)
0.10 logMAR or Better	237 (73.4)	17 (10.6)
0.20 logMAR or Better	295 (91.3)	70 (43.8)
0.30 logMAR or Better	318 (98.5)	124 (77.5)
Worse than 0.30 logMAR	5 (1.5)	36 (22.5)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	144 (44.6)	4 (2.5)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	268 (83.0)	38 (23.8)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	305 (94.4)	90 (56.3)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	320 (99.1)	134 (83.8)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	3 (0.9)	26 (16.3)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.077 (0.0886)	0.241 (0.1130)
Median	0.060	0.240
Min, Max	-0.16, 0.40	-0.12, 0.56

Abbreviations: DCIVA = Distance Corrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note:Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 36. Photopic Binocular logMAR UCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	106 (32.8)	20 (12.5)
0.10 logMAR or Better	255 (78.9)	54 (33.8)
0.20 logMAR or Better	304 (94.1)	111 (69.4)
0.30 logMAR or Better	319 (98.8)	143 (89.4)
Worse than 0.30 logMAR	4 (1.2)	17 (10.6)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	188 (58.2)	32 (20.0)
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	288 (89.2)	76 (47.5)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	314 (97.2)	125 (78.1)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	321 (99.4)	147 (91.9)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	2 (0.6)	13 (8.1)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.054 (0.0859)	0.164 (0.1326)
Median	0.040	0.160
Min, Max	-0.18, 0.42	-0.16, 0.62

Abbreviations: UCIVA = Uncorrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 37. Photopic Binocular logMAR DCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	80 (24.8)	0
0.10 logMAR or Better	199 (61.6)	0
0.20 logMAR or Better	276 (85.4)	4 (2.5)
0.30 logMAR or Better	305 (94.4)	21 (13.1)
Worse than 0.30 logMAR	18 (5.6)	139 (86.9)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	113 (35.0)	0
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	242 (74.9)	0
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	292 (90.4)	7 (4.4)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	310 (96.0)	38 (23.8)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	13 (4.0)	122 (76.3)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.099 (0.1421)	0.446 (0.1302)
Median	0.100	0.420
Min, Max	-0.16, 1.10	0.16, 0.80

Abbreviations: DCNVA = Distance Corrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 38. Photopic Binocular logMAR UCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
0.00 logMAR or Better	47 (14.6)	0
0.10 logMAR or Better	175 (54.2)	4 (2.5)
0.20 logMAR or Better	280 (86.7)	21 (13.1)
0.30 logMAR or Better	307 (95.0)	50 (31.3)
Worse than 0.30 logMAR	16 (5.0)	110 (68.8)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	323	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	85 (26.3)	0
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	226 (70.0)	11 (6.9)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	293 (90.7)	34 (21.3)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	314 (97.2)	68 (42.5)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	9 (2.8)	92 (57.5)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	323	160
Mean (SD)	0.111 (0.1075)	0.383 (0.1566)
Median	0.100	0.380
Min, Max	-0.16, 0.46	0.06, 1.10

Abbreviations: UCNVA = Uncorrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 39. Mesopic Monocular logMAR DCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	322	160
0.00 logMAR or Better	1 (0.3)	0
0.10 logMAR or Better	2 (0.6)	0
0.20 logMAR or Better	7 (2.2)	2 (1.3)
0.30 logMAR or Better	62 (19.3)	6 (3.8)
Worse than 0.30 logMAR	260 (80.7)	154 (96.3)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	322	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	1 (0.3)	0
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	4 (1.2)	0
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	20 (6.2)	2 (1.3)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	111 (34.5)	18 (11.3)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	211 (65.5)	142 (88.8)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	322	160
Mean (SD)	0.404 (0.1122)	0.480 (0.1009)
Median	0.400	0.500
Min, Max	0.00, 0.70	0.18, 0.74

Abbreviations: DCIVA = Distance Corrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 40. Mesopic Monocular logMAR DCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	322	160
0.00 logMAR or Better	0	0
0.10 logMAR or Better	1 (0.3)	0
0.20 logMAR or Better	9 (2.8)	0
0.30 logMAR or Better	62 (19.3)	1 (0.6)
Worse than 0.30 logMAR	260 (80.7)	159 (99.4)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	322	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	0	0
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	2 (0.6)	0
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	21 (6.5)	0
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	104 (32.3)	1 (0.6)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	218 (67.7)	159 (99.4)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	322	160
Mean (SD)	0.418 (0.1242)	0.699 (0.1230)
Median	0.400	0.700
Min, Max	0.08, 0.80	0.30, 0.94

Abbreviations: DCNVA = Distance Corrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 41. Mesopic Binocular logMAR DCIVA (66 cm) – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60A n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	322	160
0.00 logMAR or Better	0	0
0.10 logMAR or Better	4 (1.2)	2 (1.3)
0.20 logMAR or Better	37 (11.5)	6 (3.8)
0.30 logMAR or Better	172 (53.4)	26 (16.3)
Worse than 0.30 logMAR	150 (46.6)	134 (83.8)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	322	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	1 (0.3)	0
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	6 (1.9)	2 (1.3)
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	87 (27.0)	11 (6.9)
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	224 (69.6)	50 (31.3)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	98 (30.4)	110 (68.8)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	322	160
Mean (SD)	0.316 (0.0988)	0.402 (0.1007)
Median	0.300	0.420
Min, Max	0.04, 0.62	0.06, 0.60

Abbreviations: DCIVA = Distance Corrected Intermediate Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Table 42. Mesopic Binocular logMAR DCNVA – All-Implanted Analysis Set – First Operative Eyes

Visit Category	FINEVISION HP n (%)	AcrySof® SN60AT n (%)
Categorical Summary by logMAR Score and Visit Visit 4 (Day 150 to 180)		
N	322	160
0.00 logMAR or Better	0	0
0.10 logMAR or Better	4 (1.2)	0
0.20 logMAR or Better	46 (14.3)	0
0.30 logMAR or Better	141 (43.8)	0
Worse than 0.30 logMAR	181 (56.2)	160 (100.0)
Categorical Summary by Snellen Score and Visit Visit 4 (Day 150 to 180)		
N	322	160
$20/20^{-2}$ or Better (≤ 0.04 logMAR)	0	0
$20/25^{-2}$ or Better (≤ 0.14 logMAR)	13 (4.0)	0
$20/32^{-2}$ or Better (≤ 0.24 logMAR)	71 (22.0)	0
$20/40^{-2}$ or Better (≤ 0.34 logMAR)	186 (57.8)	2 (1.3)
Worse than $20/40^{-2}$ (> 0.34 logMAR)	136 (42.2)	158 (98.8)
Continuous Summary by Visit Visit 4 (Day 150 to 180)		
N	322	160
Mean (SD)	0.338 (0.1164)	0.621 (0.1052)
Median	0.320	0.620
Min, Max	0.08, 0.78	0.32, 0.92

Abbreviations: DCNVA = Distance Corrected Near Visual Acuity; logMAR = Logarithm of the Minimum Angle of Resolution.

Note: Percentages are based on the number of eyes (N) with non-missing data at each visit for the respective treatment group for the population being analyzed.

Defocus Curves

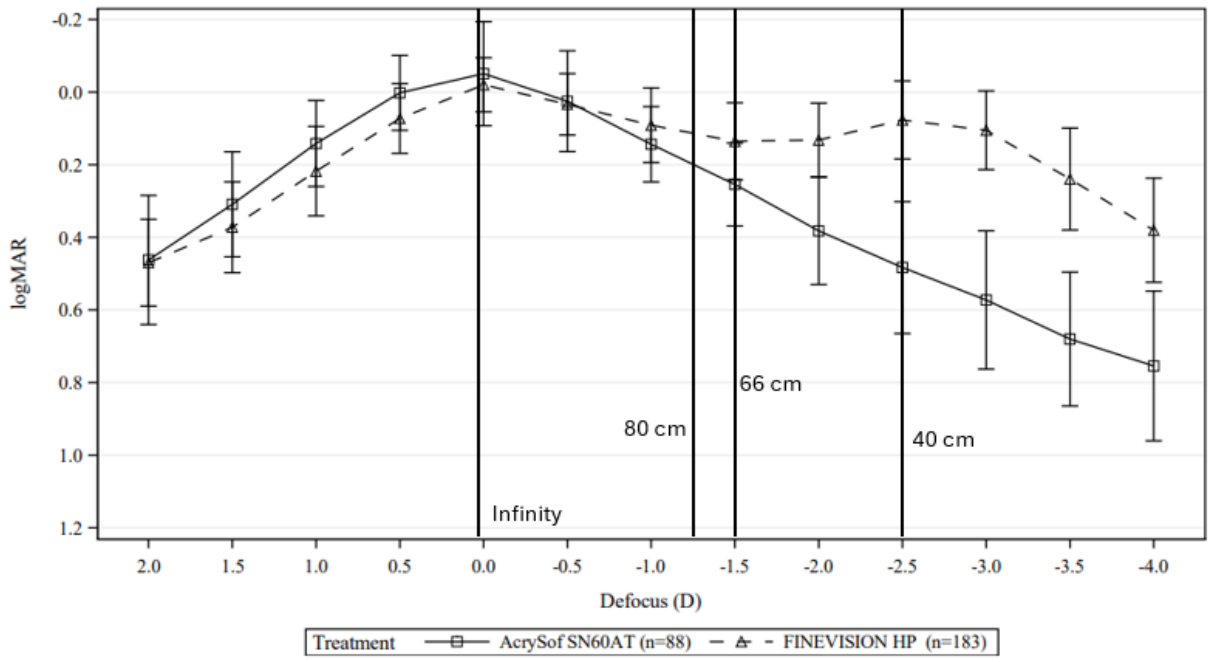
Monocular/Binocular defocus curves were obtained under photopic conditions at a test distance of 4 m at Visit 4 and Visit 5 for the FINEVISION HP Trifocal IOL and the Monofocal IOL. All analyses were primarily conducted using the Best-Case Set. Each subject was defocused with spherical lenses from +2.00 D through -4.00 D over the subject's manifest distance correction in -0.50 D increments.

Binocular Defocus curve is shown in **Figure 9** with error bars representing 1 Standard Deviation. Vertical lines indicate the distance (optical infinity), intermediate (66 cm), and near (40 cm) visual acuity testing distance. An additional vertical line representing 80 cm testing distance has been added to the defocus curve as it is commonly used to represent functional intermediate vision and can be particularly relevant when illustrating the continuous range of

vision—especially the transition between far vision and the standard intermediate distance of 66 cm. Binocular Defocus curves obtained at Visit 4 stratified by post-operative pupil size are presented in **Figures 10-11**. For summaries of binocular defocus curves by pupil size, the average pupil size at Visit 4 computed over both eyes was used to determine the pupil size subgroup.

Data were obtained from best-case subjects in each arm using a computerized visual acuity test system (CTS, M&S Technologies, Niles, IL). For distance vision (0.0 D defocus which corresponds to optical infinity) there was no notable difference between treatment groups in measured logMAR. At near distance (-2.5 D defocus which corresponds to 40 cm distance and -3.0 D defocus which corresponds to 33 cm distance) the FINEVISION HP Trifocal IOL group had substantially greater measured logMAR values than the control group. The FINEVISION HP Trifocal IOL provided mean performance of 0.2 logMAR or better vision (depth of focus) from -3.0 D to 0.00 D, corresponding to a range of distances from approximately 33 cm to infinity. There were no significant differences between defocus curves for pupil size sub-groups in any of the assessments. Results of binocular defocus curves at Visit 5 by treatment group and by pupil size were comparable with the binocular defocus curve findings at Visit 4.

Figure 9- Mean Binocular Defocus Curves with Standard Deviation Error Bars, Best Case Set – at Visit 4 (Day 150 to 180)

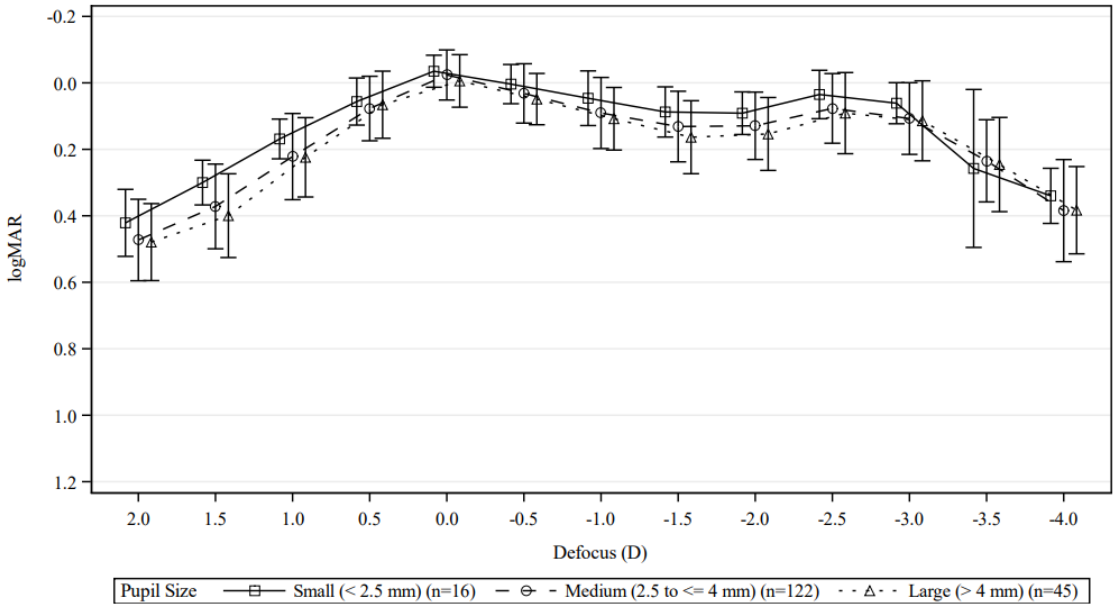


D = Diopters.

Note: n represents the number of subjects with non-missing data for the respective visit and treatment group.

Figure 10 -Mean Binocular Defocus Curves with Standard Deviation Error Bars by Post-Operative Photopic Pupil Size, Best Case Set – at Visit 4

Treatment= FINEVISION HP Trifocal IOL

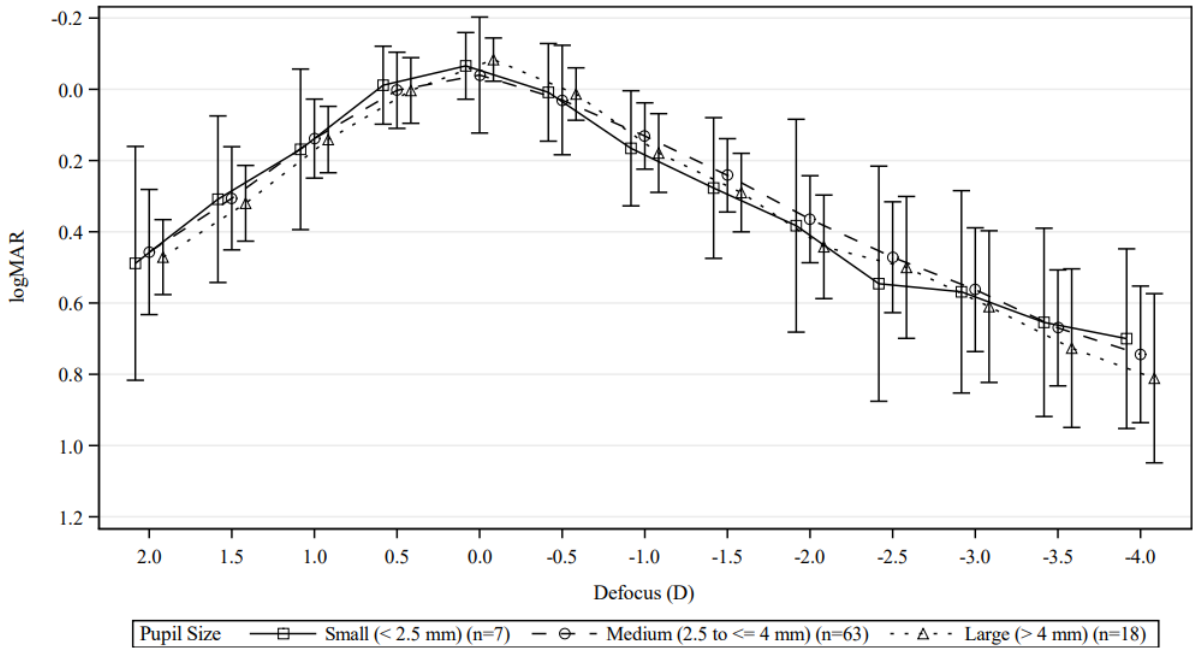


D = Diopters.

Note: n represents the number of subjects with non-missing data for the respective visit, treatment group, and subgroup. The average pupil size computed over both eyes is used to determine the pupil size subgroup. Photopic pupil size is from the respective visit. Defocus curves are offset slightly for ease of reading.

Figure 11 -Mean Binocular Defocus Curves with Standard Deviation Error Bars by Post-Operative Photopic Pupil Size, Best Case Set – at Visit 4

Treatment= Monofocal IOL (AcrySof SN60AT)



D = Diopters.

Note: n represents the number of subjects with non-missing data for the respective visit, treatment group, and subgroup. The average pupil size computed over both eyes is used to determine the pupil size subgroup. Photopic pupil size is from the respective visit. Defocus curves are offset slightly for ease of reading.

3. Subgroup Analyses

A subgroup analysis of the primary and secondary effectiveness and safety endpoints was completed by pupil size and the results were similar to the primary analysis thereby indicating no impact of pupil size on the effectiveness and safety of the FINEVISION HP Trifocal IOL.

A subgroup analysis of the primary and secondary effectiveness endpoints was completed by age, sex, ethnicity, and race and the results were similar to the primary analysis thereby indicating no impact of these demographic variables on the effectiveness and safety of the FINEVISION HP Trifocal IOL. The study was not specifically powered for any of the above subgroups.

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 20 investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

N/A

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

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic 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 overall effectiveness of the FINEVISION HP Trifocal IOL was demonstrated based on the 12-month results of the IDE clinical investigation.

The first co-primary effectiveness endpoint (non-inferiority of mean monocular BCDVA) was met. The second co-primary effectiveness endpoint (superiority of DCNVA) was met with both a statistically significant and clinically meaningful difference between the FINEVISION Trifocal HP IOL and monofocal control arms of approximately 4 logMAR lines of vision. The first secondary effectiveness endpoint (superiority of mean monocular DCIVA) was also met with a statistically significant and clinically meaningful difference between arms of approximately 1.8 logMAR lines.

Overall, this study has demonstrated effectiveness of the FINEVISION HPTrifocal IOL to provide improved intermediate and near visual acuity compared to a monofocal IOL while maintaining comparable distance visual acuity.

B. Safety Conclusions

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

The results of nonclinical laboratory testing and animal studies on the FINEVISION HP Trifocal IOL acrylic material and the one-piece lens design support the safety of this lens model. The results

of biocompatibility testing, dimensional, optical and mechanical testing, and chemical testing demonstrated conformance to applicable sections of ISO 10993-4, ISO 10993-6, ISO 10993-11, ISO 10993-6, ISO 11979-2, ISO 11979-3, ISO 11979-5, ANSI Z80.12, and internal product specifications.

The 12-month results of the IDE clinical investigation of the FINEVISION HP Trifocal IOL, Model POD F GF provide reasonable assurance of the safety of this lens model. There was a single SSI (IOL explant) due to the optical properties of the study lens reported in first eyes of the FINEVISION HP Trifocal IOL group. Mean monocular distance contrast sensitivity was slightly better for monofocal control IOL in all testing conditions versus FINEVISION HP Trifocal IOL in first operative eyes at Month 12 (Visit 5), however, the difference in means was not clinically significant. Rates of cumulative and persistent adverse events were not significantly greater in the FINEVISION HP Trifocal IOL group than the SPE rates defined in ISO 11979-7 at Month 12 (Visit 5).

Outcomes of the QoV questionnaire and QoV Supplemental Questions related to visual disturbances were also comparable between groups, meeting the additional safety endpoint objective. While two symptoms—starbursts and halos—were reported more frequently by participants with the FINEVISION HP Trifocal IOLs than those with the monofocal control lens, based on the QoV Supplemental Questionnaire, however, a larger proportion of participants reported they would have this device implanted again in the FINEVISION HP Trifocal IOL group as compared to the control group.

The overall rates of ocular device-related TEAEs were acceptable in both treatment groups. A CAPA and root cause analysis was performed for haptic breakage in 10 FINEVISION Trifocal HP IOLs (1.5% [10/661] of the treatment arm). Half of these occurred prior to insertion of the IOL into the eye. Bench testing determined the root cause was likely related to improper loading of the IOL into the injector. Based on the CAPA findings, the DFU and warnings/precautions in the professional label have been updated to mitigate future haptic breakage events. In addition, training will be available and provided as necessary to surgeons and support staff. Reported deaths and adverse events leading to discontinuation were determined to not be related to the study devices.

Overall, this study has demonstrated safety of the FINEVISION HP Trifocal IOL in adult eyes.

C. Benefit-Risk Determination

The probable benefits and risks of the FINEVISION HP Trifocal IOL are based on data collected in a clinical study conducted to support PMA approval as described above. This study has demonstrated statistically significant and clinically meaningful results in favor of the FINEVISION HP Trifocal IOL regarding preservation of BCDVA, and improvement in DCNVA and DCIVA, compared to a monofocal control.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. Medical adverse events and complications were similar

to those associated with most other intraocular lenses. There was a very low rate of SSIs (<1% [1/332]) due to optical properties. Although contrast sensitivity was lower for FINEVISION HP Trifocal IOL group, the difference was minimal and not clinically meaningful.

Additional factors to be considered in determining probable risks and benefits for the FINEVISION HP Trifocal IOL device included:

1. Patient Perspective

Patient perspectives considered during the review included:

- Most visual symptoms—such as glare, hazy or blurred vision, image distortion, double or multiple images, trouble focusing, difficulty judging distance or depth, and vision fluctuations—occurred at similar or slightly lower rates in the FINEVISION HP Trifocal IOL group compared to the control group except two visual symptoms-starbursts and haloes-which occurred more frequently in FINEVISION HP Trifocal IOL group.
- Subjects favored the trifocal IOL for near vision and slightly favored the monofocal IOL for distance vision.
- Perceived trouble with night driving was lower in the monofocal IOL group by a moderate margin
- Perceived trouble with color disturbances was comparable between the study groups.
- A larger proportion of participants reported they would have this device implanted again in the FINEVISION HP Trifocal IOL group as compared to the control group.

In conclusion, given the available information above, the data support that the probable benefits of the FINVEISION HP Trifocal IOL outweigh the probable risks for the indication of primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, 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 compared to a monofocal IOL.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

Key effectiveness endpoints related to near, intermediate, and distance visual acuity were met, demonstrating the ability of the FINEVISION HP Trifocal IOL to provide clinically meaningful improvements in intermediate visual acuity and near visual acuity, compared to a monofocal IOL. Adverse events were compared favorably to grid rates established in an FDA-recognized international standard. There were no clinically meaningful differences between the FINEVISION HP Trifocal IOL and the monofocal IOL with respect to contrast sensitivity.

XV. CDRH DECISION

CDRH issued an approval order on 9/10/2025.

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

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

International Standard Organization 10993, Biological Evaluation of Medical Devices

International Standard Organization 11979-5, Ophthalmic Implants- Intraocular Lenses- Part 5: Biocompatibility

International Standard Organization 11979-2 Ophthalmic Implants – Intraocular Lenses – part 2: Optical Properties and Test Methods

International Standard Organization 11979-3 Ophthalmic Implants – Intraocular Lenses – Part 3: Mechanical Properties and Test Methods

International Standard Organization 11979-7 -Intraocular Lenses – Part 7: Clinical Investigations

Masket S, Rorer E, Stark W, Holladay JT, MacRae S, Tarver ME, et al. Special Report: The American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with Intraocular Lenses. Ophthalmology. 2017 Jan;124(1):142-144