SUMMARY OF SAFETY AND EFFECTIVNESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Ultraviolet and Blue Light Filtering Acrylic Foldable Toric Optic Single-Piece Posterior Chamber Intraocular Lens

Device Trade Names: AcrySof® Toric Intraocular Lens Models SN60T6, SN60T7, SN60T8, and SN60T9; and AcrySof® IQ Toric Intraocular Lens Models SN6AT6, SN6AT7, SN6AT8, and SN6AT9

Applicant Name/Address:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P930014 / S045

Date of Notice of Approval to Applicant: May 03, 2011

Expedited: Not Applicable

The original AcrySof® Toric Intraocular Lenses PMA (P930014/S015) was approved on September 14, 2005 and is indicated 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 supplement was submitted to expand the cylinder power range of the AcrySof® Toric High Cylinder Power Intraocular Lenses.

II. 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.

III. CONTRAINDICATIONS

None listed in the labeling.

IV. WARNINGS AND PRECAUTIONS

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

V. DEVICE DESCRIPTION

The ACRYSOF® Toric Intraocular Lens Models SN60T6, SN60T7, SN60T8, and SN60T9 are ultraviolet (UV)-absorbing foldable intraocular lenses (IOL). These IOLs have a biconvex toric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). The single-piece design consists of a high refractive index 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 (Boettner and Wolter, 1962). In addition to standard UV-light filtering, the blue-light filtering chromophore reduces transmittance of blue light wavelengths. The biconvex toric 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. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance. The supporting haptics provide for proper positioning and fixation of the IOL optic within the eye. In addition to the spherical version, the AcrySof® IQ Toric IOL Models SN6AT6, SN6AT7, SN6AT8, and SN6AT are manufactured in an aspheric version. The physical characteristics are summarized in Table 1.

Table 1: Physical Characteristics

	Model			
AcrySof® Toric	SN60T6	SN60T7	SN60T8	SN60T9
AcrySof® IQ Toric	SN6AT6	SN6AT7	SN6AT8	SN6AT9
Optic Type	Biconvex Toric Optic (AcrySof® Toric) Biconvex Toric Aspheric Optic (AcrySof® IQ Toric)			
Optic / Haptic Material	Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer UV cutoff at 10% Transmittance: 399 nm (+6.00 diopter lens) 407 nm (+34.00 diopter lens)			
IOL Powers (spherical equivalent diopters)	+6.00D to +34.00D in 0.50D increments			
IOL Cylinder Power (Diopters)	3.75 D	4.50 D	5.25 D	6.00 D
Index Of Refraction	1.55			
Haptic Configuration	STABLEFORCE®			
Optic Diameter (mm)	6.0			
Overall Length (mm)	13.0			
Haptic Angle	0°			

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed. 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.

1. Other approved IOLs may be used for visual correction after cataract surgery, including non-toric IOL implantation with supplemental astigmatism correction such as spectacles, toric contact lenses and refractive surgery.

2. The following are non-surgical alternatives to implantation of an IOL following cataract extraction.

a. Spectacles: Spectacles, or eyeglasses, are the safest means for improving vision after cataract surgery. However, they are rarely used after modern cataract surgery as the lenses are required to be thick, which causes distorted vision and may be uncomfortable or cosmetically unappealing to the patient.

b. Contact lenses: Contact lenses are rarely prescribed for patients after cataract extraction, although they may provide excellent vision. Contact lenses have risks associated with their use including infection.

VII. MARKETING HISTORY

The ACRYSOF® Toric IOL Models SN60T6-SN60T9 are currently commercially available in Australia, Canada, European Union, Russia, Turkey, Ukraine, and Venezuela. The lenses have not been withdrawn from any country for any reason related to safety or effectiveness.

The ACRYSOF® IQ Toric IOL Models SN6AT6-T9 are currently commercially available in Australia, European Union, Russia, and Venezuela. The lenses have not been withdrawn from any country for any reason related to safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

As with any surgical procedure, there are risks involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, and retinal detachment repair. Amongst those directly related to the IOL are decentering and subluxation, precipitates on the surface of the IOL. Silicone oil, particularly when used in the surgical treatment of detached retina, may stick to the IOL if the posterior capsule of the crystalline lens is not intact.

For the specific adverse events that occurred in the ACRYSOF® Toric High Cylinder Power IOLs clinical study, please see the adverse effects section below.

IX. SUMMARY OF PRECLINICAL STUDIES

Preclinical testing demonstrated the safety and effectiveness of the ACRYSOF® Toric High Cylinder Power IOLs. Summaries of the preclinical testing conducted are listed below.

A. Laboratory Studies

Chemical Characterization:

The chemical characterization tests meet the requirements of ISO 11979-5, *Ophthalmic Implants – Intraocular Lenses – Part 5: Biocompatibility*. The chemical characterization tests are summarized in Table 2.

Table 2: Chemical Characterization

Test:	Results:
Exhaustive Extraction	AcrySof® Natural IOLs were evaluated for extractable content using exhaustive extraction per ISO 11979-5, Annex A. The test results demonstrated no safety concern for potentially harmful effects due to extractable components.
Test for Leachables	AcrySof® Natural IOLs were evaluated for extractable content and optical quality using tests for leachables at physiological conditions per ISO 11979-5, Annex B. The test results demonstrated no safety concern for potentially harmful effects due to extractable components and no change in spectral transmittance of the test lenses after extraction by both acetone and aqueous medium.
Hydrolytic Stability	AcrySof® Natural IOLs were evaluated for extractable content and optical quality using tests for hydrolytic stability at physiological conditions per ISO 11979-5, Annex C. The chemical test results demonstrated that there is no safety concern for potentially harmful effects due to instability of the material in an aqueous environment. Lenses were found to be optically stable and met specifications for power, resolution and spectral transmittance. No changes to the optical surfaces resulting from exposure to an aqueous environment were noted in photographs collected by both light microscopy and SEM.
Photostability	No significant change in light transmission capabilities before and after the exposure; no leaching of materials; no significant change in surface quality
Stability against Nd-YAG laser exposure	Damage similar or less in size to that of silicone or PMMA IOLs. No change in optical quality. No detectable monomer or UV chromophore in aqueous extracts, noncytotoxic in agarose overlay tests after YAG laser irradiation.
Insoluble inorganics (Heavy Metal Analysis	Insoluble inorganic analysis demonstrated that AcrySof® Natural IOLs contained no insoluble inorganic within a 10 ppm detection limit.

Optical / Mechanical Testing:

The pre-clinical optical / mechanical tests were performed as outlined in EN ISO 11979-3 Ophthalmic Implants – Intraocular Lenses – Part 3: *Mechanical Properties and Test Methods* and in accordance with EN ISO 11979-2 Ophthalmic Implants – Intraocular Lenses – Part 2: *Optical Properties and Test Methods*. The optical / mechanical tests are summarized in Table 3.

Table 3: Optical / Mechanical Testing

Test:	Results:
Haptic Compression Force	≥0.08 mN and ≤2.0 mN Meets requirements to be considered a Level A modification of Parent IOL Model SA60T3.
Haptic Compression Force Decay	≥ 0.08 mN and ≤ 2.0mN. Meets requirements to be considered a Level A modification of Parent IOL Model SA60T3
Axial Displacement	Optic vault less than 0.35 mm in the anterior or posterior direction while IOL is compressed to a diameter of 10 mm.
Optic Decentration	Sum of mean optic decentration plus 2 standard deviations ≤ 0.6 mm when compressed to 10.0 mm.
Optic Tilt	Sum of mean optic tilt plus 2 standard deviations < 5° when compressed to 10.0 mm in 35 ± 2°C water.
Angle of Contact	Haptic contact angle >15°. Meet Requirements to be considered a Level A modification of Parent IOL Model SA60T3
Haptic Fatigue	No micro-cracks observed at 20X following 250,000 cycles at ± 0.25 mm displacement around 10 mm compressed diameter.
Haptic Pull Strength	>0.25 N
Spectral Transmittance	Max %T is ≥85% at ≥ 550 nm
Modulation Transfer Function	Lens shall exhibit a MTF value ≥ 0.43 at 100 lp/mm or 70% of the calculated maximum attainable for the design whichever is the smaller, but always greater than 0.28 using an ISO model eye system.
Optical Evaluation after Multiple Folds	No change in the optical and physical properties of the IOL
Refractive Index	1.5550 ± 0.0007 @ 25°C ± 0.5°C in D-light λ=589 nm (1.5542 ± 0.0007 @ 37°C λ=550 nm)
Delivery Systems Qualification	6.0 – 34.0 D with B delivery system cartridge 6.0 – 27.0 D with C delivery system cartridge 6.0 – 23.0 D with D delivery system cartridge

Microbiology / Sterilization Adoption:

The ACRYSOF® Toric Intraocular Lens Models SN60T6, SN60T7, SN60T8, and SN60T9 are packaged in a polypropylene wagon-wheel lens case, which is then sealed in a polyester/Tyvek pouch. The lenses are terminally sterilized using ethylene oxide (EO). The tests conducted in support of the sterilization validation, package integrity, shelf life, and transport stability studies for the device are summarized in Table 4.The device in its packaging is validated for a shelf life of 5 years.

Table 4: Sterilization, Packaging, Shelf Life & Transport Tests

Test	Test Result
Sterilization Validation	Validated per ANSI/AAMI/ISO 11135-1994, Medical Device – Validation and routine control of ethylene oxide (Section 4.2), and BS EN 556 – 1: 2001, Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices.
Sterilant Residuals	Ethylene Oxide (EO) residuals are below FDA's requirements of 1.25 µg per lens. Ethylene Chlorohydrin (ECH) residuals are below FDA's requirements of 5 µg/lens.
Bioburden test	Pre-sterilization bioburden levels were within acceptable limits.
Bacterial Endotoxin	≤ 0.2 EU / lens
Sterility Test	No microbial growth was detected.
Bacteriostasis/fungistasis test	No bacteriostatic/fungistatic effect was observed.
Package Integrity	Results support a shelf life of 5 years.
Transport Stability	The results showed that the lenses would not be damaged during shipping.

B. Animal Studies

Biocompatibility Testing:

ACRYSOF® Toric High Cylinder Power Intraocular Lenses (IOLs) are made of the same raw material and manufacturing contact materials previously qualified with other IOL designs within this PMA (P930014). A battery of toxicity studies were performed with the ACRYSOF® raw material and previously qualified and PMA approved ACRYSOF® IOL models. The toxicology studies conducted meet the requirements of ISO 10993, Biological Evaluation of Medical Devices, and ISO 11979-5, Ophthalmic Implants – Intraocular Lenses – Part 5: Biocompatibility guidelines. Studies were conducted in accordance with Good Laboratory Practices. The biocompatibility tests are summarized in Table 5.

Table 5: Biocompatibility Testing

Test:	Results:
Genotoxicity – Ames Test	Non-mutagenic
Genotoxicity – Mouse Lymphoma Assay	Non-mutagenic
Hemolysis Test	Non-hemolytic
Cytotoxicity – Agarose Overlay (Extract)	Non-cytotoxic
Cytotoxicity – Agarose Overlay (Direct)	Non-cytotoxic
Cytotoxicity – MEM Elution	Non-cytotoxic
Inhibition of Cell Growth (V79 colony formation assay)	Non-inhibitory
Muscle Implantation – 7, 30 days	No evidence of irritation or toxicity
Intracutaneous Toxicity	No significant irritation or toxicity
Sensitization – Guinea Pig Maximization	Non-sensitizing
Acute Systemic Toxicity	No systemic toxicity
Implantation – Ocular Implantation (6 months)	Non-inflammatory/ no material changes

C. Additional Studies

Additional chemical characterization testing was conducted, and is summarized in Table 6.

Table 6: Additional Chemical Characterization Testing

Process Extractable Analysis	AcrySof® Natural IOLs were evaluated for process extractables content using tests for exhaustive extraction and leachables. The test results demonstrated no safety concern for potentially harmful effects due to extractable components resulting from processing and treatment of the IOLs.
Fourier Transform/Infrared Spectroscopy	Matches standard scan for Al-37884
Contact Angle	Goniometric method was used to determine the contact angle of a sessile drop of water on EtO sterilized IOLs.
X-Ray Photoelectron Spectroscopy (ESCA)	The data from the curve fit the carbon 1s envelope and was found to be similar to that of the controls and in good agreement with the expected composition.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The safety and effectiveness of previously-approved models under this PMA have been demonstrated in prior studies. Therefore, in this clinical study, Alcon investigated the rates of spatial distortions related to axial misalignment of higher cylindrical powers for the ACRYSOF® Toric High Cylinder Power IOL Model SN60T9. Data from this clinical study were the basis for the PMA supplement approval decision. A summary of the clinical study is presented below. The AcrySof® IQ Toric (aspheric) designs were not studied in this clinical investigation.

A. Study Design

Subjects were treated between August 18, 2009 and May 3, 2010. The database for this PMA supplement reflected data collected through June 03, 2010 and included 15 subjects. There were 6 investigational sites.

The ACRYSOF® Toric High Cylinder Power Intraocular Lenses were evaluated in a 6-month, prospective, multi-center, non-randomized, unmasked, uncontrolled clinical investigation.

The draft American National Standard for Ophthalmics: Toric Intraocular lenses (ANSI Z80.30, dated December 16, 2008) suggests that visual disturbances may

be associated with axis misalignment of higher cylinder power toric intraocular lenses (e.g., greater than 2.00 D at the corneal plane). Therefore, this study was conducted to investigate the rate of spatial distortions due to lens axis misalignment.

Fifteen subjects were bilaterally implanted with the ACRYSOF® Toric High Cylinder Power IOL Model SN60T9 in the first eye and either the ACRYSOF® Toric High Cylinder Power IOL Model SN60T9 or Model SN60T8 in the second eye. The qualifying astigmatism range was calculated by the study-specific, web-based Alcon® Toric Calculator, and the eye that qualified for IOL Model SN60T9 was implanted first. In the event that both eyes qualified for IOL Model SN60T9, the first operative eye was determined for Model SN60T9 implantation based on investigator's clinical judgment. The second eye surgery followed within 30 days after the first eye study lens was implanted but not prior to 7 days after the first eye surgery.

The four IOL models which were the subject of this PMA supplement are described in Table 7 below.

Table 7: ACRYSOF® Toric High Cylinder Power IOLs

IOL Model	Cylinder Power at IOL Plane	Cylinder Power at corneal plane*	Corneal Astigmatism range to be corrected
SN60T6	3.75 D	2.57 D	2.57 - 3.07 D
SN60T7	4.50 D	3.08 D	3.08 - 3.59 D
SN60T8	5.25 D	3.60 D	3.60 - 4.10 D
SN60T9	6.00 D	4.11 D	4.11 – 4.62 D

* Based on an average pseudophakic human eye

Descriptive statistics (mean, median, standard deviation, sample size, minimum, and maximum) were provided for continuous variables. Simple descriptive statistics including the number and percent of subjects were provided for categorical variables. Fifteen subjects had IOLs implanted bilaterally (ACRYSOF® Toric High Cylinder Power IOL Model SN60T9 in the first eye and either Model SN60T9 or SN60T8 in the second eye). This was done to ensure that there would be at least 10 subjects available at 6 months in the Implanted – No Refractive Secondary Surgical Intervention (SSI) cohort for the visual distortion questionnaire analysis. With 10 subjects, if there are zero observations of yes for a 'yes/no' distortion question, then a 95% one-sided upper confidence interval

estimate for the population proportion of subjects reporting 'yes' for distortion is 25.9%.

All data were used in the analyses. No imputation was carried out for missing data.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the ACRYSOF® Toric High Cylinder Power IOL study was limited to subjects who met the following selection criteria:

- Adults, 21 years of age or older, diagnosed with bilateral cataracts.
- Planned cataract removal by phacoemulsification.
- Potential postoperative visual acuity of 0.2 logMAR or better in study eyes.
- Preoperative astigmatism of 4.11–4.62 D in the first operative eye and 3.60–4.62 D in the second operative eye.
- Preoperative Best Corrected Distance Visual Acuity (BCDVA) worse than 0.2 logMAR.
- Pupil size greater than or equal to 6 mm after dilation.

Subjects were not permitted to enroll in the clinical study if they met any of the following exclusion criteria before surgery:

- Uncontrolled systemic or ocular disease.
- Irregular corneal astigmatism.
- Previous or planned ocular surgery, other than cataract surgery.
- Extremely shallow anterior chamber, not due to swollen cataract.

2. Follow-up Schedule

All subjects were scheduled to return for follow-up examinations at 1-2 days, 7-14 days, 30-60 days, 80-100 days, and 120-180 days. Preoperatively, subjects scheduled to undergo cataract extraction and IOL implantation were screened for eligibility, and eligible subjects were evaluated to obtain a medical history and establish a baseline for ocular condition.

Postoperatively, subjects underwent a complete ophthalmic evaluation at regularly scheduled intervals to assess the condition of their eyes and visual function for 12 months after their cataract surgery. Postoperatively, the objective parameters measured during the study included adverse events and complications were recorded at all visits.

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

3. Clinical Endpoints

With regard to safety, the primary endpoint was the rate of spatial distortions related to IOL misalignment for the ACRYSOF® Toric High Cylinder Power IOL Model SN60T9 in the first eye and, either, IOL Model SN60T9 or SN60T8 in the second eye. Distortions were evaluated using the Visual Distortion Questionnaire (VDQ).

Secondary safety endpoints included: serious adverse events, clinical observations, posterior capsulotomy, IOL observations, IOL position change, intraocular pressure, surgical problems, IOL damage, distance vision questions, Visual Function-14 Questionnaire composite score, and evaluation of visual symptoms.

With regard to effectiveness, the primary endpoints were reduction of cylinder (percent reduction in absolute cylinder and percent of eyes with reduction of cylinder within 0.50 D and within 1.00 D of intended cylinder correction) and lens axis misalignment.

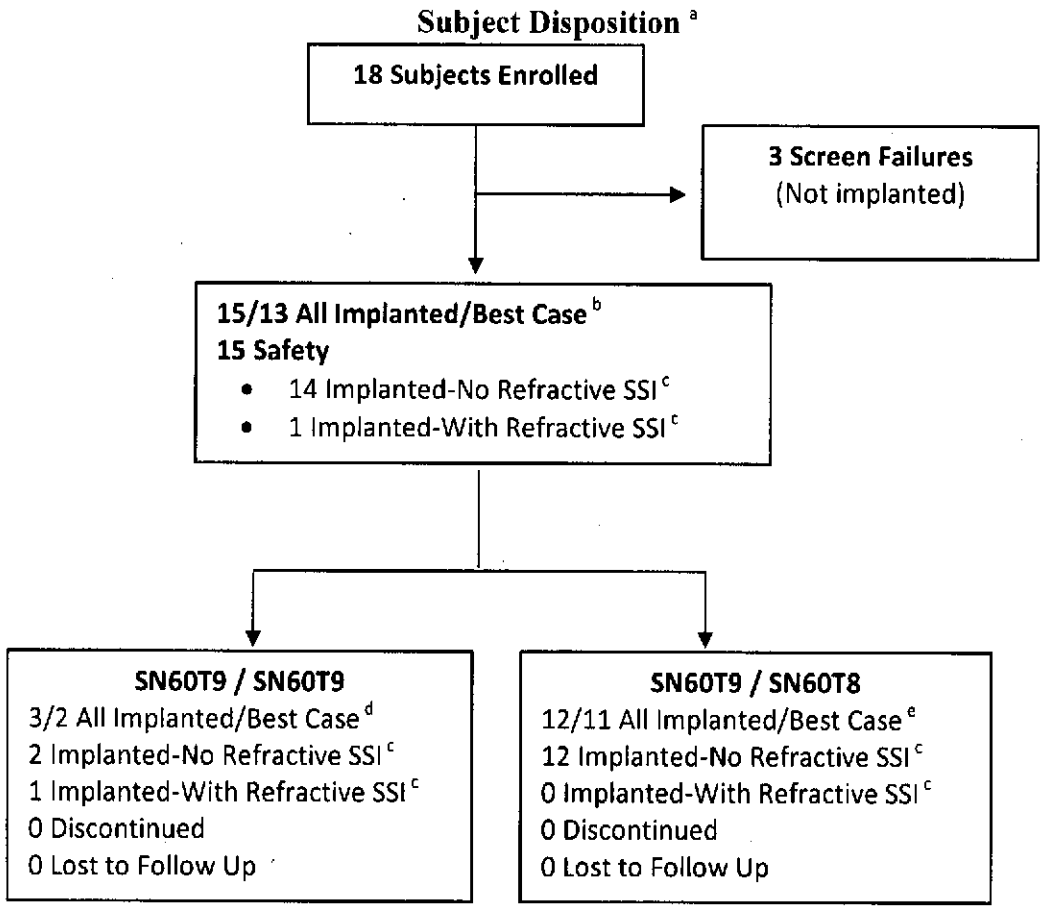
Secondary effectiveness endpoints included stability of axis, percent of eyes that achieved predictability of manifest refraction spherical equivalent (MRSE), uncorrected visual acuity (UCVA), accuracy of cylinder, lens axis misalignment compared to target, and best corrected distance visual acuity (BCDVA).

Success/failure criteria were not required for this study.

B. Accountability of PMA Cohort

At the time of database lock, 18 subjects were enrolled, with 15 subjects implanted in the PMA study, all (n=15) subjects are available for analysis at the completion of the study at Visit 5A, the final visit evaluated for safety and effectiveness as the basis for the PMA panel track submission. Figure 1 is the patient accountability tree.

Figure 1: Patient Accountability Tree



[a] - *There were no lost to follow-up or missed visits during the study and no subject discontinued prior to completion of the final study visit.*

[b] - *Best Case is defined as subjects with both successfully implanted eyes that had at least one postoperative visit and had no preoperative pathology or macular degeneration. 15 implanted subjects were included in the All Implanted analysis; 13 of those subjects were included in the Best Case analysis.*

[c] - *SSI is defined as a Secondary Surgical Intervention.*

[d] - *3 subjects were implanted with IOL Model SN60T9 in both eyes; 2 of those subjects were included in the Best Case analysis.*

[e] - *12 subjects were implanted with IOL Model SN60T9 in the first operative eye and SN60T8 in the second eye; 11 of those subjects were included in the Best Case analysis.*

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an IOL study performed in the US. Demographics of the All Implanted study cohort were as follows: 3/15 (20%) of the population was male and 12/15 (80%) of the population was female. All 15 (100%) of the implanted subjects were white. The mean age was 67.1 years with a range of 43 to 82 years. The study population demographics are summarized in Table 8.

Table 8: Patient Population
N=15

	Lens Model* SN60T9/SN60T9 N = 3		Lens Model* SN60T9/SN60T8 N = 12		Total Implanted
Demographics	n	% (n/N)	n	% (n/N)	N
Age Category					
< 60	2	66.7% (2/3)	2	16.6% (2/12)	4
60 to < 70	0	0.0% (0/3)	3	25.0% (3/12)	3
70 to < 80	1	33.3% (1/3)	6	50.0% (6/12)	7
≥ 80	0	0.0% (0/3)	1	8.3% (1/12)	1
Sex					
Male	0	0.0% (0/3)	3	25.0% (3/12)	3
Female	3	100.0% (3/3)	9	75.0% (9/12)	12
Race					

White	3	100.0% (3/3)	12	100.0% (12/12)	15
Black or African American	0	0.0	0	0.0	0
Ethnicity					
Hispanic, Latino or Spanish	0	0.0% (0/3)	0	0.0% (0/12)	0
Not Hispanic, Latino or Spanish	3	100.0% (3/3)	12	100.0% (12/12)	15

* Lens Model=First Operative Eye/Second Operative Eye

(n/N)(100)=%

Pre-operative corneal astigmatism for implanted eyes is depicted for the first and second operative eyes in Tables 9 and 10, respectively.

Table 9

Analysis of Corneal Cylinder at Visit 0, 1st Operative Eye, All Implanted

		3.0 < 3.5		3.5 < 4.0		4.0 < 4.5		> 4.5	
	Lens Model	n	% (n/N)	n	% (n/N)	n	% (n/N)	n	% (n/N)
1st Operative Eye	SN60T9	0	0.0% (0/15)	6	40.0% (6/15)	4	26.7% (4/15)	5	33.3% (5/15)

(n/N)(100)=%

Table 10

Analysis of Corneal Cylinder at Visit 0A, 2nd Operative Eye, All Implanted

		3.0 < 3.5		3.5 < 4.0		4.0 < 4.5		> 4.5	
2st Operative Eye	Lens Model	n	% (n/N)	n	% (n/N)	n	% (n/N)	n	% (n/N)
	SN60T9 (N=3)	0	0.0% (0/3)	1	33.3% (1/3)	1	33.3% (1/3)	1	33.3% (1/3)
	SN60T8 (N=12)	3	25.0% (3/12)	5	41.7% (5/12)	4	33.3% (4/12)	0	0/0% (0/12)
(n/N)(100)=%									

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the implanted study cohort of 15 subjects available for the Visit 5A (120-180 days) evaluation. The key safety outcomes for this study are presented below in tables 9 through 12. There was one adverse effect, residual refractive error due to inaccurate pre-operative keratometry, which is described below.

The primary endpoint was to describe the rates of spatial distortion related to IOL misalignment for ACRYSOF® Toric High Cylinder Power IOL Model SN60T9. A Visual Distortion Questionnaire was administered preoperatively (Visit 0) and at the Final Visit (Visit 5A). The analysis of spatial distortion was based on a cohort of 14 subjects who did not undergo a secondary surgical intervention at any time during the study. The overall rate of spatial distortion decreased postoperatively relative to the preoperative baseline. The Visual Distortion Questionnaire results are summarized in Table 11.

Table 11: Visual Distortion Questionnaire Results by Visit

During the past 4 weeks, have you had		PreOp (N = 14)		Final Visit (N = 14)	
		n	% (n/N)	n	% (n/N)
1) ...trouble with things appearing distorted?	No	3	21.4% (3/14)	12	85.7% (12/14)
	Yes	11	78.6% (11/14)	2[a,b]	14.3% (2/14)
2) ...trouble with flat surfaces (like floors) appearing curved?	No	12	85.7% (12/14)	13	92.9% (13/14)
	Yes	2	14.3% (2/14)	1[c]	7.1% (1/14)
3) ...trouble with straight lines (like door or window frames) appearing tilted?	No	10	71.4% (10/14)	14	100% (14/14)
	Yes	4	28.6	0	0.0
4) ...trouble with feeling sick to your stomach due to distortion of your vision?	No	14	100% (14/14)	14	100% (14/14)
	Yes	0	0.0% (0/14)	0	0.0% (0/14)

[a] Reported with or without glasses at PreOp and Final Visit.

[b] Reported with or without glasses at PreOp but only with glasses (progressive lenses) at Final Visit.

[c] Same subject as in (b). Reported only with glasses (progressive lenses) at Final Visit. Not reported at PreOp.

(n/N)(100)=%

Based on the questionnaire responses, spatial distortions associated with high pre-existing corneal astigmatism may not completely resolve postoperatively.

Two subjects at Visit 5A (Final Visit) continued to report "trouble with things appearing distorted" versus 11 subjects preoperatively. One of these subjects had "trouble with flat surfaces appearing curved," which was noted only postoperatively, but no longer experienced the preoperative visual phenomena of straight lines appearing tilted. Neither subject had IOL misalignment requiring secondary surgical intervention to address problems of spatial distortion. There were no reports of subjects feeling sick to their stomachs due to distortion of vision.

Responses to visual distortion sub-questions related to spectacle wear, frequency of experiencing distortion, and degree of bother are presented in Tables 12 through 14.

Table 12: Visual Distortion Questionnaire Results, Trouble With Things Appearing Distorted

1) For subjects who had trouble with things appearing distorted in the last 4 weeks:		PreOp (N = 11)		Final Visit (N = 2)	
		n	% (n/N)	n	% (n/N)
Do you notice this only when you wear your glasses?	No	10	90.9% (10/11)	1[a]	50.0% (1/2)
	Yes	1	9.1% (1/11)	1[b]	50.0% (1/2)
How often have you noticed this?	Rarely	2	18.2% (2/11)	0	0.0% (0/2)
	Sometimes	2	18.2% (2/11)	0	0.0% (0/2)
	Frequently	3	27.3% (3/11)	1[b]	50.0% (1/2)
	All the time	4	36.4% (4/11)	1[a]	50.0% (1/2)

How much does it bother you?	None	1	9.1% (1/11)	1[a]	50.0% (1/2)
	A Little	4	36.4% (4/11)	0	0.0% (0/2)
	A Lot	6	54.5% (6/11)	1[b]	50.0% (1/2)

[a] Reported with or without glasses at PreOp and Final Visit.

[b] Reported with or without glasses at PreOp but only with glasses (progressive lenses) at Final Visit.

(n/N)(100)=%

Table 13: Visual Distortion Questionnaire Results, Trouble With Flat Surfaces Appearing Curved

2) For subjects who had trouble with flat surfaces (like floors) appearing curved in the last 4 weeks:		PreOp (N = 2)		Final Visit (N = 1)	
		n	% (n/N)	n	% (n/N)
Do you notice this only when you wear your glasses?	No	2	100% (2/2)	0	0.0% (0/1)
	Yes	0	0.0% (0/2)	1	100% (1/1)
How often have you noticed this?	Rarely	0	0.0% (0/2)	0	0.0% (0/1)
	Sometimes	0	0.0% (0/2)	0	0.0% (0/1)
	Frequently	1	50.0% (1/2)	1	100% (1/1)
	All the time	1	50.0% (1/2)	0	0.0% (0/1)

How much does it bother you?	None	0	0.0% (0/2)	0	0.0% (0/1)
	A Little	0	0.0% (0/2)	0	0.0% (0/1)
	A Lot	2	100% (2/2)	1	100% (1/1)
(n/N)(100)=%					

Table 14: Visual Distortion Questionnaire Results, Trouble With Straight Lines Appearing Tilted

3) For subjects who had trouble with straight lines (like door or window frames) appearing tilted in the last 4 weeks:		PreOp (N = 4)		Final Visit (N = 0)	
		n	% (n/N)	n	% (n/N)
Do you notice this only when you wear your glasses?	No	3	75.0% (3/4)	0	0.0% (0/0)
	Yes	1	25.0% (1/4)	0	0.0% (0/0)
How often have you noticed this?	Rarely	0	0.0% (0/4)	0	0.0% (0/0)
	Sometimes	2	50.0% (2/4)	0	0.0% (0/0)
	Frequently	0	0.0% (0/4)	0	0.0% (0/0)
	All the time	2	50.0% (2/4)	0	0.0% (0/0)

How much does it bother you?	None	0	0.0% (0/4)	0	0.0% (0/0)
	A Little	1	25.0% (1/4)	0	0.0% (0/0)
	A Lot	3	75.0% (3/4)	0	0.0% (0/0)
(n/N)(100)=%					

Adverse effects that occurred in the PMA clinical study:

During the study, 1 of 15 subjects (6.7%) underwent a secondary surgical intervention (IOL repositioning) in the first eye to resolve residual refractive error due to an inaccurate preoperative manual keratometry. The surgery occurred one week postoperatively. This subject was satisfied with uncorrected distance vision and did not experience any spatial distortion at Visit 5A (Final Visit). No other serious adverse events were reported in the study. This complication is consistent with those seen for subjects in this age group and who have been implanted with a posterior chamber IOL.

2. Effectiveness Results

The analysis of effectiveness was based on the implanted study cohort of 15 subjects available for the Visit 5A (120-180 days) evaluation. Key effectiveness outcomes are presented below in Figures 2 to 5.

The amount of pre-existing corneal astigmatism to be corrected for each operative eye was determined by the crossed cylinder result of preoperative corneal astigmatism and surgically induced astigmatism, as determined by the Alcon® provided study-specific, web-based ACRYSOF® Toric IOL calculator.

Refractive cylinder at the Final Visit (Visit 5A) postoperatively was reduced for all subjects implanted with either an ACRYSOF® Toric High Cylinder Power IOL Model SN60T8 and SN60T9 compared to preoperative baseline (Visit 0). Results show a statistically significant reduction (p-value <.0001) in residual refractive cylinder in eyes implanted with IOL Model SN60T9 [85.7% in first eyes (n=15), 87.8% in second eyes (n=3)] and IOL Model SN60T8 [87.3% (n=12)].

Clinical data reveals that 33.3% (5/15) of subjects were within 0.50 D of target cylinder at Visit 5A (Final Visit) and 93.3% (14/15) of subjects were within 1.00 D of the target cylinder.

Lens axis alignment was evaluated by comparing the intended axis of placement to the achieved axis orientation at the operative visit. The clinical data demonstrate accuracy of lens axis placement where a mean difference of 0.3 degrees was observed between the intended lens axis orientation and the achieved axis of placement at the operative visit.

A summary of the change in axis orientation (rotation) from the operative visit to Visit 5A (Final Visit) is presented in Figure 2 and 3. The rotational stability of the ACRYSOF® Toric High Cylinder Power lenses are established with the majority of the lenses rotating ≤ 5 degrees at the Final Visit (Visit 5A).

Figure 2: Change in Lens Axis Orientation between Visit 5A (Final Visit) to Target (Baseline)

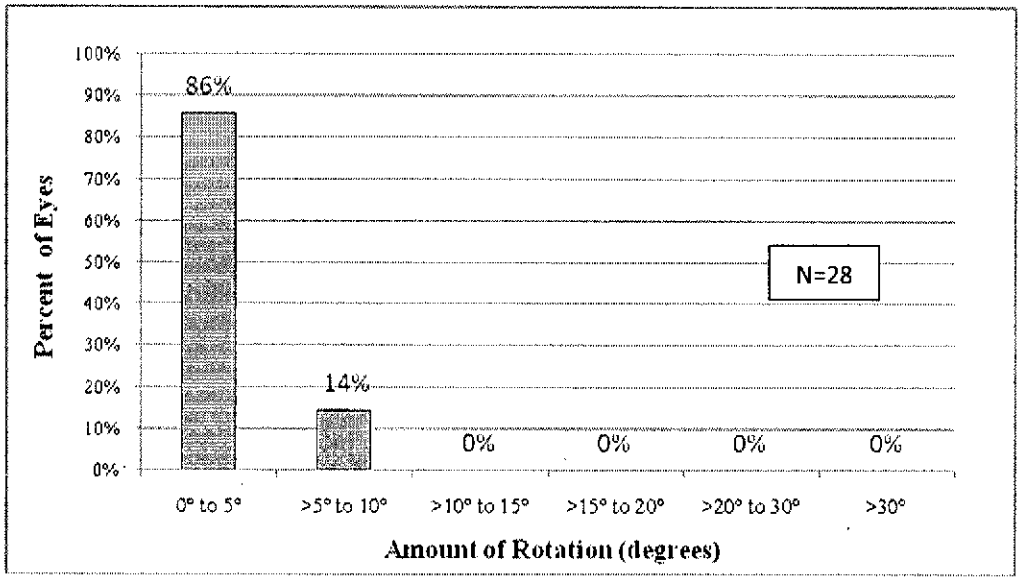
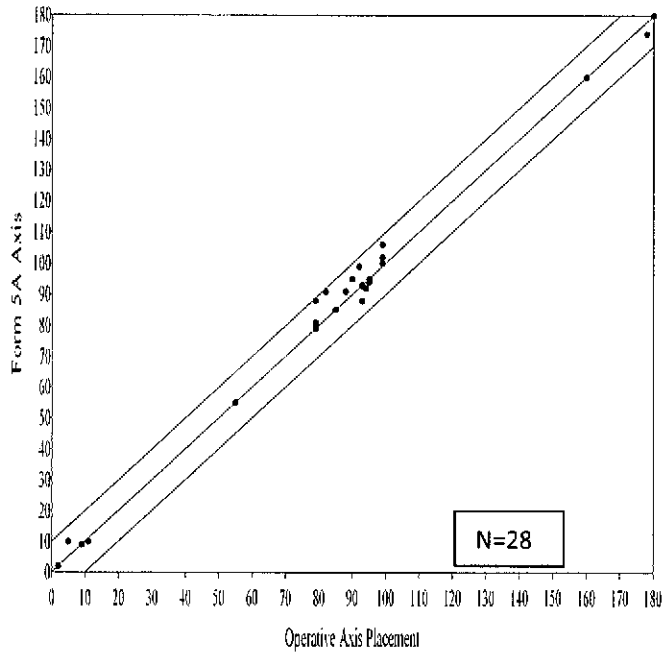


Figure 3: Orientation of Lens Axis, Operative Visit versus Visit 5A (Final Visit)

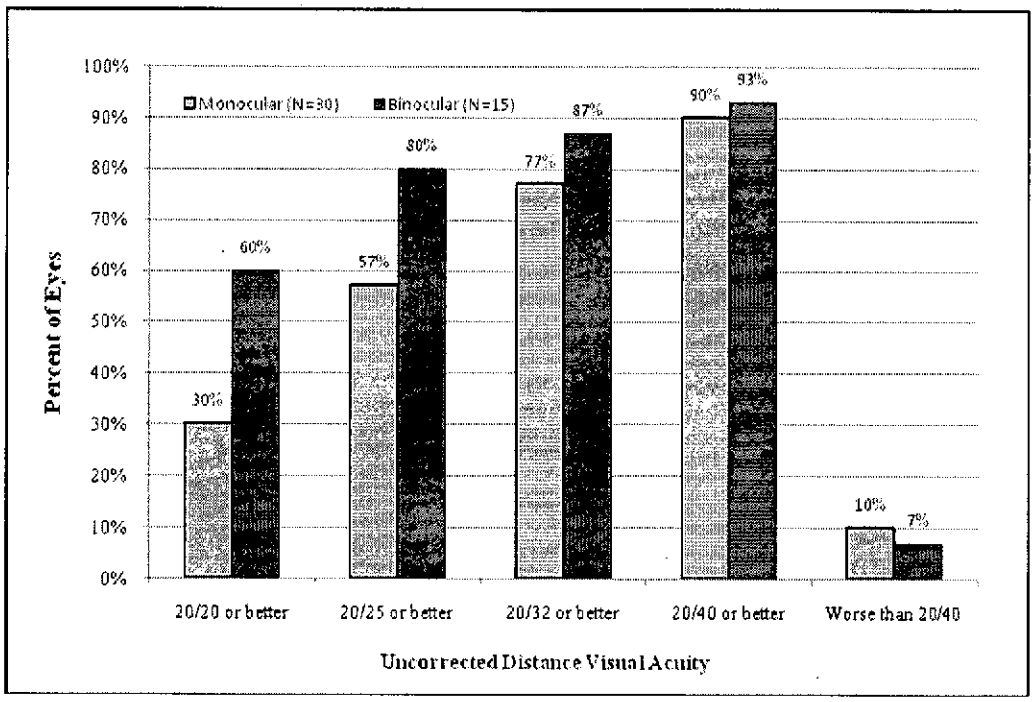
IOL Models SN60T9 and SN60T8



At the final visit, predictability of manifest refractive spherical equivalent (MRSE) was demonstrated by 93.3% (14/15) of all implanted first eyes achieving MRSE within 1.00 D of the target, and with 66.7% (10/15) of eyes within 0.50 D of target cylinder.

All subjects implanted bilaterally with the ACRYSOF® Toric High Cylinder Power IOL Models SN60T8 or SN60T9 achieved improved binocular uncorrected distance visual acuity at the Final Visit (Visit 5A) postoperatively. Figure 4 demonstrates that 60% (9/15) of subjects achieved 20/20 or better binocular uncorrected distance visual acuity compared to 30% (9/30) for monocular eyes, while 93% (14/15) of subjects achieved 20/40 or better binocular uncorrected distance visual acuity compared to 90% (27/30) of monocular eyes. Less than 10% of subjects had monocular or binocular uncorrected distance visual acuity worse than 20/40 at the Final Visit (Visit 5A) postoperatively.

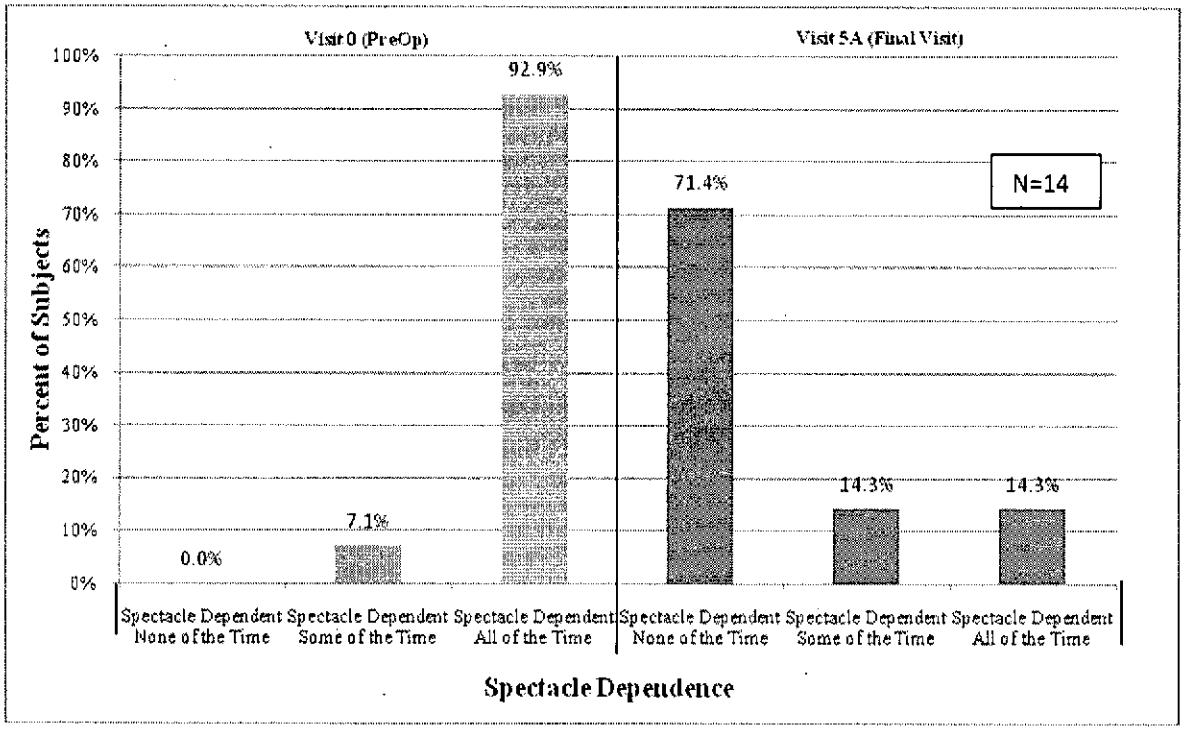
Figure 4: Cumulative UCDVA at Visit 5A (Final Visit), Monocular versus Binocular



Preoperatively all subjects were spectacle dependent, with 92.9% (13/14) having reported frequency of spectacle wear as all-the-time and 7.1% (1/14) as some-of-the-time. At the Final Visit (Visit 5A) postoperatively, 71.4% (10/14) of subjects were spectacle independent. Figure 5 depicts Bilateral Distance-Vision Spectacle Independence.

Figure 5: Bilateral Distance Vision Spectacle Independence

Frequency-of-Spectacle-Wear Visit 0 (PreOp) versus Visit 5A (Final Visit)



3. Subgroup Analysis

No subgroup analysis was performed in this study.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

No clinical evaluations were conducted with this device outside of the US.

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

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmology Devices Advisory 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. Safety Conclusions

The adverse effects of the device are based on data collected in a clinical study conducted to support PMA panel track supplement approval as described above. The rate of spatial distortion is expected to decrease from preoperative baseline following the implantation of the ACRYSOF® Toric High Cylinder Power IOL for the correction of pre-existing high corneal astigmatism. Spatial distortions associated with high pre-existing corneal astigmatism may not completely resolve postoperatively.

B. Effectiveness Conclusions

The effectiveness of the device is based on data collected in a clinical study conducted to support PMA panel track supplement approval as described above. The ACRYSOF® Toric High Cylinder Power IOL corrects pre-existing corneal astigmatism by significantly reducing the amount of residual refractive cylinder. The ACRYSOF® Toric High Cylinder Power IOL demonstrates rotational stability. The ACRYSOF® Toric High Cylinder Power IOL is effective in improving uncorrected visual acuity.

C. 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: primary implantation in the capsular bag of the eye for visual correction of aphakia, secondary to removal of a cataractous lens, and pre-existing corneal astigmatism 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.

XIV. CDRH DECISION

CDRH issued an approval order on May 03, 2011. The final conditions of approval cited in the approval order are described below.

The applicant's manufacturing facility was 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. (See General hints)

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.

XVI. REFERENCES

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

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

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

ISO 11135 Medical Devices – *Validation and Routine Control of Ethylene Oxide Sterilization*

EN 556-1: Sterilization of Medical Devices – *Requirements for Medical Devices to be designated "Sterile"*

EN 550: *Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*

ISO 10993, *Biological Evaluation of Medical Devices*