SUMMARY of SAFETY and EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Devices Generic Name:	Extended Depth of Focus Intraocular Lens
Devices trade name:	AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (Model DFT015) AcrySof™ IQ Vivity™ Toric Extended Vision IOLs (DFT315, DFT 415, DFT515) AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOL (DAT015) AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOLs (DAT315, DAT415, DAT515)
Device Procode:	POE
Applicant's Name and Address:	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas 76134
Date of Panel recommendation:	None

Premarket Approval Application (PMA) Number: P930014/S126

Date of FDA Notice of Approval: February 26, 2020

The AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (Model DFT015) is based on the parent device AcrySof™ Natural Single-Piece Intraocular lens (IOL) Model SB30AL approved under the 180-day Supplement P930014/S009 on June 24, 2003, with the following Indications for Use:

> AcrySof™ Natural posterior chamber intraocular lenses are indicated for the replacement of the human lens to achieve visual correction of aphakia in adults when extracapsular cataract extraction or phacoemulsification are performed. These lenses are intended for placement in the capsular bag.

The AcrySof™ IQ Vivity™ Extended Vision Ultraviolet (UV) Absorbing IOL (DAT015) is based on the parent device AcrySof™ Acrylic Single-Piece Foldable Posterior Chamber IOL Model SA30EL, approved under the 180-day Supplement P930014/S006 on September 20, 1999, with the following Indications for Use:

AcrySof™ posterior chamber intraocular lenses are indicated for the replacement of the human lens to achieve visual correction of aphakia in adult patients when extracapsular cataract extraction or phacoemulsification are performed. These lenses are intended for placement in the capsular bag.

For the toric optical design, the AcrySof™ IQ Vivity™ Toric Extended Vision IOLs (DFT315, DFT 415, DFT515) and AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOLs (DAT315, DAT415, DAT515) are based on the parent toric device AcrySof™ Toric (Models SA60T3-T5) under the Panel Track Supplement P930014/S015, approved on September 14, 2005 with the following Indications for Use:

The AcrySof™ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

The SSED to support the indication is available on the CDRH website and is incorporated by reference here.

The current Panel Track Supplement was submitted to expand the indications and include the AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (Model DFT015), AcrySof™ IQ Vivity™ Toric Extended Vision IOLs (DFT315, DFT 415, DFT515), AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOL (DAT015), and the AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOLs (DAT315, DAT415, DAT515) for an extended depth of focus indication.

II. INDICATIONS FOR USE

AcrySof™ IQ Vivity™ Extended Vision IOL
The AcrySof™ IQ Vivity™ Extended Vision IOL Model DFT015 is indicated for primary implantation for the visual correction of aphakia in adult patients with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof™ IQ Vivity™ IOL is intended for capsular bag placement only.

AcrySof™ IQ Vivity™ Toric Extended Vision IOLs
The AcrySof™ IQ Vivity™ Toric Extended Vision IOL Models DFT315, DFT415, and DFT515 are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult

patients with pre-existing corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lenses provide improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof™ IQ Vivity™ Toric IOLs are intended for capsular bag placement only.

AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOL
The AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOL Model DAT015 is indicated for primary implantation for the visual correction of aphakia in adult patients with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof™ IQ Vivity™ UV Absorbing IOL is intended for capsular bag placement only.

AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOLs
The AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOL Models DAT315, DAT415, and DAT515 are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof™ IQ Vivity™ Toric UV Absorbing IOLs are intended for capsular bag placement only.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS and PRECAUTIONS

The warnings and precautions can be found in the AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens labeling.

V. DEVICE DESCRIPTION

AcrySof™ IQ Vivity™ Extended Vision IOLs
The non-diffractive AcrySof™ IQ Vivity™ Extended Vision Posterior Chamber Intraocular Lenses (IOLs) Model DFT015 and Toric Models DFT315, DFT415, and DFT515 are UV-absorbing and blue light filtering (BLF) foldable IOLs which, compared to a monofocal IOL, provide an extended depth of focus. The

AcrySof™ IQ Vivity™ Toric Extended Vision IOL models also compensate for corneal astigmatism.

The single-piece design consists of a high refractive index hydrophobic acrylic material with proprietary blue light filtering chromophore, which filters light in a manner that approximates the human crystalline lens in the 400-475 nm blue light wavelength range (1). In addition to standard UV-light filtering, the blue-light filtering chromophore reduces transmittance of blue light wavelengths. The biconvex aspheric optic consists of a high refractive index 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 13.0mm. After surgical insertion into the eye, the lens unfolds to restore its intended shape. The supporting haptics provide proper positioning and fixation of the IOL optic within the eye.

The extended depth of focus is achieved through the patented Wavefront-Shaping technology located on the anterior surface of the IOL. The location of the Wavefront-Shaping optic is identical for all lens powers. The anterior surface of the AcrySof™ IQ Vivity™ Extended Vision IOL is also designed with negative spherical aberration to compensate for the positive spherical aberration of the cornea. The posterior surface of the Toric lens is biconic creating a toricity to correct the astigmatism on the cornea. The flat meridian of the AcrySof™ IQ Vivity™ Toric IOLs is identified with the indentations (dots; axis marks) on the posterior surface of the optic. Alignment of the toric IOL cylinder axis marks with the post-operative steep corneal meridian allows the lens to correct astigmatism. The physical characteristics of the AcrySof™ Vivity™ IOL are summarized in Figures 1, 2, and 3, as well as Table 1. The modulation transfer function (MTF) through-focus response of a Vivity IOL in a model eye using polychromatic light (white light) is depicted in Figure 4.

AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOLs

The non-diffractive AcrySof ™IQ Vivity™ Extended Vision UV Absorbing Posterior Chamber IOLs Model DAT015 and Toric Models DAT315, DAT415, and DAT515 are UV-absorbing (UVA) foldable IOLs which, compared to a monofocal IOL, provide an extended depth of focus. The AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOL models also compensate for corneal astigmatism.

The biconvex aspheric optic consists of a high refractive index 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 13.0mm. After surgical insertion into the eye, the lens unfolds to restore its intended shape. The supporting haptics provide proper positioning and fixation of the IOL optic within the eye.

The extended depth of focus is achieved through the patented Wavefront-Shaping technology located on the anterior surface of the IOL. The location of the Wavefront-Shaping optic is identical for all lens powers. The anterior surface of the AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOL is designed with negative spherical aberration to compensate for the positive spherical aberration of the cornea. The posterior surface of the Toric lens is biconic creating a toricity to correct the astigmatism on the cornea. The flat meridian of the AcrySof™ IQ Vivity™ Toric UV Absorbing IOLs is identified with the indentations (dots; axis marks) on the posterior surface of the optic. The physical characteristics of the AcrySof™ IQ Vivity™ IOL are summarized in Figures 1,2, and 3, as well as Table 1. The modulation transfer function (MTF) through-focus response of a Vivity™ IOL in a model eye using polychromatic light (white light) is depicted in Figure 4.

Figure 1: Physical Characteristics of the AcrySof™ IQ Vivity™ IOL
All dimensions in millimeters

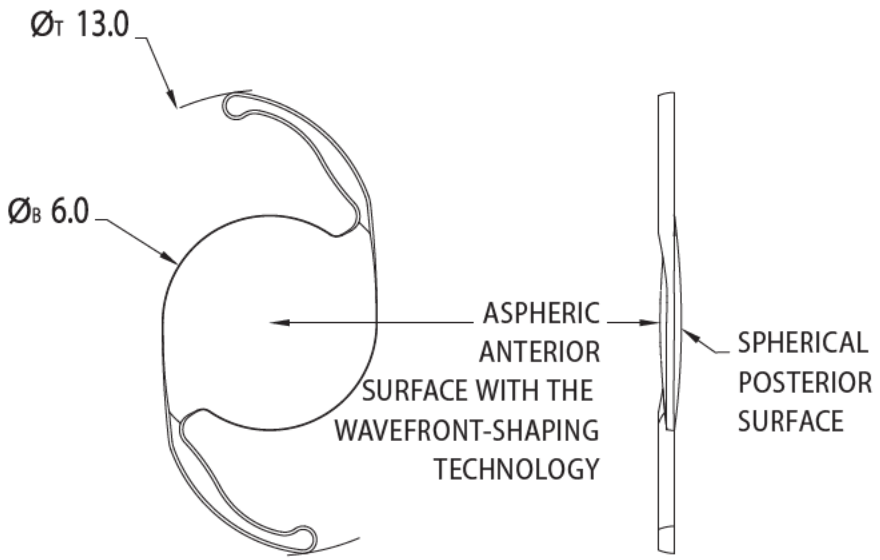


Figure 2: Physical Characteristics of the AcrySof™ IQ Vivity™ Toric IOL
All dimensions in millimeters

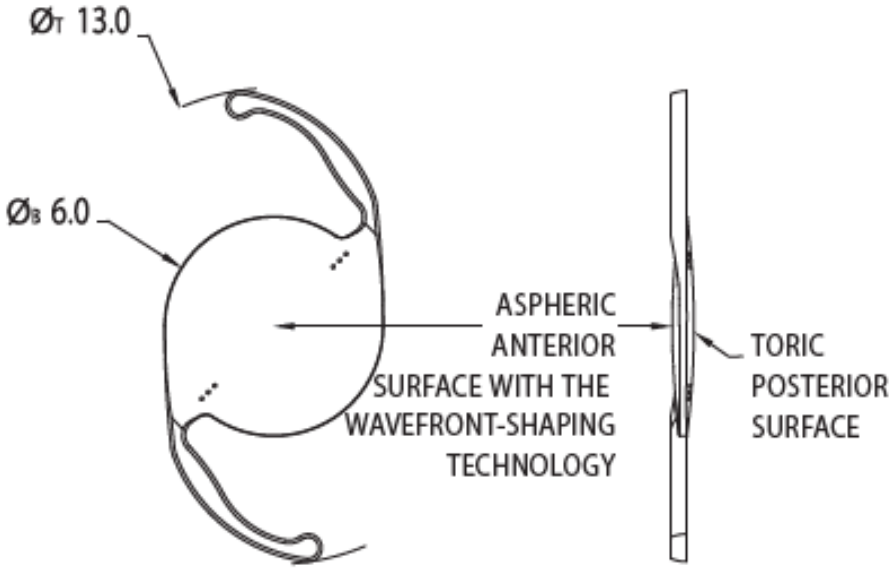


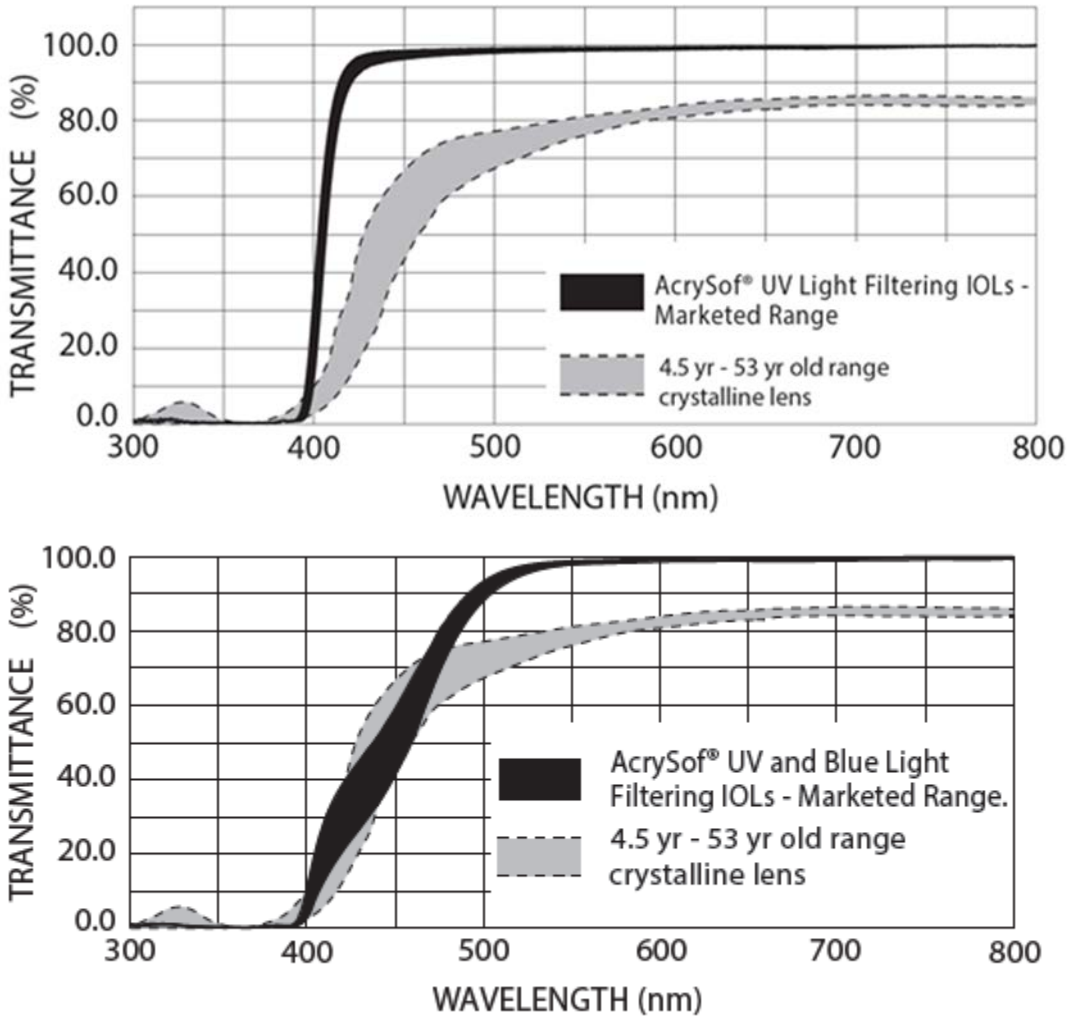
Table 1: Physical Characteristics of AcrySof™ IQ Vivity™ IOLs

Characteristic	Model			
	DFT015/ DAT015	DFT315/ DAT315	DFT415/ DAT415	DFT515/ DAT515
Optic Type	Biconvex Wavefront-Shaping Optic	Biconvex toric Wavefront-Shaping Optic		
Optic / Haptic Material	DFT Models: Ultraviolet and blue light filtering hydrophobic Acrylate/Methacrylate Copolymer UV cutoff at 10% T: 401 nm (+20.0 diopter (D) lens) DAT Models: Ultraviolet filtering hydrophobic Acrylate/Methacrylate Copolymer UV cutoff at 10% T: 396 nm (+20.0 diopter lens)			
Spherical Powers	+15.0 diopters – +25.0 diopters in 0.5 diopter increments			
IOL Cylinder Power – IOL Plane (diopters)	N/A	1.50	2.25	3.00
IOL Cylinder Power – Corneal Plane* (Diopters)	N/A	1.03	1.55	2.06
Index of Refraction	1.55			
Haptic Configuration	STABLEFORCE Modified-L Haptics			
Optic Diameter (mm) $Ø_B$	6.0			
Overall Length (mm) $Ø_T$	13.0			
Haptic Angle	0º			

*Based on the average pseudophakic human eye

Figure 3: Spectral Transmittance

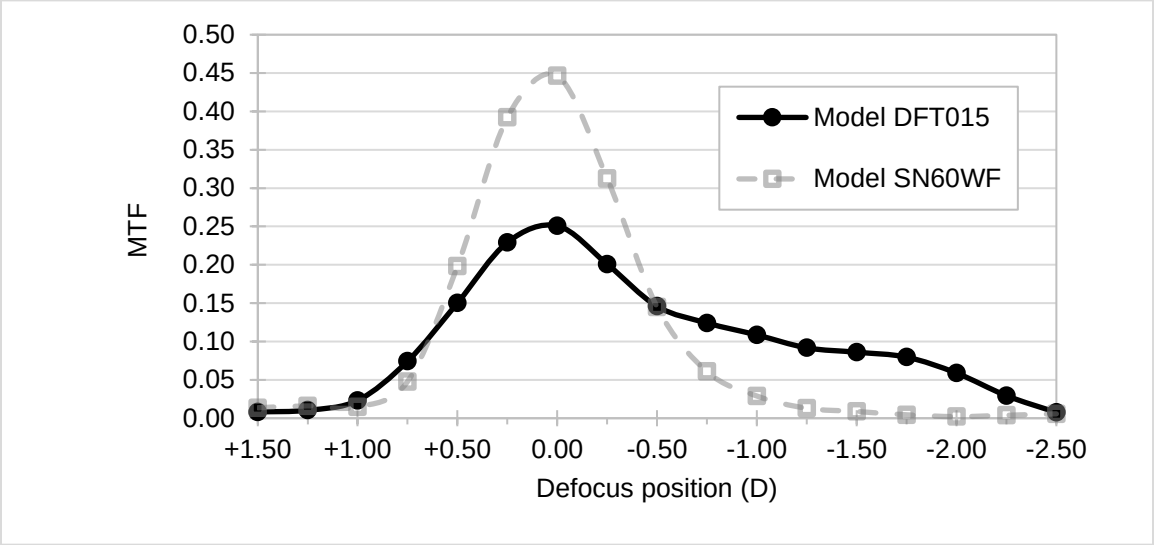
Top panel: AcrySof™ UV Absorbing (UVA); Lower panel: AcrySof™ BLF



NOTES:

1. The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values of IOLs made from hydrophobic acrylate/methacrylate copolymer with bonded UV-absorber (AcrySof™ UVA, Figure 3 upper panel) or IOLs made from hydrophobic acrylate/methacrylate copolymer with bonded UV-absorber and Alcon's proprietary blue light filtering chromophore (AcrySof™ BLF, Figure 3 lower panel).
2. Measurements were by direct transmittance using AcrySof™ IOLs with center thickness equivalent to the marketed range.
3. Human crystalline lens data is from Boettner and Wolter (1962) (1).

Figure 4: Modulation Transfer Function (MTF) Through-Focus Response of 20.0 D IOLs in a Model Eye (White Light, 50 lp/mm, 3 mm Aperture)



An Alcon web-based calculator is used in conjunction with the AcrySof™ IQ Vivity™ Toric IOLs to determine the appropriate intraocular alignment and cylinder power for the patient. During standard cataract surgery and implantation of the AcrySof™ IQ Vivity™ IOL, an Alcon qualified delivery system and viscoelastic combination should be used. Alcon recommends using the qualified MONARCH® IOL Delivery System or any other Alcon qualified combination. Currently qualified combinations that can be used with these lenses are listed in Table 2.

Table 2: Qualified Combinations of Compatible Products

Lens Model	Diopter Range	Cartridge	Handpiece	Ophthalmic Viscosurgical Device (OVD)
DAT015/DFT015	+15.0 to +25.0	MONARCH™ III D (8065977763)	MONARCH™ III (blue) (8065977773)	VISCOAT™ OVD
DAT315/DFT315				PROVISC™ OVD
DAT415/DFT415				DISCOVISC™ OVD
DAT515/DFT515				

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Patients who undergo cataract extraction presently have several non-surgical and surgical alternatives for restoring functional vision of the aphakic eye. Non-surgical options 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 AcrySof™ IQ Vivity™ IOLs are registered and commercialized in the European Union and Australia. The lenses have not been withdrawn from marketing 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:

- lens epithelial cell down-growth
- corneal endothelial damage
- infection (endophthalmitis)
- retinal detachment/tear
- vitritis
- cystoid macular edema
- corneal edema
- pupillary block
- cyclitic membrane
- iris prolapse
- hypopyon
- anterior uveitis
- hyphema
- pigment dispersion
- posterior capsule opacification
- transient or persistent glaucoma
- IOL dislocation, tilt, or decentration requiring surgical repositioning
- residual refractive error resulting in secondary surgical intervention
- increased visual symptoms (compared to a monofocal IOL) related to the optical characteristics of the IOL, including reduction in contrast sensitivity

Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration, iridectomy for pupillary block, wound leak repair, and retinal detachment repair.

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

IX. SUMMARY OF NONCLINICAL STUDIES

Biocompatibility and chemical characterization were performed on the parent lenses and is incorporated by reference. These studies were conducted in accordance with International Standard Organization (ISO) 10993-1, Biological

evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and ISO 11979-5, Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility and relevant parts of ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. Studies were conducted in accordance with Good Laboratory Practices (GLP).

Optical/Mechanical Testing

Pre-clinical optical / mechanical tests were performed with the AcrySof™ IQ Vivity™ IOLs (Toric and non-Toric) manufactured from the AcrySof™ Natural material and were measured in accordance with ISO 11979-2 Ophthalmic Implants – Intraocular Lenses – Part 2: Optical Properties and Test Methods, ISO 11979-3 Ophthalmic Implants – Intraocular Lenses – Part 3: Mechanical Properties and Test Methods, and American National Standard (ANSI) for Ophthalmics Z80.35-2018: Extended Depth of Focus Intraocular Lenses. Test results are presented in Table 3.

Table 3: Optical and Mechanical Testing

Test	**Results**
Clear Optic Diameter	Passed
Optic Diameter	Passed
Overall Diameter	Passed
Vault Height	Passed
Sagitta	Passed
Optic Edge Thickness	Passed
Recovery of Properties following Simulated Surgical Manipulation	Passed
Spherical Dioptric Power	Passed
Cylindrical Dioptric Power (Toric only)	Passed
Imaging Quality	Passed
MTF through-focus Response	Completed
MTF testing with Tilt and Decentration	Completed
Expected Visual Acuity	Completed
Depth of Focus Range	Completed

X. SUMMARY OF PIVOTAL CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of the safety and effectiveness of the AcrySof™ IQ Vivity™ Extended Vision IOLs for the proposed indications. This study was conducted in the U.S. under investigational device exemption (IDE) G170175. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

The AcrySof™ IQ Vivity™ Toric Extended Vision IOL models involved imposing the toric feature from the toric design parents onto the posterior surface of the AcrySof™ IQ Vivity™ Toric Extended Vision IOL models. Since the study for the AcrySof™ IQ Vivity™ Extended Vision IOL Model DFT015 established safety and the applicant has approved toric parent IOLs, additional clinical data was not required to support safety and effectiveness of the toric models, because the only difference is in cylinder powers.

A. Study Design

Subjects were treated between October 2017 and October 2018. The database for this Panel Track PMA Supplement reflected data collected through October 2018 and included 220 implanted subjects. There were 11 investigational sites in the U.S.

A prospective, 6-month, multicenter, randomized, subject masked, vision-assessor masked, parallel-group study was designed to evaluate bilateral implantation a total of 220 subjects (110 bilaterally implanted subjects in each arm). This study was designed to evaluate the effectiveness and safety of the AcrySof™ IQ Vivity™ IOL (Model DFT015) in providing increased depth of focus and improved intermediate and near visual acuity, compared to the aspheric monofocal IOL, the AcrySof™ Monofocal IOL Model SN60WF.

The monofocal control IOL is a legally-marketed alternative with similar indications for use, except that it is not intended to provide improved vision at intermediate and near distances.

Statistical analyses were frequentist. A total of 220 subjects were planned for bilateral implantation in a randomized 1:1 ratio, in order to ensure that at least 200 eligible subjects (100 in each arm) completed the study. This sample size assumed a dropout rate of 10%, approximately. A brief description of the statistical assumptions used to perform the sample size calculations is presented in Table 4.

Table 4: Vivity Pivotal Study Sample Size Calculations

	Margin	Expected Difference	SD	Type I error 1-sided	Power
Non-Inferiority					
BCDVA	0.10	0.04	0.16	5%	84%
Superiority					
DCNVA (40 cm)		0.12	0.18	2.5%	99%
DCIVA (66 cm)		0.12	0.18	2.5%	99%
Spectacle need		25%		2.5%	94%

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the AcrySof™ IQ Vivity™ Extended Vision IOL study was limited to subjects who met the following inclusion criteria in both eyes:

   1. Adults (22 years or older at the time of participation in the study) diagnosed with cataract in both eyes
   2. Best-corrected distance visual acuity (BCDVA) of 0.3 logMAR (20/40 Snellen) or worse either with or without a glare source present (e.g., Brightness Acuity Tester).
   3. Clear intraocular media other than cataract
   4. Planned cataract removal by routine small incision surgery
   5. Calculated lens power between 18.0 and 25.0 D [when targeted for emmetropia (0.00 D)]
   6. Willing and able to complete all required postoperative visits
   7. Able to comprehend and sign an IRB/IEC (Institutional Review Board/Independent Ethics Committee) approved statement of informed consent
   8. Potential postoperative BCDVA of 0.2 logMAR (20/32 Snellen) or better in each eye based on Investigator's medical opinion
   9. Preoperative keratometric astigmatism of less than 1.0 D in both operative eyes

   Subjects were not permitted to enroll in the AcrySof™ IQ Vivity™ Extended Vision IOL study if they, or either eye, met any of the following exclusion criteria:

   1. Any disease or pathology, other than cataract, that (in the expert opinion of the Investigator) is expected to reduce the potential postoperative BCDVA to a level worse than 0.2 logMAR (including, but not limited to the following: amblyopia, clinically severe corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy), diabetic retinopathy, extremely shallow anterior chamber, not due to swollen cataract, microphthalmos, previous retinal detachment, previous corneal transplant, recurrent severe anterior or posterior segment inflammation of unknown etiology, iris neovascularization, uncontrolled glaucoma, aniridia, or optic nerve atrophy, epiretinal membrane, macular degeneration, or diagnosis of pseudoexfoliation)
   2. History of recurrent anterior segment/posterior segment inflammation.
   3. Clinically significant (in the Investigator's opinion) corneal pathology (epithelial, stromal, endothelial) or ocular surface disease that would adversely affect the visual outcome including but not limited to old significant corneal scars (including Salzman's nodular degeneration), corneal irregularity (including dry eye syndrome), active or inactive keratitis with compromise of

the refractive capability of the cornea, keratoconjunctivitis sicca with compromise of visual function, active keratouveitis, endothelial dystrophy (Fuch's and non-guttate), keratoconus, etc.

4. Clinically significant ocular surface disease that would affect study measurements based on Investigator expert medical opinion
5. History of previous intraocular or corneal surgery
6. Pregnant/lactating or has another condition with associated fluctuation of hormones that could lead to refractive changes
7. History of amblyopia or monofixation syndrome with poor stereoscopic vision
8. Current or recent use of an alpha-1-selective adrenoceptor blocking agent or an antagonist of alpha1A adrenoceptor (e.g. Flomax (tamsulosin HCL), Hytrin, or Cardura) that in the opinion of the investigator would potentially require mechanical or surgical manipulation to enlarge the pupil
9. Concurrent participation in another clinical trial that, in the Investigator's opinion, may confound the results of the current study
10. Any other ocular condition or systemic co-morbidity that, in the opinion of the Investigator, may confound the results of this study or prohibit the completion of the study assessments or increase the risk for the subject
11. Subjects with conditions that, in the Investigator's opinion, increase the risk of zonular rupture during cataract extraction procedure (e.g., pseudoexfoliation syndrome, Marfan syndrome) that may affect the postoperative centration or tilt of the lens
12. Any other planned ocular surgical procedures including but not limited to limbal relaxing incision (LRI), astigmatic keratotomy, laser-assisted in situ keratomileusis (LASIK), and retinal laser treatment within the study time frame
13. Subjects who desire monovision correction

The following were intraoperative criteria for not implanting the device:

1. Surgical complications including but not limited to loss of zonular integrity/zonular weakness, zonular rupture, anterior capsular rupture interfering with the stability of the IOL, posterior capsule rupture, any evidence of fluid misdirection during the cataract procedure with progressive shallowing of the anterior chamber, uncontrollable intraocular pressure (IOP)
2. Mechanical or surgical manipulation of the pupil
3. Excessive iris mobility
4. Inability to place the IOL in the capsular bag due to surgical complications

2. Follow-up Schedule

All subjects were scheduled to return for follow-up examinations postoperatively at the time points described in Table 5.

Preoperatively and postoperatively, several clinical evaluations were performed, as listed in Table 6. Adverse events and complications were recorded at all visits.

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

Table 5: Pivotal Study Design

Time from Implantation	**First Eye**	**Second Eye**
-28 to 0 days pre-operatively	Visit 0 (Screening [First and Second eye])	
Within 2 business days of first eye operative visit (Visit 00)	Randomization	
Operative (IOL implantation)	Visit 00	Visit 00A*
1 - 2 days post-operatively	Visit 1 (monocular)	Visit 1A (monocular)
7 - 14 days post operatively	Visit 2 (monocular)	Visit 2A (monocular)
30 - 60 days post-operatively (after Second eye implantation)	Visit 3A (monocular [First and Second eye] and binocular)	
120 - 180 days post-operatively (after Second eye implantation)	Visit 4A (monocular [First and Second eye] and binocular)	

*NOTE: IOL implantation in the second eye was intended to occur between 7 and 14 days after IOL implantation in the first eye.

Table 6: Schedule of Visits

	Both Eyes	1st Operative Eye			2nd Operative Eye			Both Eyes		
Visit	**Visit 0** Day -28-0 Preoperative	**Visit 00** [1] Day 0 Operative	**Visit 1** Day 1-2 Post Visit 00	**Visit 2** Day 7-14 Post Visit 00	**Visit 00A**[2] 7-14 Days Post Visit 00	**Visit 1A** Day 1-2 Post Visit 00A	**Visit 2A** 7-14 Days Post Visit 00A	**Visit 3A** 30-60 Days Post Visit 00A	**Visit 4A**[3] 120-180 Days Post Visit 00A	**Early Exit**
General Assessments and Procedures										
Informed Consent	X									
Demographics	X									
Medical History	X									
Concomitant Medications	X	X	X	X	X	X	X	X	X	X
Urine Pregnancy Test[4]	X									
Inclusion/Exclusion	X	X			X					
Ophthalmic Assessments										
QUVID questionnaire (for visual disturbance)	X							X	X	X
IOLSAT questionnaire (for spectacle need)	X							X	X	X
Anterior Chamber Depth	X									
Axial Length	X									
Keratometry	X									
Predicted Target Residual Refractive Error[5]	X									
Manifest Refraction (4 m)	X			X			X	X	X	X
Distance VA at 4 m										
• Photopic Uncorrected	X		X	X		X	X	X	X[6]	X
• Photopic Corrected	X			X			X	X	X[6]	X
• Low Contrast (10%) Photopic Best Corrected									X	
• Low Contrast (25%) Photopic Best Corrected									X	
Defocus Curve (4 m)									X[6]	
Photopic Pupil Size (VA Chart)	X								X	
Intermediate VA at 66 cm										
• Photopic Uncorrected								X	X[6]	
• Photopic Distance Corrected								X	X[6]	

	Both Eyes	1st Operative Eye			2nd Operative Eye			Both Eyes		
Visit	**Visit 0** Day -28-0 Preoperative	**Visit 00** [1] Day 0 Operative	**Visit 1** Day 1-2 Post Visit 00	**Visit 2** Day 7-14 Post Visit 00	**Visit 00A**[2] 7-14 Days Post Visit 00	**Visit 1A** Day 1-2 Post Visit 00A	**Visit 2A** 7-14 Days Post Visit 00A	**Visit 3A** 30-60 Days Post Visit 00A	**Visit 4A**[3] 120-180 Days Post Visit 00A	**Early Exit**
• Low Contrast (10%) Photopic Distance Corrected									X	
• Low Contrast (25%) Photopic Distance Corrected									X	
Near VA at 40 cm										
• Photopic Uncorrected								X	X[6]	
• Photopic Distance Corrected								X	X[6]	
• Low Contrast (10%) Photopic Distance Corrected									X	
• Low Contrast (25%) Photopic Distance Corrected									X	
Mesopic Pupil Size (Contrast Chart)									X	
Contrast Sensitivity										
• Mesopic without Glare									X	
• Mesopic with Glare									X	
Slit Lamp Examination	X		X	X		X	X	X	X	X
Aqueous Signs			X	X		X	X	X	X	X
IOL Observations			X	X		X	X	X	X	X
IOL Position Change			X	X		X	X	X	X	X
Subjective PCO			X	X		X	X	X	X	X
Posterior Capsulotomy			X	X		X	X	X	X	X
Intraocular Pressure	X		X	X		X	X	X	X	X
Dilated Fundus Exam	X							X	X	X
Fundus Visualization								X	X	X
Surgical Procedure & Assessments										
Cataract Surgery		X			X					
Lens Information		X			X					
Incision Location[7]		X			X					

	Both Eyes	1st Operative Eye			2nd Operative Eye			Both Eyes		
Visit	**Visit 0** Day -28-0 Preoperative	**Visit 00** [1] Day 0 Operative	**Visit 1** Day 1-2 Post Visit 00	**Visit 2** Day 7-14 Post Visit 00	**Visit 00A**[2] 7-14 Days Post Visit 00	**Visit 1A** Day 1-2 Post Visit 00A	**Visit 2A** 7-14 Days Post Visit 00A	**Visit 3A** 30-60 Days Post Visit 00A	**Visit 4A**[3] 120-180 Days Post Visit 00A	**Early Exit**
Final Incision Size[7,8]		X			X					
Problems during Surgery		X			X					
Other Surgical Procedures		X			X					
Adverse Events & Device Deficiencies										
Adverse Events[9]	X	X	X	X	X	X	X	X	X	X
Secondary Surgical Interventions		X	X	X	X	X	X	X	X	X
Device Deficiencies		X	X	X	X	X	X	X	X	X

1. Visit 00 (1st eye surgery) must occur within 28 calendar days from Pre-Operative Visit (Visit 0).
2. Visit 00A (2nd eye surgery) must occur between 7 and 14 calendar days after Visit 00.
3. If necessary, Visit 4A may be completed over 2 days within a two-week period. Both days must fall within the specified visit window.
4. In women of child bearing potential only.
5. Data is reported in EDC at the surgical visit but may be collected at a previous visit.
6. Testing is conducted monocular (bilaterally) and binocular.
7. Capture in source (not captured in EDC).
8. Only measure in cases with surgical complications.
9. Collected from time of consent onward.

3. Clinical Endpoints
   - With regard to effectiveness, the co-primary effectiveness endpoints were:
     - AcrySof™ IQ Vivity™ IOL is superior to the control in mean monocular photopic distance-corrected intermediate visual acuity (DCIVA).
     - Monocular photopic BCDVA (logMAR). To demonstrate that the AcrySof ™IQ Vivity™ IOL is non-inferior to the control in mean monocular photopic BCDVA.
     - Monocular depth of focus (measured in the negative direction from 0) at 0.20 logMAR. To demonstrate that the monocular mean defocus curve for the AcrySof™ IQ Vivity™ IOL has a range of defocus at least 0.5 D greater negative range than the control at 0.20 logMAR.
     - Percentage of eyes achieving monocular photopic DCIVA of 0.20 logMAR or better. To demonstrate that the AcrySof™ IQ

Vivity™IOL has at least 50% of eyes achieving DCIVA of 0.20 logMAR or better.

- With regard to effectiveness, the secondary effectiveness endpoints were:
  - To demonstrate that AcrySof™ IQ Vivity™ IOL is superior to the control in mean monocular photopic distance-corrected near visual acuity (DCNVA). In addition, the following performance targets will also be assessed to demonstrate clinical significance:
    - Demonstrate at least 50% of eyes with the AcrySof™ IQ Vivity™ IOL achieve a monocular DCNVA of 0.30 logMAR or better
    - Percentage of eyes achieving monocular DCNVA of 0.30 logMAR or better in the AcrySof™ Vivity™ IOL group is at least 25 percentage points higher than the control group
  - To demonstrate that the AcrySof™ IQ Vivity™ IOL is superior to the control with respect to proportion of subjects who respond "Never" to Q1 of the IOLSAT questionnaire (Overall, in the past 7 days, how often did you need to wear eyeglasses to see?)
  - To describe mean monocular photopic uncorrected intermediate visual acuity (UCIVA) outcomes
  - To describe mean monocular photopic uncorrected distance visual acuity (UCDVA) outcomes

- With regard to safety, the co-primary safety objectives were:
  - To demonstrate that the AcrySof™ IQ Vivity™ IOL adverse event rates are not worse than the historical control SPE rates, as defined in IS EN ISO 11979-7:2014
  - To describe monocular mesopic contrast sensitivity test (with and without glare) outcomes

  The Secondary Safety Objective was to estimate rates of severe and most bothersome (separately) visual disturbances as reported by subjects using a questionnaire at Visit 4A (120-180d postoperative).

All of these clinical endpoints were evaluated at 6 months postoperatively (Visit 4A). Because AcrySof™ IQ Vivity™ IOLs are modifications to other existing IOLs, conclusions regarding device safety and effectiveness are also substantiated by the results of the studies of the parent IOLs.

B. Accountability of PMA Cohort

At the time of database lock, of 242 subjects enrolled in the PMA study, 220 subjects were implanted with a study lens in at least one eye and attended at least one follow-up visit. The remaining subjects either failed screening (n=21) or were discontinued prior to implantation (n=1 due to a worsening of

a pre-existing condition). Of the 220 subjects, 107 subjects received the AcrySof™ IQ Vivity™ IOL and 113 received the aspheric Monofocal Control IOL. One of the subjects in the AcrySof™ IQ Vivity™ IOL group was not bilaterally implanted and did not contribute to binocular assessments. Two subjects in the monofocal control group discontinued the study prior to 6 months. Subject accountability information is presented in Table 7 for the AcrySof™ IQ Vivity™ IOL first eyes and Table 8 for the Monofocal Control IOL first eyes. Subject compliance with the follow-up schedule was excellent at 6 months for an overall percent accountability of first implanted eyes of 100% (n= 107) and 99.1% (n=106) for the AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL eyes respectively.

Table 7: AcrySof™ IQ Vivity First Eyes Accountability

Subject Status	**N**	**1 Day n (%)**	**1 Week n (%)**	**1 Month n (%)**	**6 Months n (%)**
	107				
Available for Analysis		107 (100.0)	107 (100.0)	107 (100.0)	107 (100.0)
Missing Subjects					
Discontinued		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missed Visit		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lost to follow-up		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Active		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Percent Accountability		(100.0)	(100.0)	(100.0)	(100.0)

Table 8: Monofocal Control IOL First Eyes Accountability

Subject Status	**N**	**1 Day n (%)**	**1 Week n (%)**	**1 Month n (%)**	**6 Months n (%)**
	113				
Available for Analysis		113 (100.0)	113 (100.0)	113 (100.0)	111 (98.2)
Missing Subjects					
Discontinued		0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)
Missed Visit		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lost to follow-up		0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)
Active		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Percent Accountability		(100.0)	(100.0)	(100.0)	(99.1)

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 subject demographics and first eye baseline characteristics were similar between the AcrySof™ IQ Vivity™ and Monofocal IOL groups.

Approximately two-thirds of the subjects in each group were ≥ 65 years of age, and a higher rate of female participation was observed in both groups. Tables 9 and 10 present the study population demographics and baseline parameters.

Table 9: Demographic Statistics (All-Implanted Set)

Parameter	AcrySof™ IQ Vivity IOL (N = 107)	Monofocal Control IOL (N = 113)	Overall (N = 220)
Age (Years), n (%)			
<65	25 (23.4)	30 (26.5)	55 (25.0)
≥65	82 (76.6)	83 (73.5)	165 (75.0)
Mean (SD)	68.8 (7.82)	68.8 (6.63)	68.8 (7.22)
Median	69.0	69.0	69.0
(Min, Max)	(29, 83)	(50, 82)	(29, 83)
Sex, n (%)			
Female	59 (55.1)	64 (56.6)	123 (55.9)
Male	48 (44.9)	49 (43.4)	97 (44.1)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
Undifferentiated	0 (0.0)	0 (0.0)	0 (0.0)
Race, n (%)			
White	105 (98.1)	110 (97.3)	215 (97.7)
Black or African American	1 (0.9)	1 (0.9)	2 (0.9)
American Indian or Alaska Native	0 (0.0)	1 (0.9)	1 (0.5)
Asian	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Other Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Multi-Racial	0 (0.0)	0 (0.0)	0 (0.0)
Other	1 (0.9)	1 (0.9)	2 (0.9)
Ethnicity, n (%)			
Hispanic or Latino	2 (1.9)	2 (1.8)	4 (1.8)
Not Hispanic or Latino	104 (97.2)	111 (98.2)	215 (97.7)
Not Reported	0 (0.0)	0 (0.0)	0 (0.0)
Unknown	1 (0.9)	0 (0.0)	1 (0.5)

Table 10: Baseline Characteristics, First Eye (All-Implanted Analysis Set)

	AcrySof™ IQ Vivity IOL (N = 107)	**Monofocal Control IOL (N = 113)**	**Overall (N = 220)**
Best Corrected Distance VA (logMAR)			
n	107	113	220
Mean (SD)	0.230 (0.1877)	0.243 (0.2216)	0.237 (0.2054)
Median	0.20	0.20	0.20
(Min, Max)	(-0.08, 1.10)	(-0.18, 1.10)	(-0.18, 1.10)
Axial Length (mm)			
n	107	113	220
Mean (SD)	23.643 (0.7663)	23.733 (0.7242)	23.689 (0.7446)
Median	23.58	23.72	23.69
(Min, Max)	(21.86, 25.67)	(21.89, 25.78)	(21.86, 25.78)
Axial Length Category, n (%)			
Total	107	113	220
Short (<21 mm)	0 (0.0)	0 (0.0)	0 (0.0)
Medium (21-26 mm)	107 (100.0)	113 (100.0)	220 (100.0)
Long (>26 mm)	0 (0.0)	0 (0.0)	0 (0.0)
Anterior Chamber Depth (mm)			
n	107	113	220
Mean (SD)	3.246 (0.3174)	3.205 (0.3117)	3.225 (0.3144)
Median	3.22	3.17	3.21
(Min, Max)	(2.58, 4.21)	(2.54, 3.97)	(2.54, 4.21)
Corneal Astigmatism = abs (K1-K2)			
n	107	113	220
Mean (SD)	0.516 (0.2450)	0.507 (0.2690)	0.511 (0.2571)
Median	0.50	0.47	0.50
(Min, Max)	(0.00, 0.98)	(0.00, 1.26)	(0.00, 1.26)

A summary of photopic pupil size for Vivity and Monofocal Control first implanted eyes at baseline is presented in Table 11.

Table 11: Baseline Photopic Pupil Size of Vivity and Monofocal Control IOL First Eyes

	Vivity™ IOL First Eyes N = 107	**Monofocal Control IOL First Eyes** N = 113
n	107	113
Mean (SD)	4.03 (0.859)	4.08 (0.981)
Median	4.0	4.0
(Min, Max)	(2.4, 6.5)	(2.0, 7.8)

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the safety cohort of 220 implanted subjects (219 bilaterally implanted): 107 AcrySof™ IQ Vivity™ subjects (106 bilaterally implanted) and 113 control subjects (113 bilaterally implanted).

The key safety outcomes for this study are presented below in Tables 12 to 20. Adverse effects are reported in Tables 12 to 18.

The first co-primary safety objective was to demonstrate that the AcrySof™IQ Vivity™ IOL adverse event rates are not worse than the historical control SPE rates, as defined in ISO 11979-7:2014.

Adverse effects that occurred in the PMA clinical study:

The incidences of cumulative and persistent adverse events (AEs) including 1-sided 95% lower confidence limits (CL) for the AcrySof™ IQ Vivity™ IOL and the Monofocal Control IOL as compared to the ISO 11979-7:2014 historical grid rates are provided in Table 12 (first implanted eyes in each IOL group), Table 13 (second implanted eyes in each IOL group), and Table 14 (all implanted eyes in each IOL group). If the same event occurred multiple times in an eye, only the first occurrence is counted in the tables below. The safety and performance endpoint (SPE) rate is considered not exceeded if the 1-sided 95% lower CL for an AE is less than the SPE%. No cumulative adverse events exceeded the established rates according to ISO 11979-7:2014.

No persistent adverse events (adverse events in the ISO grid that are observed at the 6-month postoperative visit) were observed for 107 subjects implanted with AcrySof™ IQ Vivity™ IOL.

Secondary Surgical Interventions (SSIs) occurred in 2 second eyes implanted with the AcrySof™ IQ Vivity™ IOL that each had 1 SSI; both cases were assessed as not related to the IOL (n = 1 cortical remnant removal and n = 1 surgical removal of retained nuclear fragment).

No AEs specifically related to AcrySof™ IQ Vivity™ IOL design features were observed.

In first and second eyes with the AcrySof™ IQ Vivity™ IOL, ocular AEs occurring at a rate of ≥ 2% were posterior capsule opacification (PCO) (4.7% (n=5) and 5.7% (n=6), respectively), punctate keratitis (3.7% (n=4) and 2.8% (n=3), respectively), vitreous detachment (3.7% (n=4) and 3.8% (n=4), respectively), blepharitis (2.8% (n=3), second eye only), and eye pain (2.8% (n=3), second eye only) (Tables 15 and 16). For comparison, in first and second eyes with the Monofocal Control IOL, ocular AEs occurring at a rate of ≥ 2% were PCO (8.0% (n=9) and 7.1% (n=8), respectively), punctate keratitis (2.7% (n=3) and 3.5% (n=4),

respectively), vitreous detachment (2.7% (n=3) and 2.7% (n=3), respectively), and IOP increased (3.5% (n=4), first eye only).

Table 12: Cumulative and Persistent Serious Adverse Events in First Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)

	AcrySof™ IQ Vivity™ IOL First Implanted Eyes N = 107		**Monofocal Control IOL First Implanted Eyes N = 113**		
Cumulative Serious Adverse Events	**n (%)**	**1-sided 95% Lower CL**	**n (%)**	**1-sided 95% Lower CL**	**SPE %**
Cystoid macular oedema	1 (0.9)	0.05	1 (0.9)	0.05	3.0
Hypopyon	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Endophthalmitis	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Lens dislocated from posterior chamber	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Pupillary block	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Retinal detachment	0 (0.0)	0.00	1 (0.9)	0.05	0.3
Secondary surgical intervention	0 (0.0)	0.00	2 (1.8)*	0.32	0.8
Other					
Hyphaema	1 (0.9)	0.05	0 (0.0)	0.00	N/A
Transient ischaemic attack	1 (0.9)	0.05	0 (0.0)	0.00	N/A
Photopsia	0 (0.0)	0.00	1 (0.9)	0.05	N/A
Persistent Serious Adverse Events					
Corneal stroma oedema	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Cystoid macular oedema	0 (0.0)	0.00	0 (0.0)	0.00	0.5
Iritis	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Raised IOP requiring treatment	0 (0.0)	0.00	0 (0.0)	0.00	0.4

Percentages are calculated as (n/N)(100)

*One SSI was a pars plana vitrectomy and one SSI was an IOL explant

Table 13: Cumulative and Persistent Serious Adverse Events in Second Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)

	AcrySof™ IQ Vivity™ IOL Second Implanted Eyes N = 106		**Monofocal Control IOL Second Implanted Eyes N = 113**		
Cumulative Serious Adverse Events	**n (%)**	**1-sided 95% Lower CL**	**n (%)**	**1-sided 95% Lower CL**	**SPE %**
Cystoid macular oedema	0 (0.0)	0.00	1 (0.9)	0.05	3.0
Hypopyon	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Endophthalmitis	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Lens dislocated from posterior chamber	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Pupillary block	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Retinal detachment	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Secondary surgical intervention	2 (1.9)*	0.34	0 (0.0)	0.00	0.8
Other					
Cataract operation complication**	2 (1.9)	0.34	0 (0.0)	0.00	N/A
Persistent Serious Adverse Events					
Corneal stroma oedema	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Cystoid macular oedema	0 (0.0)	0.00	0 (0.0)	0.00	0.5
Iritis	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Raised IOP requiring treatment	0 (0.0)	0.00	0 (0.0)	0.00	0.4

Percentages are calculated as (n/N)(100)

*****Both SSIs were unrelated to the IOL and were performed to remove retained cataract material from the eye.

**Both events were due to retained cataract material in the eye

Table 14: Cumulative and Persistent Serious Adverse Events in All Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)

	AcrySof™ IQ Vivity™ IOL All Implanted Eyes N = 213		**Monofocal Control IOL All Implanted Eyes N = 226**		
Cumulative Serious Adverse Events	**n (%)**	**1-sided 95% Lower CL**	**n (%)**	**1-sided 95% Lower CL**	**SPE %**
Cystoid macular oedema	1 (0.5)	0.02	2 (0.9)	0.16	3.0
Hypopyon	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Endophthalmitis	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Lens dislocated from posterior chamber	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Pupillary block	0 (0.0)	0.00	0 (0.0)	0.00	0.1
Retinal detachment	0 (0.0)	0.00	1 (0.4)	0.02	0.3
Secondary surgical intervention	2 (0.9)*	0.17	2 (0.9)***	0.16	0.8
Other					
Cataract operation complication**	2 (0.9)	0.17	0 (0.0)	0.00	N/A
Hyphaema	1 (0.5)	0.02	0 (0.0)	0.00	N/A
Transient ischaemic attack	1 (0.5)	0.02	0 (0.0)	0.00	N/A
Photopsia	0 (0.0)	0.00	1 (0.4)	0.02	N/A
Persistent Serious Adverse Events					
Corneal stroma oedema	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Cystoid macular oedema	0 (0.0)	0.00	0 (0.0)	0.00	0.5
Iritis	0 (0.0)	0.00	0 (0.0)	0.00	0.3
Raised IOP requiring treatment	0 (0.0)	0.00	0 (0.0)	0.00	0.4

Percentages are calculated as (n/N)(100)

*****Both SSIs in the Vivity IOL group were unrelated to the IOL and were performed to remove retained cataract material from the eye

**Both events were due to retained cataract material in the eye

*******One SSI with the Monofocal Control IOL was a pars plana vitrectomy and the other was an IOL explant

Table 15: Ocular Adverse Events (Serious and Non-Serious Combined), First Eye (Safety Analysis Set)

	AcrySof™ IQ Vivity™ IOL N = 107			Monofocal Control IOL N = 113		
Preferred Term	**n (%)**	**2-sided 95% CI**	**E**	**n (%)**	**2-sided 95% CI**	**E**
Posterior capsule opacification	5 (4.7)	(1.53, 10.57)	5	9 (8.0)	(3.71, 14.58)	9
Punctate keratitis	4 (3.7)	(1.03, 9.30)	4	3 (2.7)	(0.55, 7.56)	3
Vitreous detachment	4 (3.7)	(1.03, 9.30)	4	3 (2.7)	(0.55, 7.56)	3
Intraocular pressure increased	2 (1.9)	(0.23, 6.59)	2	4 (3.5)	(0.97, 8.82)	4
Blepharitis	2 (1.9)	(0.23, 6.59)	2	2 (1.8)	(0.22, 6.25)	2
Iritis	1 (0.9)	(0.02, 5.10)	1	2 (1.8)	(0.22, 6.25)	2
Cystoid macular oedema	1 (0.9)	(0.02, 5.10)	1	1 (0.9)	(0.02, 4.83)	1
Dry eye	1 (0.9)	(0.02, 5.10)	1	1 (0.9)	(0.02, 4.83)	1
Macular fibrosis	2 (1.9)	(0.23, 6.59)	2	0 (0.0)	(0.00, 3.21)	0
Photopsia	0 (0.0)	(0.00, 3.39)	0	2 (1.8)	(0.22, 6.25)	2
Cataract operation complication	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Chalazion	1 (0.9)	(0.02, 5.10)	1	0 (0.0)	(0.00, 3.21)	0
Corneal erosion	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Eye pain	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Eyelid pain	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Hyphaema	1 (0.9)	(0.02, 5.10)	1	0 (0.0)	(0.00, 3.21)	0
Lacrimation increased	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Lens disorder	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Lens extraction	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Migraine with aura	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Photophobia	1 (0.9)	(0.02, 5.10)	1	0 (0.0)	(0.00, 3.21)	0
Retinal detachment	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Retinal exudates	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Retinal haemorrhage	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Retinal telangiectasia	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Retinopathy	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1

Preferred Term	AcrySof™ IQ Vivity™ IOL N = 107			Monofocal Control IOL N = 113		
	n (%)	2-sided 95% CI	E	n (%)	2-sided 95% CI	E
Sweat gland tumour	1 (0.9)	(0.02, 5.10)	1	0 (0.0)	(0.00, 3.21)	0
Transient ischaemic attack	1 (0.9)	(0.02, 5.10)	1	0 (0.0)	(0.00, 3.21)	0
Vision blurred	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Vitrectomy	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Vitreous degeneration	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1

If an eye has multiple occurrences of an AE, the eye is presented only once in the respective eye count column (n) for the corresponding AE. Events are counted each time in the event (E) column.
N= Number of eyes in each treatment group; n= Number of eyes with event; E= Number of events; CI= Confidence Interval
Percentages are calculated as (n/N)(100).

Table 16: Ocular Adverse Events (Serious and Non-Serious Combined), Second Eye (Safety Analysis Set)

Preferred Term	AcrySof™ IQ Vivity™ IOL (N = 106)			Monofocal Control IOL (N = 113)		
	n (%)	2-sided 95% CI	E	n (%)	2-sided 95% CI	E
Posterior capsule opacification	6 (5.7)	(2.11, 11.91)	6	8 (7.1)	(3.11, 13.47)	8
Punctate keratitis	3 (2.8)	(0.59, 8.05)	3	4 (3.5)	(0.97, 8.82)	4
Vitreous detachment	4 (3.8)	(1.04, 9.38)	4	3 (2.7)	(0.55, 7.56)	3
Blepharitis	3 (2.8)	(0.59, 8.05)	3	2 (1.8)	(0.22, 6.25)	2
Intraocular pressure increased	2 (1.9)	(0.23, 6.65)	2	2 (1.8)	(0.22, 6.25)	2
Iritis	2 (1.9)	(0.23, 6.65)	3	2 (1.8)	(0.22, 6.25)	2
Eye pain	3 (2.8)	(0.59, 8.05)	3	0 (0.0)	(0.00, 3.21)	0
Macular fibrosis	2 (1.9)	(0.23, 6.65)	2	2 (1.8)	(0.22, 6.25)	2
Cataract operation complication	2 (1.9)	(0.23, 6.65)	2	0 (0.0)	(0.00, 3.21)	0
Dry eye	1 (0.9)	(0.02, 5.14)	1	1 (0.9)	(0.02, 4.83)	1
Photophobia	1 (0.9)	(0.02, 5.14)	1	1 (0.9)	(0.02, 4.83)	1
Retinal haemorrhage	1 (0.9)	(0.02, 5.14)	1	1 (0.9)	(0.02, 4.83)	1
Surgical procedure repeated	2 (1.9)	(0.23, 6.65)	2	0 (0.0)	(0.00, 3.21)	0
Chemical burn	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1

Preferred Term	AcrySof™ IQ Vivity™ IOL (N = 106)			Monofocal Control IOL (N = 113)		
	n (%)	2-sided 95% CI	E	n (%)	2-sided 95% CI	E
Conjunctival deposit	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Conjunctival laceration	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Corneal dystrophy	1 (0.9)	(0.02, 5.14)	1	0 (0.0)	(0.00, 3.21)	0
Cystoid macular oedema	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Eye inflammation	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Lens disorder	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Meibomian gland dysfunction	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Migraine with aura	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Ophthalmic herpes simplex	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Pinguecula	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Retinal telangiectasia	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Retinopathy	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Seidel test positive	1 (0.9)	(0.02, 5.14)	1	0 (0.0)	(0.00, 3.21)	0
Vision blurred	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Visual acuity reduced	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Vitreous floaters	0 (0.0)	(0.00, 3.42)	0	1 (0.9)	(0.02, 4.83)	1
Vitreous haemorrhage	1 (0.9)	(0.02, 5.14)	1	0 (0.0)	(0.00, 3.21)	0

If an eye has multiple occurrences of an AE, the eye is presented only once in the respective eye count column (n) for the corresponding AE. Events are counted each time in the event (E) column.
N= Number of eyes in each treatment group; n= Number of eyes with event; E= Number of events; CI= Confidence Interval
Percentages are calculated as (n/N)(100).

The results of adverse events analyses based on the consensus definitions as set forth by the American Academy of Ophthalmology's Task Force (Masket et al. Ophthalmology 2017) are shown in Tables 17 and 18 for first and second implanted eyes, respectively.

Table 17: Supportive Characterization of Ocular Adverse Events in First Eyes based on a Modified Version of AAO Consensus (Masket et al., 2017) for AcrySof™ IQ Vivity™ and Monofocal IOL Groups (Safety Analysis Set)

	AcrySof™ IQ Vivity™ IOL First Eyes N = 107			Monofocal IOL First Eyes N = 113		
Adverse Event	**n (%)**	**2-sided 95% CI**	**E**	**n (%)**	**2-sided 95% CI**	**E**
Chronic anterior uveitis	0 (0.0)	(0.00, 3.39)	0	0 (0.0)	(0.00, 3.21)	0
Clinically significant cystoid	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Visually significant corneal	0 (0.0)	(0.00, 3.39)	0	0 (0.0)	(0.00, 3.21)	0
Endophthalmitis	0 (0.0)	(0.00, 3.39)	0	0 (0.0)	(0.00, 3.21)	0
Mechanical pupillary block	0 (0.0)	(0.00, 3.39)	0	0 (0.0)	(0.00, 3.21)	0
Increased IOP	2 (1.9)	(0.23, 6.59)	2	3 (2.7)	(0.55, 7.56)	3
Rhegmatogenous RD	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Toxic anterior segment	0 (0.0)	(0.00, 3.39)	0	0 (0.0)	(0.00, 3.21)	0
Secondary IOL intervention –	0 (0.0)	(0.00, 3.39)	0	0 (0.0)	(0.00, 3.21)	0
Secondary IOL intervention –	0 (0.0)	(0.00, 3.39)	0	1 (0.9)	(0.02, 4.83)	1
Secondary IOL intervention –	0 (0.0)	(0.00, 3.39)	0	0 (0.0)	(0.00, 3.21)	0

Percentages are calculated as (n/N)*100; CI – confidence interval; E - Events

Table 18: Supportive Characterization of Ocular Adverse Events in Second Eyes based on a Modified Version of AAO Consensus (Masket et al., 2017) for AcrySof™ IQ Vivity™ and Monofocal IOL Groups (Safety Analysis Set)

	AcrySof™ IQ Vivity™ IOL Second Eyes N = 106			Monofocal IOL Second Eyes N = 113		
Adverse Event	**n (%)**	**2-sided 95% CI**	**E**	**n (%)**	**2-sided 95% CI**	**E**
Chronic anterior uveitis	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Clinically significant cystoid	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Visually significant corneal edema	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Endophthalmitis	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Mechanical pupillary block	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Increased IOP	2 (1.9)	(0.23, 6.65)	2	2	(0.22, 6.25)	2
Rhegmatogenous RD	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Toxic anterior segment syndrome	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Secondary IOL intervention –	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Secondary IOL intervention –	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0
Secondary IOL intervention –	0 (0.0)	(0.00, 3.42)	0	0	(0.00, 3.21)	0

Percentages are calculated as (n/N)*100; CI – confidence interval; E - Events

Device-Related Adverse Events

Two eyes (both from 1 subject) out of 213 eyes implanted with the Vivity™ IOL experienced non-serious AEs of photophobia. One eye out of 226 eyes implanted with the Monofocal IOL experienced a serious AE of photopsia which subsequently led to surgical explantation of the IOL.

Intraoperative Problems

One intraoperative problem was reported during the study: an event of iris damage during second eye implantation with the Vivity™ IOL. The IOL was successfully implanted and the subject completed the study. An iris transillumination defect was noted during the slit-lamp exam for this eye at the 1 Day, 1 Month, and 6 Month visits. However, no other adverse sequelae associated with the iris damage during surgery were reported during the study.

Contrast Sensitivity

Monocular mesopic contrast sensitivity (with and without glare) was assessed at 6 months for the AcrySof™ IQ Vivity™ IOL and the Monofocal Control IOL. Data were obtained from 107 and 111 subjects in the Vivity™ and Monofocal Control IOL groups, respectively, in each arm using a backlit sine wave grating chart system (CSV1000-HGT, VectorVision, Greenville, OH).

A summary of median contrast sensitivity data is depicted in Table 19. The AcrySof™ IQ Vivity™ IOL was associated with a reduction in monocular mesopic contrast sensitivity with and without glare compared to the Monofocal Control IOL, as evidenced by reductions in the median log contrast with increasing spatial frequency test condition (Table 19). Additionally, more subjects were unable to see the reference pattern at higher spatial frequencies with the AcrySof™ IQ Vivity™ IOL as compared to the Monofocal Control IOL (17.8% (n=19) vs. 3.6% (n=4) without glare and 18.7% (n=20) vs. 4.5% (n=5) with glare at 6 cpd; and 43.0% (n=46) vs. 20.7% (n-23) without glare and 52.3% (n=56) vs. 25.2% (n28) with glare at 12 cpd). This safety concern was mitigated by professional and patient warnings regarding the reduction in contrast sensitivity.

Table 19. Monocular Mesopic Contrast Sensitivity at 6 Months

			Mesopic Without Glare			Mesopic With Glare		
				Eyes that did not see the reference pattern[a]			Eyes that did not see the reference pattern[a]	
Spatial Frequency	IOL Group	N	Median (log units)	n	%	Median (log units)	n	%
1.5 Cycles Per Degree (CPD)	Vivity	107	1.52	0	0.0	1.52	0	0.0
	Monofocal	111	1.52	0	0.0	1.37	1	0.9
3 Cycles Per Degree (CPD)	Vivity	107	1.34	0	0.0	1.34	1	0.9
	Monofocal	111	1.49	1	0.9	1.49	1	0.9
6 Cycles Per Degree (CPD)	Vivity	107	1.38	19	17.8	1.38	20	18.7
	Monofocal	111	1.55	4	3.6	1.55	5	4.5
12 Cycles Per Degree (CPD)	Vivity	107	0.61	46	43.0	≤0.61	56	52.3
	Monofocal	111	0.91	23	20.7	0.91	28	25.2

[a]Number of eyes unable to see a target spatial frequency at any available contrast

Low Contrast Visual Acuity

Monocular (first implanted eye) low contrast visual acuity assessments were performed using 10% and 25% low contrast visual acuity computerized logMAR charts. Best corrected visual acuity at distance (4 m) and distance corrected visual acuity at Intermediate (66 cm) and Near (40 cm) were tested under photopic conditions, with results depicted in Table 20. Differences in mean best corrected distance visual acuity between the 2 groups for both contrast levels were approximately 1 line or less. Greater than 1 line improvements in intermediate visual acuity (improvement of 0.132 logMAR and 0.141 logMAR at 10% and 25% contrast respectively) and near visual acuity (improvement of 0.118 logMAR and 0.137 logMAR) were observed for the Vivity™ IOL over the Monofocal Control IOL, at both contrast levels.

Table 20: Summary of Monocular, Photopic, Low Contrast Distance, Intermediate, and Near VAs by Test Condition and IOL Group

Test Condition	IOL Group	Monocular, Photopic, Low Contrast VA (Mean logMAR, Approximate Snellen Line Equivalent)		
		Distance	Intermediate (66 cm)	Near (40 cm)
10% Contrast	Vivity IOL	0.393, 20/50	0.534, 20/63	0.764, 20/125
	Monofocal Control IOL	0.281, 20/40	0.666, 20/100	0.882, 20/160
25% Contrast	Vivity IOL	0.223, 20/32	0.372, 20/50	0.593, 20/80
	Monofocal Control IOL	0.137, 20/25	0.513, 20/63	0.730, 20/100

Visual Disturbances

A Patient Reported Outcome Measure instrument was developed and validated for use in this clinical study to assess visual disturbances. Subjects who reported experiencing a particular visual disturbance (glare, halos, starbursts, hazy vision, blurred vision, double vision in one or both eyes, color distortion, or peripheral dark area) were asked to rate the severity ("none", "a little", "mild", "moderate", "severe"), frequency ("never", "rarely", "sometimes", "most of the time", "always"), and bothersomeness ("not at all", "a little bit", "somewhat", "quite a bit", "very much") of the disturbance. A subject may report multiple symptoms. As demonstrated in Tables 21 and 22, rates of reports of severe or very bothersome visual disturbances/distortions were low (< 4%) for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL (< 3%) groups at 6 months.

Table 21: Comparison of Visual Disturbance Bothersomeness for AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL 6 months Postoperative (following second eye implantation)

	AcrySof IQ Vivity IOL N = 106						**Monofocal Control IOL N = 113**					
Visual Disturbance	**Total (N)**	**Not at all bothered[A] n (%)**	**A Little bit %**	**Some what %**	**Quite a bit %**	**Very much %**	**Total (N)**	**Not at all bothered[A] %**	**A Little bit %**	**Some what %**	**Quite a bit %**	**Very much %**
Starbursts	106	78 (73.6)	15 (14.2)	10 (9.4)	1 (0.9)	2 (1.9)	110	79 (71.8)	16 (14.5)	12 (10.9)	2 (1.8)	1 (0.9)
Halos	106	88 (83.0)	13 (12.3)	3 (2.8)	1 (0.9)	1 (0.9)	110	98 (89.1)	6 (5.5)	5 (4.5)	1 (0.9)	0 (0.0)
Glare	105	82 (78.1)	12 (11.4)	7 (6.7)	4 (3.8)	0 (0.0)	111	75.7 (84)	11 (9.9)	13 (11.7)	3 (2.7)	0 (0.0)
Hazy Vision	105	94 (89.5)	5 (4.8)	3 (2.9)	3 (2.9)	0 (0.0)	111	98 (88.3)	4 (3.6)	7 (6.3)	2 (1.8)	0 (0.0)
Blurred Vision	106	97 (91.5)	0 (0.0)	5 (4.7)	3 (2.8)	1 (0.9)	111	89 (80.2)	10 (9.0)	8 (7.2)	2 (1.8)	2 (1.8)
Double Vision	106	104 (98.1)	1 (0.9)	1 (0.9)	0 (0.0)	0 (0.0)	111	110 (99.1)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)
Dark Area *Negative Dysphotopsia*	106	98 (92.5)	6 (5.7)	0 (0.0)	1 (0.9)	1 (0.9)	111	100 (90.1)	6 (5.4)	3 (2.7)	1 (0.9)	1 (0.9)

[A] Includes subjects who did not experience the disturbance and those reporting being not at all bothered

Table 22: Comparison of Visual Disturbance Severity for AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL 6 months Postoperative (following second eye implantation)

	AcrySof™ IQ Vivity™ IOL N = 106						Monofocal Control IOL N = 113					
Visual Disturbance	**Total (N)**	**None[a] n (%)**	**A Little n (%)**	**Mild n (%)**	**Moderate n (%)**	**Severe n (%)**	**Total (N)**	**None[a] n (%)**	**A Little n (%)**	**Mild n (%)**	**Moderate n (%)**	**Severe n (%)**
Starbursts	106	70 (66.0)	3 (2.8)	15 (14.2)	14 (13.2)	4 (3.8)	110	68 (61.8)	8 (7.3)	18 (16.4)	13 (11.8)	3 (2.7)
Halos	106	78 (73.6)	6 (5.7)	12 (11.3)	9 (8.5)	1 (0.9)	110	91 (82.7)	5 (4.5)	9 (8.2)	4 (3.6)	1 (0.9)
Glare	105	81 (77.1)	0 (0.0)	15 (14.3)	9 (8.6)	0 (0.0)	111	81 (73.0)	8 (7.2)	11 (9.9)	11 (9.9)	0 (0.0)
Hazy Vision	105	93 (88.6)	2 (1.9)	5 (4.8)	5 (4.8)	0 (0.0)	111	96 (86.5)	3 (2.7)	3 (2.7)	9 (8.1)	0 (0.0)
Blurred Vision	106	96 (90.6)	1 (0.9)	8 (7.5)	1 (0.9)	0 (0.0)	111	89 (80.2)	9 (8.1)	10 (9.0)	3 (2.7)	0 (0.0)
Double Vision	106	104 (98.1)	1 (0.9)	1 (0.9)	0 (0.0)	0 (0.0)	111	110 (99.1)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)
Dark Area *Negative Dysphotopsia*	106	96 (90.6)	5 (4.7)	2.8	1 (0.9)	1 (0.9)	111	96 (86.5)	6 (5.4)	7 (6.3)	1 (0.9)	1 (0.9)

[a] Includes subjects who did not experience the disturbance and those reporting severity of "none"

2. Effectiveness Results

The analysis of effectiveness was based on the 107 evaluable Vivity IOL subjects and 111 evaluable control IOL subjects at the 6-month time point. Key effectiveness outcomes are presented in Tables 24 and Figures 5 and 6.

IOL Power Calculation and Postoperative Manifest Refraction

In this study, surgeons were instructed to select the lens power that targeted emmetropia (closest to 0.0D) for both the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL prior to randomization. Table 23 summarizes the absolute manifest refraction spherical equivalent (MRSE)

data for AcrySof™ IQ Vivity™ IOL and monofocal control IOL subjects at 6 Months.

Table 23: Mean Absolute MRSE at 6 Months by Treatment Group

MRSE Category	AcrySof™ IQ Vivity™ IOL		Monofocal Control IOL	
	First Eyes N = 107 n (%)	Second Eyes N = 106 n (%)	First Eyes N = 113 n (%)	Second Eyes N = 113 n (%)
≤ 0.25 D	69 (64.5)	72 (67.9)	63 (56.8)	69 (62.2)
≤ 0.5 D	98 (91.6)	92 (86.8)	96 (86.5)	93 (83.8)
≤ 1.00 D	107 (100.0)	106 (100.0)	108 (97.3)	110 (99.1)
> 1.00 D	0 (0.0)	0 (0.0)	3 (2.7)	1 (0.9)
Total	107	106	111	111

Percentage are calculated as (n/Total)x100

Monocular Visual Acuity

Visual Acuity was assessed under high-contrast, photopic using a computerized test system (CTS, M&S Technologies, Niles, IL). The following subsections present monocular visual acuity data collected at distance, intermediate (66 cm), and near (40 cm). Primary and secondary study endpoints included the following assessments of monocular visual acuity:

- Mean monocular BCDVA, DCIVA and DCNVA by treatment group
- Monocular defocus curves by treatment group

These analyses are discussed in the following subsections. Monocular visual acuity was also assessed in low-contrast, photopic conditions; results of this testing is presented in the "Safety" section of this document.

Table 24 presents monocular, photopic BCDVA (4 meters), DCIVA (66 cm), and DCNVA (40 cm) for first eyes treated with the AcrySof™ IQ Vivity™ or monofocal control IOLs at 6 Months.

Table 24: Comparison of Mean Monocular Photopic (First Eyes) BCDVA, DCIVA, and DCNVA Using Least Square Estimates All Implanted, 6 Months Postoperative

Monocular Mean Visual Acuity	AcrySof™ IQ Vivity™ IOL			Monofocal Control IOL			95% One-Sided UCL	P-Value
	Total	Mean logMAR	Standard Error	Total	Mean logMAR	Standard Error		
BCDVA	107	0.016	0.0091	111	-0.036	0.0089	0.073[a]	N/A
DCIVA	107	0.148	0.0120	111	0.312	0.0118	N/A	< 0.001[b]
DCNVA	107	0.359	0.0147	111	0.515	0.0144	N/A	< 0.001[b]

[a]Non-inferiority of AcrySof IQ Vivity IOL to the Monofocal Control IOL is demonstrated by the one-sided 95% Upper Confidence Limit (UCL) for treatment difference < 0.10 logMAR
[b]Superiority of AcrySof IQ Vivity IOL over the Monofocal Control IOL is demonstrated by the upper bound of two-sided 95% CI for treatment difference is < 0.00 logMAR and p-value is less than alpha = 0.05.

The AcrySof™ IQ Vivity™ IOL met the clinical performance co-primary endpoint for mean photopic BCDVA non-inferior to the monofocal control IOL (non-inferiority margin of 0.10 logMAR). The upper limit of the one-sided 95% confidence interval (CI) of the mean difference in BCDVA between IOL groups was less than 0.10 logMAR, demonstrating that the AcrySof™ IQ Vivity™ IOL is statistically non-inferior to the control lens in providing BCDVA. Additionally, the subjects implanted with the AcrySof™ IQ Vivity™ IOL in the first eyes achieved BCDVA of 0.30 logMAR or better at a rate of 99.1% and 100.0% in the AAS and Best-Case Analysis Set (BAS) set, respectively. This exceeded the ISO BCDVA Safety and Performance Endpoint (SPE) rates of 92.5% and 96.7%, respectively.

The AcrySof™ IQ Vivity™ IOL provided mean photopic monocular DCIVA superior to the monofocal control IOL with an increase in 1.6 lines read and met the clinical performance co-primary endpoint with > 50% (72.9%) of first eyes achieving DCIVA of 0.20 logMAR or better at 6 Months.

AcrySof™ IQ Vivity™ IOL provided mean photopic monocular DCNVA that was statistically superior to the monofocal control IOL, based on the observed 95% upper confidence limit of -0.115 logMAR for the difference in least squares means (LSMean) between the 2 groups (Model DFT015 – Model SN60WF), which was less than the upper confidence limit of 0.0 logMAR. A statistically significant difference in LSMeans of -0.156 logMAR (approximately 1.6 lines), in favor of Model DFT015, was observed with a two-sided p-value < 0.05 from a two-sample t-test ($p < 0.001$).
In addition, 40.2% (95% CI: 30.8%, 50.1%) of AcrySof IQ Vivity IOL first eyes achieved monocular DCNVA of 0.30 logMAR or better at 6 Months, at a rate > 25% above that of the monofocal control IOL. However, this result did not meet the pre-specified performance target of $\geq$ 50% of AcrySof™ IQ Vivity™ IOL subjects achieving monocular DCNVA ≤ 0.30 logMAR.

Monocular Defocus Curve

Monocular defocus curves at 6 months for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL reflecting 95% confidence limits and ±1 standard deviation (SD) are depicted in Figures 5 and 6. Data were obtained from 107 and 111 subjects respectively in each arm using a

computerized visual acuity test system (CTS, M&S Technologies, Niles, IL). The Vivity™ IOL group demonstrated a mean defocus range of 1.53 D compared to 0.99 D for the Monofocal Control IOL, providing an increase of 0.54 D in depth of focus at 0.20 logMAR. Therefore, the AcrySof™ IQ Vivity™ IOL met the clinical performance co-primary endpoint, demonstrating a monocular defocus range of > 0.5 D greater than the monofocal control IOL at 0.20 logMAR at 6 Months.

Figure 5: Mean Monocular (First Eyes) Defocus Curve with 95% Confidence Limits by Lens Model at 6 Months Postoperative
All Implanted

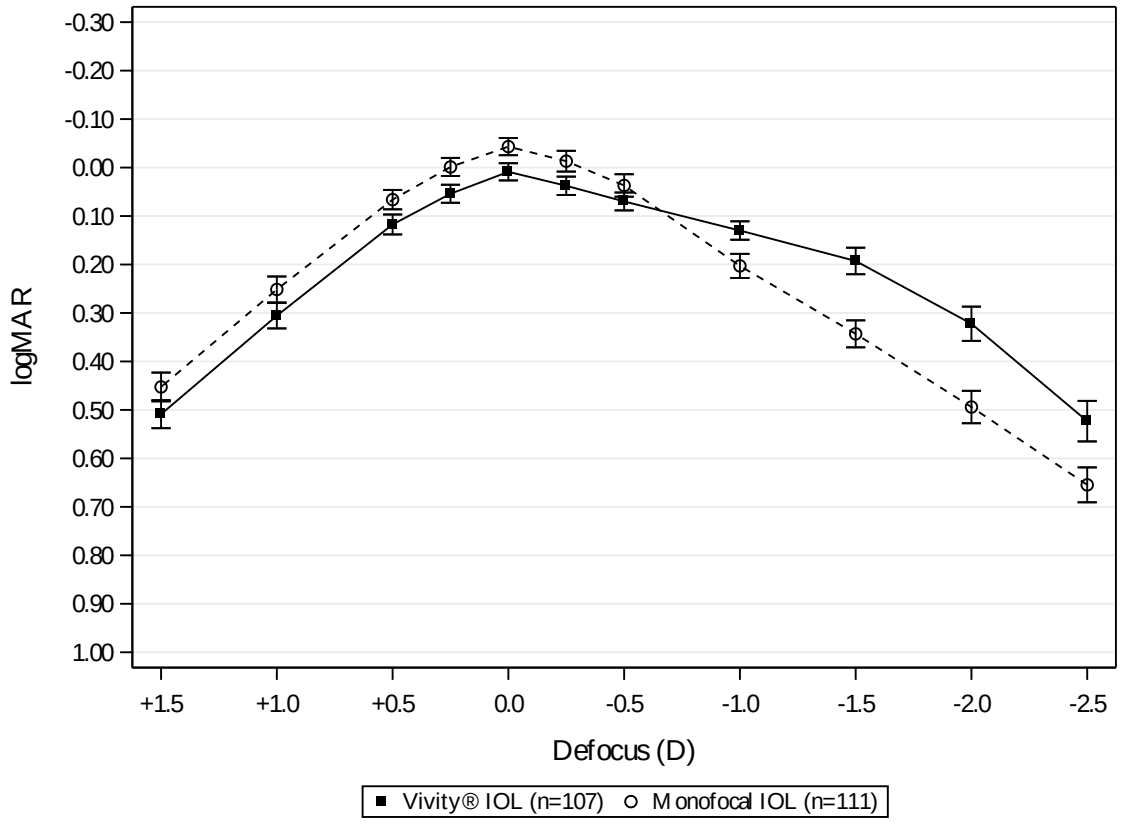
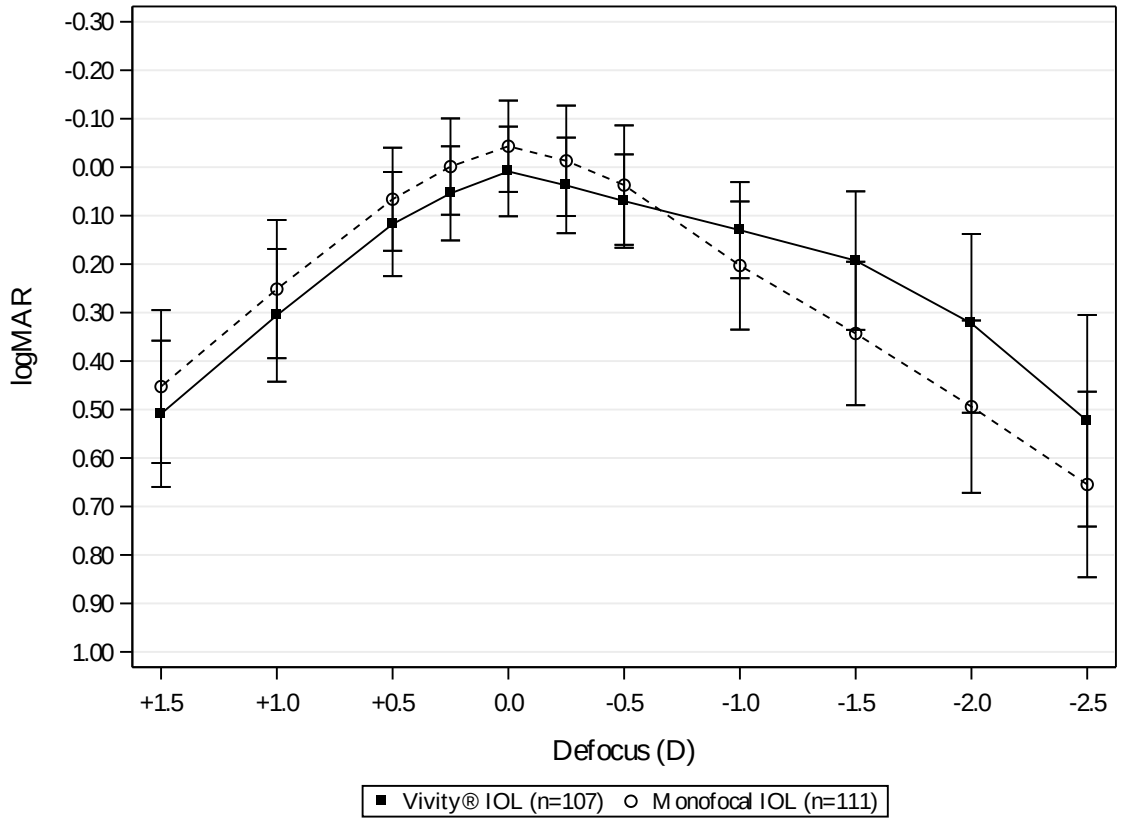


Figure 6: Mean Monocular (First Eyes) Defocus Curve with ±1 SD by Lens Model at 6 Months Postoperative
All Implanted



Monocular defocus curves stratified by post-operative (Month 6) photopic pupil size in the Vivity and Monofocal IOL groups are presented in Figures 7 and 8, respectively.

Figure 7: Monocular Mean Defocus Curve by Post-Operative Pupil Size at 6 Months, Vivity IOL Group
All Implanted

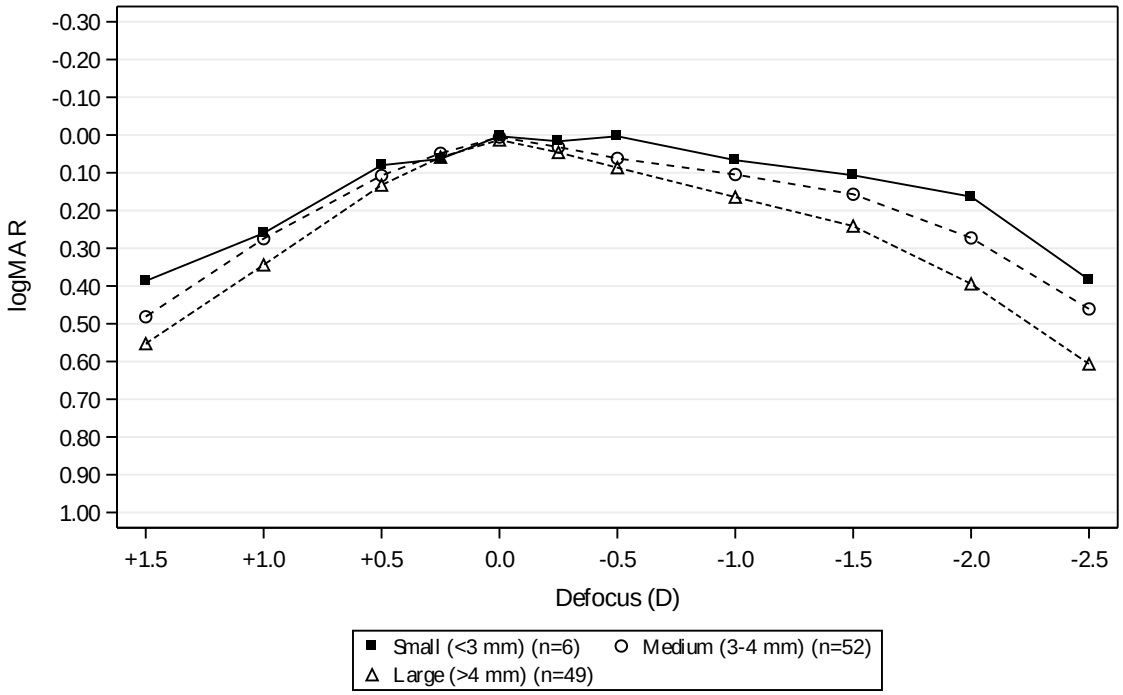
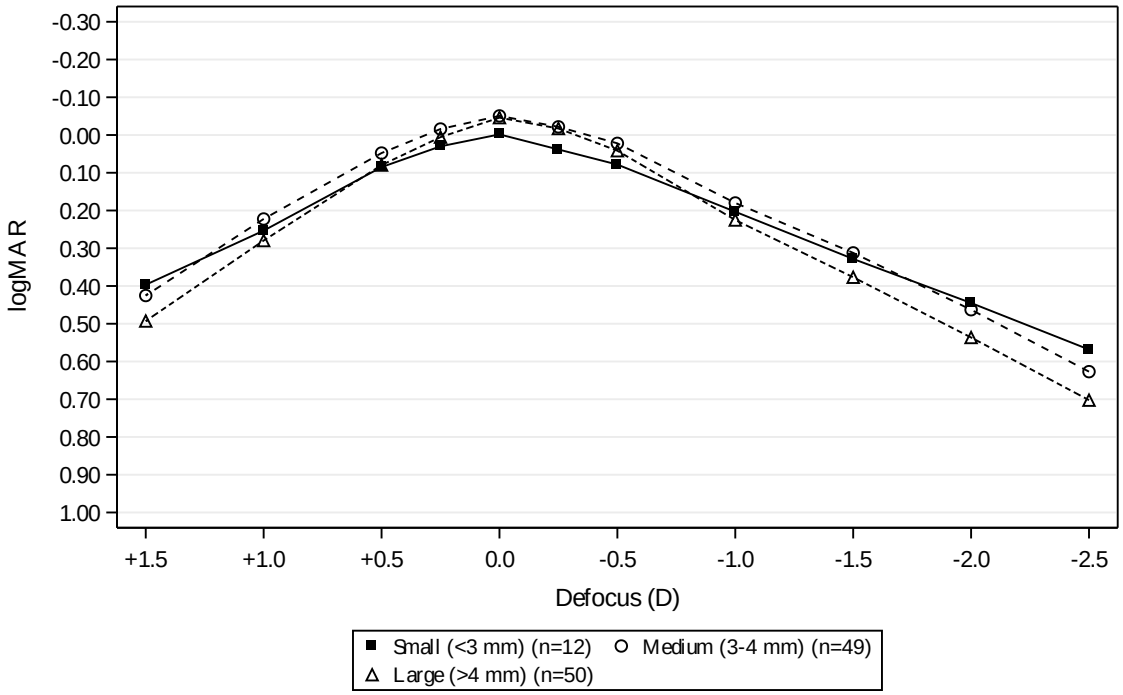


Figure 8: Monocular Mean Defocus Curve by Post-Operative Pupil Size at 6 Months, Monofocal IOL Group
All Implanted



Binocular Visual Acuity

Binocular visual acuities were analyzed as supportive effectiveness endpoints. Descriptive and categorical analyses of binocular uncorrected and best corrected distance visual acuities (UCDVA and BCDVA), uncorrected and distance corrected intermediate visual acuities (UCIVA and DCIVA), and uncorrected and distance corrected near visual acuities (UCNVA and DCNVA), in addition to binocular defocus curves are presented in the following subsections.

Binocular mean BCDVA, UCDVA, DCIVA, UCIVA, DCNVA, and UCNVA are presented by treatment group in Table 25. One of the subjects in the AcrySof™ IQ Vivity™ IOL group was not bilaterally implanted and does not contribute to binocular assessments.

Table 25: Comparison of Binocular Mean Photopic BCDVA, UCDVA, DCIVA, UCIVA, DCNVA, and UCNVA
All Implanted, 6 Months Postoperative

Binocular Mean Visual Acuity	AcrySof™ IQ Vivity™ IOL N = 106			Monofocal Control IOL N = 113		
	n	Mean logMAR	Standard Deviation	n	Mean logMAR	Standard Deviation
BCDVA	106	-0.028	0.084	111	-0.071	0.086
UCDVA	106	0.035	0.102	111	-0.022	0.107
DCIVA	106	0.054	0.093	111	0.196	0.113
UCIVA	106	0.058	0.083	111	0.139	0.122
DCNVA	106	0.253	0.118	111	0.391	0.135
UCNVA	106	0.208	0.104	111	0.339	0.149

Binocular Categorical Visual Acuity

Tables 26 and 27 present the percentage of subjects achieving binocular photopic BCDVA and UCDVA by Snellen and logMAR categories, respectively, at 6 Months.

Table 26: Binocular Photopic Distance Best Corrected and Uncorrected Visual Acuity (Snellen)
All Implanted, 6 Months Postoperative

Binocular Snellen Distance Visual Acuity	AcrySof™ IQ Vivity™ IOL N = 106		Monofocal Control IOL N = 113	
	Uncorrected n (%)	Best Corrected n (%)	Uncorrected n (%)	Best Corrected n (%)
$20/20^{-2}$ or better	65 (61.3)	93 (87.7)	85 (76.6)	105 (94.6)
$20/25^{-2}$ or better	94 (88.7)	103 (97.2)	105 (94.6)	109 (98.2)
$20/32^{-2}$ or better	102 (96.2)	104 (98.1)	109 (98.2)	111 (100.0)
$20/40^{-2}$ or better	105 (99.1)	106 (100.0)	111 (100.0)	111 (100.0)
Worse than $20/40^{-2}$	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
Total Responses	106	106	111	111

Snellen VA was converted from logMAR VA. A Snellen notation of $20/20^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
Percentages are calculated as (n/Total)*100

Table 27: Binocular Photopic Distance Best Corrected and Uncorrected Visual Acuity (logMAR)
All Implanted, 6 Months Postoperative

Binocular logMAR Visual Acuity	AcrySof™ IQ Vivity™ IOL N = 106		Monofocal Control IOL N = 113	
	Uncorrected n (%)	Best Corrected n (%)	Uncorrected n (%)	Best Corrected n (%)
0.00 or better	47 (44.3)	78 (73.6)	77 (69.4)	99 (89.2)
0.10 or better	88 (83.0)	102 (96.2)	96 (86.5)	108 (97.3)
0.20 or better	98 (92.5)	104 (98.1)	109 (98.2)	111 (100.0)
0.30 or better	105 (99.1)	106 (100.0)	111 (100.0)	111 (100.0)
Worse than 0.30	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
Total Responses	106	106	111	111

Percentages are calculated as (n/Total)*100

Tables 28 and 29 present the percentage of subjects achieving binocular photopic DCIVA and UCIVA by Snellen and logMAR categories, respectively, at 6 Months.

Table 28: Binocular Photopic Intermediate (66 cm) Distance Corrected and Uncorrected Visual Acuity (Snellen)
All Implanted, 6 Months Postoperative

Binocular Snellen Intermediate Visual Acuity	AcrySof™ IQ Vivity™ IOL N = 106		Monofocal Control IOL N = 113	
	Uncorrected n (%)	Distance Corrected n (%)	Uncorrected n (%)	Distance Corrected n (%)
$20/20^{-2}$ or better	59 (55.7)	59 (55.7)	30 (27.0)	12 (10.8)
$20/25^{-2}$ or better	91 (85.8)	93 (87.7)	70 (63.1)	38 (34.2)
$20/32^{-2}$ or better	105 (99.1)	103 (97.2)	92 (82.9)	82 (73.9)
$20/40^{-2}$ or better	106 (100.0)	106 (100.0)	106 (95.5)	103 (92.8)
Worse than $20/40^{-2}$	0 (0.0)	0 (0.0)	5 (4.5)	8 (7.2)
Total Responses	106	106	111	111

Snellen VA was converted from logMAR VA. A Snellen notation of $20/20^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
Percentages are calculated as (n/Total)*100

Table 29: Binocular Photopic Intermediate (66 cm) Distance Corrected and Uncorrected Visual Acuity (logMAR) All Implanted, 6 Months Postoperative

Binocular logMAR Visual Acuity	AcrySof™ IQ Vivity™ IOL N = 106		Monofocal Control IOL N = 113	
	Uncorrected n (%)	Distance Corrected n (%)	Uncorrected n (%)	Distance Corrected n (%)
0.00 or better	39 (36.8)	43 (40.6)	16 (14.4)	6 (5.4)
0.10 or better	82 (77.4)	79 (74.5)	47 (42.3)	24 (21.6)
0.20 or better	100 (94.3)	99 (93.4)	87 (78.4)	66 (59.5)
0.30 or better	105 (99.1)	104 (98.1)	101 (91.0)	94 (84.7)
Worse than 0.30	1 (0.9)	2 (1.9)	10 (9.0)	17 (15.3)
Total Responses	106	106	111	111

Percentages are calculated as (n/Total)*100

Tables 30 and 31 present the percentage of subjects achieving binocular photopic UCNVA and DCNVA by Snellen and logMAR categories, respectively, at 6 Months.

Table 30: Binocular Photopic Near (40 cm) Distance Corrected and Uncorrected Visual Acuity (Snellen) All Implanted, 6 Months Postoperative

Binocular Snellen Near Visual Acuity	AcrySof™ IQ Vivity™ IOL N = 106		Monofocal Control IOL N = 113	
	Uncorrected n (%)	Distance Corrected n (%)	Uncorrected n (%)	Distance Corrected n (%)
$20/20^{-2}$ or better	3 (2.8)	1 (0.9)	1 (0.9)	0 (0.0)
$20/25^{-2}$ or better	37 (34.9)	23 (21.7)	11 (9.9)	2 (1.8)
$20/32^{-2}$ or better	71 (67.0)	61 (57.5)	32 (28.8)	18 (16.2)
$20/40^{-2}$ or better	96 (90.6)	82 (77.4)	62 (55.9)	48 (43.2)
Worse than $20/40^{-2}$	10 (9.4)	24 (22.6)	49 (44.1)	63 (56.8)
Total Responses	106	106	111	111

Snellen VA was converted from logMAR VA. A Snellen notation of $20/20^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.

Percentages are calculated as (n/Total)*100

Table 31: Binocular Photopic Near (40 cm) Distance Corrected and Uncorrected Visual Acuity (logMAR) All Implanted, 6 Months Postoperative

Binocular logMAR Visual Acuity	AcrySof™ IQ Vivity™ IOL N = 106		Monofocal Control IOL N = 113	
	Uncorrected n (%)	Distance Corrected n (%)	Uncorrected n (%)	Distance Corrected n (%)
0.00 or better	2 (1.9)	1 (0.9)	1 (0.9)	0 (0.0)
0.10 or better	17 (16.0)	9 (8.5)	8 (7.2)	2 (1.8)
0.20 or better	60 (56.6)	46 (43.4)	27 (24.3)	8 (7.2)
0.30 or better	90 (84.9)	76 (71.7)	49 (44.1)	39 (35.1)
Worse than 0.30	16 (15.1)	30 (28.3)	62 (55.9)	72 (64.9)
Total Responses	106	106	111	111

Percentages are calculated as (n/Total)*100

Binocular Defocus Curves

Binocular defocus curves were obtained at 6 months for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL and were analyzed as a supportive effectiveness endpoint. The curves are depicted with 95% confidence interval and ±1 SD error bars in Figures 9 and 10, respectively. Data were obtained from 106 and 111 subjects in each arm using a computerized visual acuity test system (CTS, M&S Technologies, Niles, IL).

Figure 9: Binocular Mean Defocus Curve with 95% Confidence Limits by Lens Model at 6 Months Postoperative All Implanted

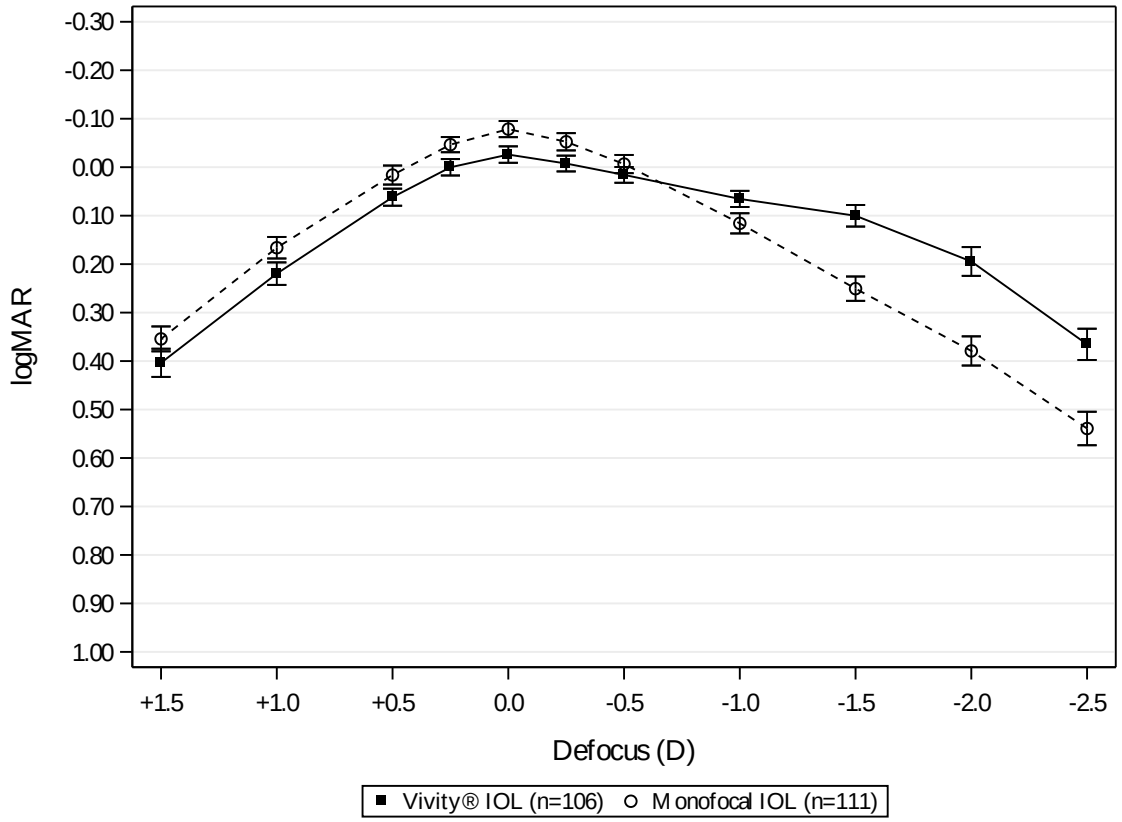
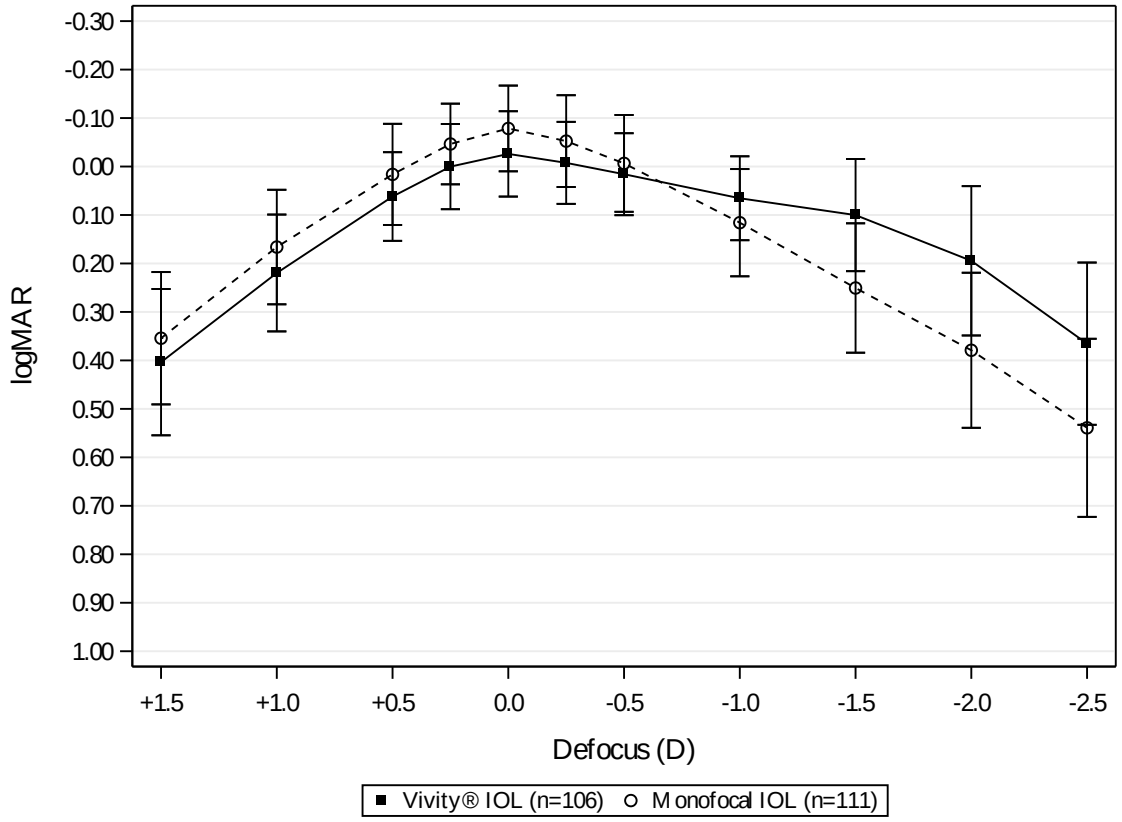


Figure 10: Binocular Mean Defocus Curve with ±1 SD by Lens Model at 6 Months Postoperative
All Implanted



Need for Eyeglasses/Contact Lenses

A Patient Reported Outcome Measure instrument was developed and validated for use in this clinical study to assess need for eyeglasses/contact lenses following implantation with the IOL. The AcrySof™ IQ Vivity™ IOL (N = 102) showed a greater proportion of subjects reporting never needing to wear eyeglasses or contact lenses at 6 months: 21.6% of subjects versus 3.6% for the Monofocal Control IOL (N = 111); however, a statistical test was not performed.

The questionnaire evaluated subject-reported use of eyeglasses or contact lenses at distance (‘far away’), intermediate (‘arm’s length’), and near (‘up close’), in bright and dim lighting conditions. Table 32 summarizes another analysis assessing the proportion of AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL subjects ‘never’ or ‘rarely’ needing eyeglasses or contact lenses. Data for this analysis are presented overall and under each lighting and distance condition.

Table 32: Proportion of Subjects Rarely or Never Needing Eyeglasses or Contact Lenses by Distance and Lighting Condition

Condition		Proportion of Subjects Rarely or Never Needing Eyeglasses or Contact Lenses					
		AcrySof™ IQ Vivity™ IOL N = 106			Monofocal Control IOL N = 113		
		Total Responses	n	%	Total Responses	n	%
Overall		102	46	45.1	111	19	17.1
Bright Light	Distance ('Far away')	102	96	94.1	111	102	91.9
	Intermediate ('At arm's length')	102	89	87.2	111	64	57.6
	Near ('Up close')	102	47	46.1	111	18	16.2
Dim Light	Distance ('Far away')	102	95	93.2	111	99	89.2
	Intermediate ('At arm's length')	102	86	84.3	111	59	53.1
	Near ('Up close')	102	40	39.2	111	12	10.8

% = n/Total Responses (100)

Subjects who reported not using eyeglasses at least some of the time (95.0% and 85.7% in the AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL groups, respectively) were asked to report their quality of vision without eyeglasses, up close, at arm's length, and far away, in dim and bright light. The proportion of subjects reporting 'good' or 'very good' vision without eyeglasses at 6 Months is presented by treatment group in Table 33.

Table 33: Proportion of Subjects Reporting 'Good' or 'Very Good' Vision Without Eyeglasses by Distance and Lighting Condition

Condition		AcrySof™ IQ Vivity™ IOL N = 106			Monofocal Control IOL N = 113		
		Total Responses	n	%	Total Responses	n	%
Bright Light	Distance ('Far away')	96	90	93.7	89	82	92.2
	Intermediate ('At arm's length')	96	88	91.6	89	56	62.9
	Near ('Up close')	96	55	57.3	89	22	24.8
Dim Light	Distance ('Far away')	96	84	87.5	90	70	77.8
	Intermediate ('At arm's length')	96	80	83.4	89	45	50.6
	Near ('Up close')	96	36	37.5	89	7	7.8

The results of this questionnaire indicate a reduced overall spectacle need in subjects implanted with the AcrySof™ IQ Vivity™ IOL compared to the monofocal control IOL. Statistical testing of this endpoint was not performed, as prespecified in the statistical analysis plan, because of failure to meet the first co-secondary effectiveness endpoint.

3. Subgroup Analyses
   The subgroup analyses by investigators, age, gender, ocular adverse events and preoperative ocular pathology were conducted for Monocular BCDVA at 4 m and 66 cm (logMar) for the AcrySof™ Vivity™ IOL and Monofocal Control IOL groups separately. The subgroups analyses contain 95% confidence interval, mean, standard deviation, max and min for each group.

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

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 34 principal and sub-investigators, of which none were full-time or part-time employees of the

sponsor and 2 had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c), and (f) as described below:

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

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

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Additional data are incorporated in the product labeling by reference to the parent lenses, AcrySof™ Natural Single Piece IOL (Model SB30AL), AcrySof™ Single-Piece IOL Model SA30EL, and the AcrySof™ Toric IOL (Models SA60T3-SA60T5).

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

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA Supplement was not referred to the Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The first co-primary effectiveness endpoint, statistical superiority of mean monocular DCIVA, was met, with a statistically significant difference between the AcrySof™ IQ Vivity™ IOL and monofocal control arms of approximately 1.6 logMAR lines of vision. The second co-primary effectiveness endpoint, non-inferiority of mean monocular BCDVA, was met. The third co-primary effectiveness endpoint, monocular depth of focus, was met, with a difference in depth of focus at 0.20 logMAR of 0.54D between the study arms. The fourth co-primary effectiveness endpoint, percentage of eyes achieving monocular photopic DCIVA of 0.20 logMAR or better, was also

met, with 72.9% of AcrySof™ IQ Vivity™ IOL first eyes achieving ≤ 0.20 logMAR DCIVA. Success on these co-primary endpoints demonstrates overall effectiveness of this lens to provide an extended depth of focus, and improved intermediate visual acuity compared to a monofocal IOL, while maintaining comparable distance visual acuity.

The first co-secondary effectiveness endpoint, monocular DCNVA, was not met. While the mean DCNVA for the AcrySof™ IQ Vivity™ IOL was statistically superior to the monofocal control, and more than 25% of Vivity IOL first eyes achieved monocular DCNVA of 0.30 logMAR or better compared to control first eyes, the following pre-specified performance target was not met: At least 50% of eyes with AcrySof™ IQ Vivity™ IOL achieve a monocular DCNVA of 0.30 logMAR or better. 40.2% of AcrySof™ IQ Vivity™ IOL first eyes achieved this acuity.

The second co-secondary effectiveness endpoint was related to eyeglass need. Statistical testing of this endpoint was not performed, as prespecified in the statistical analysis plan, because of failure to meet the first co-secondary effectiveness endpoint.

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. In addition, the clinical data from the U.S. studies for the parent IOLs, AcrySof™ Natural Single-Piece IOL Model SB30AL (P930014/S009), AcrySof™ Acrylic Single-Piece Foldable Posterior Chamber IOL Model SA30EL (P930014/S006), and AcrySof™ Toric IOL Models SA60T3-T5 (P930014/S015), provided data that are relevant to AcrySof™ IQ Vivity™ IOL device safety. The studies of the parent IOLs included 1 year of follow-up on at least 300 subjects.

The 6-month results of the IDE clinical investigation of the AcrySof™ IQ Vivity™ IOL, Model DFT015, provide reasonable assurance of the safety of this lens model. There were no unanticipated adverse events in the study, and the rates of device related adverse events were low. The rate of cumulative and persistent serious adverse events, including secondary surgical interventions, in first and second eyes were below the threshold established in ISO 11979-7:2018. There were no secondary surgical interventions due to the optical properties of the AcrySof™ IQ Vivity™ IOL. Monocular mesopic contrast sensitivity, with and without glare, was reduced in the AcrySof™ IQ Vivity™ IOL subjects compared to the control arm. This safety concern was adequately mitigated by labeling Warnings.

Subjective visual disturbances were assessed using the QUVID questionnaire. AcrySof™ IQ Vivity™ IOL subjects reported severe symptoms at 6 months

of starburst (3.8%), halo (0.9%), glare (0%) versus the monofocal control subjects reporting severe starbursts (2.7%), halo (0.9%), and glare (0%). AcrySof™ IQ Vivity™ IOL subjects reported most bothersome symptoms of starburst (1.9%), halo (0.9%), glare (0%); versus the monofocal control subjects reporting bothersome starburst (0.9%), halo (0%), and glare (0%). The totality of the evidence demonstrates a reasonable assurance of safety for the AcrySof™ IQ Vivity™ IOL when used as indicated.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. This study has demonstrated statistically significant and clinically meaningful results in favor of the AcrySof™ IQ Vivity™ IOL regarding non-inferiority of BCDVA and improvement in DCIVA, compared to a monofocal control. The study results also support that the AcrySof™ IQ Vivity™ IOL provides improved near visual acuity compared to the monofocal control IOL.

The probable risks of the device are also based on data collected in a clinical study to support PMA approval as described above. Medical adverse events and complications were similar to those associated with most other intraocular lenses, including macular edema, secondary surgical intervention, and posterior capsular opacification. The probable benefits of the device outweigh the probable risks associated with reduced contrast sensitivity and subjective visual disturbances.

Additional factors to be considered in determining probable risks and benefits for the AcrySof™ IQ Vivity™ IOL included:

- There was a low uncertainty in the quality of the study design, study conduct, and the study results.
- Potential issues related to contrast sensitivity and subjective visual symptoms are mitigated by labeling which informs users of these risks and quantifies them.

1. Patient Perspectives

   This submission did not include specific information on patient perspectives for this device.

In conclusion, given the available information above, the data support that for primary implantation for the visual correction of aphakia in adult subjects with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction, and for mitigating the effects of presbyopia by providing an extended depth of focus, the probable benefits of the AcrySof™ IQ Vivity™ IOL outweigh the probable risks.

Similarly, the data support that for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult subjects with pre-existing corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction, and for mitigating the effects of presbyopia by providing an extended depth of focus, the probable benefits of the toric models of the AcrySof™ IQ Vivity™ IOL outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The clinical data demonstrate the ability of the AcrySof™ IQ Vivity™ IOL to provide an extended depth of focus, with improvements in intermediate and near visual acuity compared to an aspheric monofocal IOL. Adverse events were compared favorably to grid rates established in an FDA-recognized international standard. Contrast sensitivity losses were observed compared to the monofocal control, while best-corrected distance high contrast visual acuity was comparable.

XIV. CDRH Decision

CDRH issued an approval order on February 26, 2020.

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

XV. Approval Specifications

Directions for use: See device labeling.

Hazards to heath 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.

XVI. References

1. Boettner, E.A. and Wolter, J.R. Transmission of the ocular media. Invest. Ophthalmol. 1962;1:776-83.