SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Toric Posterior Chamber Intraocular Lens (IOL)

Device Trade Name: Trulign™ Toric Posterior Chamber Intraocular Lens
Models AT50T, BL1AT and BL1UT;
Trulign™ Toric IOL Calculator

Device Procode: MJP

Applicant's Name and Address:
Bausch + Lomb
30 Enterprise, Suite 450
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Date(s) of Panel Recommendation: April 8, 2013

Premarket Approval Application (PMA) Number: P030002/S027

Date of FDA Notice of Approval: May 20, 2013

Expedited: not applicable

The original PMA (PMA P030002) was approved on November 14, 2003 and is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed and is intended to provide near, intermediate, and distance vision without spectacles. The Crystalens™ IOL provides approximately one diopter (D) of monocular accommodation. The SSED to support the indication is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to expand the indication for the Trulign™ Toric Posterior Chamber Intraocular Lens.

II. INDICATIONS FOR USE

The Trulign™ Toric Posterior Chamber Intraocular Lens is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia who desire reduction of residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate and distance vision.

III. CONTRAINDICATIONS

None

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Trulign™ Toric IOL labeling.

V. DEVICE DESCRIPTION

The Trulign™ Toric Intraocular Lens is a modification to the currently approved Crystalens Intraocular Lens (Model AT-45) approved on November 14, 2003 under PMA P030002. The only difference between the Trulign™ Toric IOLs and the currently approved Crystalens IOLs is in the incorporation of a toroidal posterior optic surface. The lens toricity results in a periodic change in refractive power between the flat and steep lens meridians. When the flat meridian of the toric IOL is correctly aligned with the steep corneal meridian, the toric IOL compensates the corneal astigmatism. The Trulign™ Toric, Intraocular Lenses are available in three different cylinder powers (1.25 D, 2.00 D and 2.75 D) and in spherical equivalent powers of +4 D to +33 D.

In addition to the clinically studied models, this supplement also seeks approval to add the Toric posterior surface to the currently approved Crystalens aspheric models (Model AT50AO approved October 23, 2009 under PMA P030002/S021) and Crystalens UVAM model (Model AO1UV approved August 5, 2011 under PMA P030002/S020). The physical characteristics of the Trulign™ Toric Intraocular Lens are shown in **Table 1**.

Table 1: PHYSICAL CHARACTERISTICS OF TRULIGN™ TORIC INTRAOCULAR LENS

Models			
Feature	AT50T	BL1AT	BL1UT
Power Range	+4.0 D to +10.0 D (1.0 D Increments) SE +10.5 D to +33.0 D (0.5 D Increments) SE SE - Spherical Equivalent		
Cylinder Powers	1.25 D, 2.00 D and 2.75 D		
Anterior Surface	Spherical with Axis-mark	Aspheric with Axis-mark	
Posterior Surface	Toric	Aspheric Toric	
Overall Diameter	11.5mm		
Optic Diameter	5.0 mm		
Plate Overall	10.5mm		
Plate Configuration	Rectangular		
Material Body & Plates	Silicone (10% UV Cutoff at 354nm)		Silicone (10% UV Cutoff at 400nm)

Loop (haptic) material	Polyimide
Index of Refraction at 546nm	1.4301

For optimal results, the Trulign™ Toric IOL Calculator will be used to select the appropriate cylinder power of the toric lens. The Trulign™ Toric IOL Calculator will calculate the predicted post-operative corneal astigmatism using pre-operative keratometry, phaco/insertion incision location and expected magnitude of surgically-induced astigmatism inputs from the Surgeon. The calculator will account for surgically induced astigmatism, incision location and the patient's pre-operative corneal astigmatism, and will determine the Toric IOL cylinder power needed and placement orientation in order to best correct a patient's expected post-operative corneal astigmatism. For optimal toric IOL calculations, it is recommended that surgeons customize their surgically induced corneal astigmatism values based upon individual surgical technique and past results.

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, simultaneous vision 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 Trulign™ Toric IOL has not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse events and complications accompanying cataract or implant surgery may include, but are not limited to the following: lens subluxation, corneal endothelial damage, non-pigment precipitates, cystoid macular edema, infection (endophthalmitis), retinal detachment, vitreous loss, pupillary block, corneal edema, hypopyon, secondary glaucoma, iris prolapse, vitreous- wick syndrome, uveitis, secondary surgical intervention and pupillary membrane. Secondary surgical interventions include, but are not limited to: lens repositioning (due to decentration, rotation, subluxation, lens vaulting, etc.), lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair and retinal detachment repair.

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

IX. SUMMARY OF PRECLINICAL STUDIES

Preclinical studies performed demonstrate the safety and effectiveness of the Trulign™ Toric IOL and the Trulign™ Toric IOL Toric Calculator. The Trulign™ Toric IOL is composed of identical materials to the currently approved Crystalens IOLs. Therefore, no new biocompatibility/toxicological data were provided. Biocompatibilty and physical–chemical testing consistent with ISO 10993, Biological Evaluation of Medical Devices, and ISO 11979-5, Ophthalmic Implants - Intraocular Lenses - Part 5: Biocompatibility was provided in the approved PMA P030002 (November 14, 2003) and PMA P030002/S20 on August 5, 2011). The Trulign™ Toric IOL material met the requirements of the International Standards, ISO 11979-5, *Ophthalmic Implants – Intraocular Lenses – Part 5: Biocompatibility*. In addition, sterilization, packaging, shelf life and transport stability testing was performed in P030002 and associated supplements in accordance with AAMI TIR 13: *Principles of Industrial Moist Steam Sterilization,* ISO 17665-Part 1 & 2, *Sterilization of Health Care Products-Moist Heat,* 34/29 USP 2011, *Bacterial Endotoxin Testing,* and ISO 11979-6, *Ophthalmic Implants – Intraocular Lenses – Part 6: Shelf-life and transport stability*. A shelf-life of 5-years was previously established for the Crystalens IOLs.

A. Laboratory Studies

Dimensional, Optical, and Mechanical Testing

To validate the toric modification, dimensional, optical, and mechanical testing was performed on finished, sterilized, Trulign™ Toric IOLs to verify the conformance of the design to the ANSI Standard for Toric IOLs, ANSI Z80.30 *Ophthalmics – Toric Intraocular Lenses,* as well as the International Standards ISO 11979-2 - *Part 2: Optical properties and test methods*, and ISO 11979-3, *Part 3:Mechanical properties and test methods*, and internal specifications. Folding and insertion testing was also performed to verify recovery of lens properties following simulated insertion. The Trulign™ Toric IOLs passed all requirements established in ANSI Z80.30, ISO11979-2, ISO 11979-3 standards, and product specifications. A summary of the results of the dimensional, optical and mechanical testing performed on the Trulign™ Toric IOLs are summarized in **Table 2**.

Table 2
Dimensional, Optical and Mechanical Test Requirements Summary

Requirement	Result	
Optical Requirements		
Dioptric Power	Power Range (D)	Spherical Acceptance Criteria
	4.0 to 33.0	±0.25D

Cylinder Power	Cylinder SKU range (D)	Cylinder Acceptance Criteria
	1.25, 2.00 and 2.75	±0.25D
Image Quality	Greater than 0.7 modulation unit for MTF @ 70% of design maximum attainable at 100 c/mm. This specification corresponds to the MTF specification described in ISO 11979-2:1999.	
Axis Orientation Mark(s)	Combined angular errors of the cylindrical axis mark and any deviation from orthogonality between the meridians of highest and lowest dioptric power within ±5°	
Spectral Transmittance	% T=10% at ~354 nm (for BL1AT) % T=10% at ~400 nm (for BL1UT)	
Mechanical Requirements		
Overall Diameter	11.50 ± 0.30mm	
Sagitta	± 0.45mm from nominal	
Clear Optic Diameter	4.50± 0.10mm	
Optic Body Diameter	5.00 ± 0.10mm	
Optic Decentration	Mean + 2SD< 0.45 mm (10% clear optic)	
Optic Tilt	Mean + 2SD < 5°	
Angle of Contact	Angle of Contact mean = 84.88° (within ± 40% of the angle of contact of parent model AT45, at 66.33°)	
Compression Force and Decay	Meet the guideline in ISO/TR 22979:2006 as a Level A modification of the parent model AT-45	
Dynamic Fatigue Durability	No breakage or damage after 250,000 cycles of haptic compression	
Loop Pull Strength	Loop pull strength mean = 0.74N (≥ 0.25N, per ISO 11979-3)	
Surface and Bulk Homogeneity	Essentially free from defects and deviations from intended features of design when inspected under 10x magnification	

B. Additional Studies

Software Validation

A software validation was performed for the Trulign™ Toric IOL Calculator according to the procedures described in FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software Level of Concern: MAJOR. The software for this device was developed under an appropriate software development program. A hazard analysis was performed from both the patient's and user's standpoint and all identified hazards were

addressed. These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other way.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of subjects undergoing cataract extraction and IOL implantation with the Trulign™ Toric IOL for primary implantation in the capsular bag of the eye for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia who desire reduction of residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate and distance vision in the US and Canada under IDE # G990163. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Subjects were treated between June 1, 2010 and September 22, 2011. The database for this P030002/S027 reflected data collected through October 15, 2012 and included 229 subjects. There were 9 investigational sites.

The study was a prospective, randomized, single-masked clinical trial to evaluate the safety and effectiveness of the Trulign™ Toric IOL (Models AT50T/AT52T) in reducing postoperative refractive astigmatism in subjects undergoing cataract extraction. IOL implantation was conducted in the US and Canada with study duration of up to 1 year. Subjects in the lowest astigmatic power (1.25D) cohort were randomized to undergo implantation of either the toric test lens or the non-toric spherical control lens (Crystalens Accommodating IOL Models AT50/AT52) in one eye. Subjects in the higher astigmatic power cohorts (2.00D, 2.75D) were implanted with the test lens in one eye.

The effective corneal powers for each of the lens plane cylindrical powers of the test IOLs are shown in **Table 3** below:

Table 3: Trulign™ Toric IOL Cylinder Power

Cylinder Power at IOL Plane (D)	Cylinder Power at Corneal Plane (D)	Range of Predicted Postoperative Corneal Cylinder* (D)
1.25	0.83	0.83 – 1.32
2.00	1.33	1.33 – 1.82
2.75	1.83	1.83 – 2.50

*based upon inclusion criteria and the expectation of 0.50 D incisional effect

In order to facilitate toric IOL selection and axis placement, a proprietary Toric Calculator was used to determine the appropriate Trulign™ Toric IOL model and axis of placement for each eye. The calculator accounted for SIA, incision location, and the subject's preoperative corneal astigmatism. In this trial, all cataract incisions were to be placed on the preoperative keratometric steep axis and a fixed SIA value of 0.50 D was used in the Trulign™ Toric IOL Calculator for all study subjects.

For the safety endpoints of best corrected distance visual acuity (BCDVA) and complications/adverse events, study rates for the toric IOLs were compared to ISO SPE rates using a one-sided exact test based on the binomial distribution. For rotational stability, the proportion of the toric eyes with $\leq 5^{o}$ of rotation between consecutive visits was reported in accordance with the ANSI Standard for Toric IOLs, Z80.30. Study sample size was based on the ANSI Standard for Toric IOLs, Z80.30.3

Primary effectiveness endpoints were:

- Percent reduction in cylinder, expressed as a percentage of the intended reduction in cylinder, calculated as:

$$\frac{\left(\left|\text{Postoperative Manifest Refractive Cylinder}\right| - \left|\text{Preoperative Keratometric Cylinder}\right|\right)}{\left(\left|\text{Intended Postoperative Manifest Refractive Cylinder}\right| - \left|\text{Preoperative Keratometric Cylinder}\right|\right)} * 100$$

- Percent of eyes with "reduction of cylinder" within 0.50 D and within 1.00 D of intended; and
- Lens axis misalignment as determined by a photographic method.

Analysis of the percent reduction in absolute cylinder included continuous summary statistics and 95% confidence intervals (CIs) around the mean. Additionally, a 2-sample t-test assuming unequal variance was performed using the Effectiveness Cohort to test the null hypothesis that the percent reduction of cylinder within the eyes implanted with IOL cylinder power 1.25 D was less than or equal to the percent reduction of cylinder within the eyes implanted with the control IOL. For the endpoint of the percent of eyes with reduction of cylinder within 0.50 D and 1.00 D of target, categorical summary statistics were run, including exact 95% binomial CI around the percent of eyes within 0.50 D and 1.00 D.

Analysis of lens axis misalignment included continuous summaries of the absolute value of the misalignment, the signed value of the misalignment (including a 2-sided 95% tolerance interval, which contains at least 90% of the population), and the proportion of lenses with axis misalignment in the following categories: $< 5°$, $< 10°$, $< 20°$, $\leq 30°$, and $> 30°$.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the Trulign™ Toric study was limited to subjects who met the following inclusion criteria.

   - Clinically documented diagnosis of age-related cataract (cortical, nuclear, subcapsular, or a combination) considered amenable to treatment with standard phacoemulsification/ extracapsular cataract extraction

- 18 years of age or older and met any applicable local minimum age requirements for IOL implantation following cataract surgery
- Underwent primary IOL implantation for correction of aphakia following continuous curvilinear anterior capsulotomy and phacoemulsification cataract extraction
- Ability to return for scheduled follow-up examinations and had mental capacity to cooperate when undergoing a detailed postoperative exam
- Required spherical lens power of 16.00 D to 27.00 D
- Predicted postoperative corneal astigmatism between 0.83 D and 2.50 D, as determined by the toric calculator
- Potential for BCVA of 20/32 or better in the operated eye (as measured by retinal acuity meter/potential acuity meter testing)
- BCVA equal to or worse than 20/40, with or without a glare source

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

- Anterior segment pathology for which extracapsular phacoemulsification cataract surgery would be contraindicated (e.g., chronic uveitis, iritis, iridocyclitis rubeosis, iridis, clinically significant corneal dystrophy, clinically significant Fuch's dystrophy, clinically significant anterior membrane dystrophy)
- Corneal pathology potentially affecting topography
- Diagnoses of degenerative visual disorders (e.g., macular degeneration or other retinal disorders) predicted to cause future acuity losses to a level of 20/32 or worse
- Conditions associated with increased risk of zonular rupture (zonule rupture during cataract extraction procedure that may affect postoperative rotation, centration, or tilt of the lens)
- Inability to achieve pupil dilation of 5.0 mm
- Any inflammation or edema (swelling) of the cornea, including but not limited to keratitis, keratoconjunctivitis, and keratouveitis

- Uncontrolled glaucoma
- Prior retinal detachment
- Diabetic retinopathy (proliferative or nonproliferative)
- Presence of rubella, bilateral congenital, traumatic, or complicated cataract
- Marked microphthalmos or aniridia
- Prior corneal surgery in the planned operative eye
- Irregular corneal astigmatism
- Presence of amblyopia
- Clinically significant retinal pigment or epithelium/macular changes
- Iris or chorioretinal neovascularization
- Presence of optic atrophy
- Chronic use of systemic steroids or immunosuppressive medications
- Concurrent participation in another clinical trial or participation in another clinical trial within 60 days prior to enrollment in this study
- Difference in corneal astigmatism measured with the IOL Master and the topographer greater than 0.50 D using vector analysis

2. Follow-up Schedule

Eligible subjects were evaluated preoperatively to obtain a medical history and to establish a baseline for their ocular condition. Subjects in the lowest astigmatic power group were randomized to undergo implantation of either the test or control lens. No corneal or refractive procedures (such as limbal relaxing incisions or astigmatic keratotomies) were permitted at any time during the course of the study.

Postoperatively, subjects underwent complete ophthalmic examinations at regular intervals per the following study visit schedule:

- Preoperative (Form 0A) Day -90 to Day 0
- Operative (Form 0B) Day 0
- Postoperative Visit 1 (Form 1) Day 1-2

- Postoperative Visit 2 (Form 2) Day 7-14
- Postoperative Visit 3 (Form 3) Day 30-60
- Postoperative Visit 4 (Form 4) Day 120-180
- Postoperative Visit 5 (Form 5) Day 245-301
- Postoperative Visit 6 (Form 6) Day 330-420

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

3. Clinical Endpoints
With regards to safety, the study endpoints were preservation of BCVA (distance and near) and incidence of complications and adverse events.
.
Primary effectiveness endpoints were:

- Percent reduction in cylinder, expressed as a percentage of the intended reduction in cylinder, calculated as:

$$\frac{\left(\left|\text{Postoperative Manifest Refractive Cylinder}\right| - \left|\text{Preoperative Keratometric Cylinder}\right|\right)}{\left(\left|\text{Intended Postoperative Manifest Refractive Cylinder}\right| - \left|\text{Preoperative Keratometric Cylinder}\right|\right)} * 100$$

- Percent of eyes with "reduction of cylinder" within 0.50 D and within 1.00 D of intended; and

- Lens axis misalignment as determined by a photographic method.

The secondary effectiveness endpoints were intermediate visual acuity with distance correction (DCIVA), near visual acuity with distance correction (DCNVA), with and without the minimal reading add, best corrected distance visual acuity (BDCVA), uncorrected distance (UCDVA), intermediate (UCIVA), and near visual acuity (UCNVA), absolute rotation since implantation, and rotational stability

B. Accountability of PMA Cohort

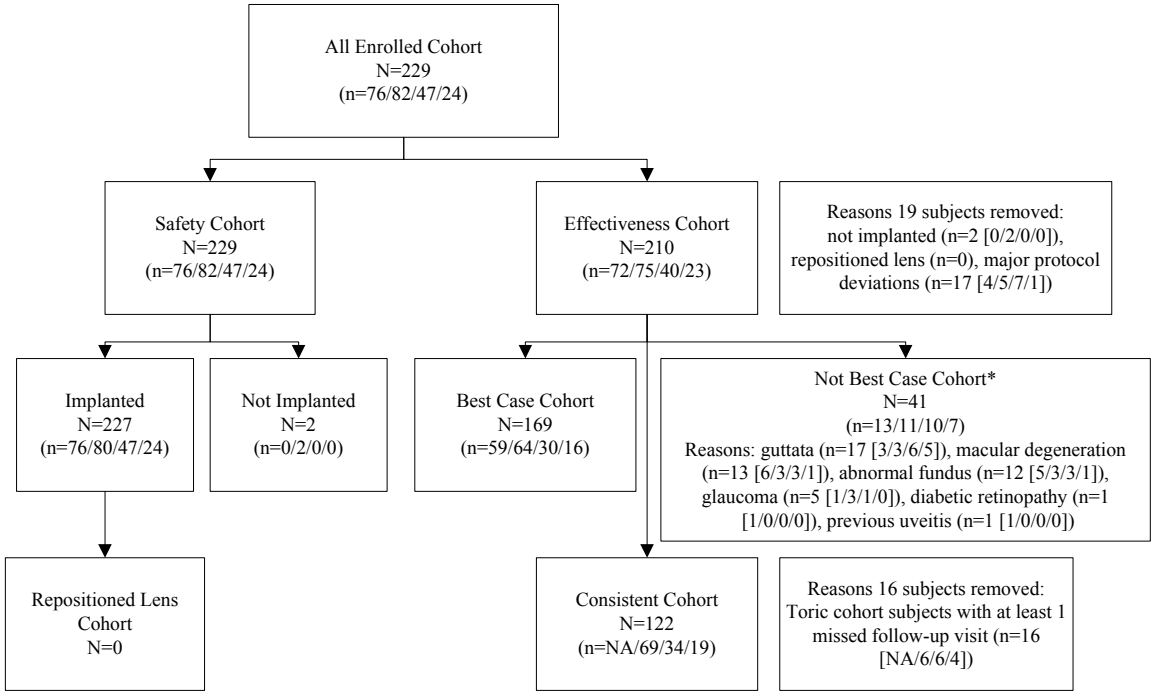
At the time of database lock, of the 229 subjects enrolled (227 implanted) in PMA study, 212 subjects (92.6%) were available for analysis at the completion of the study, the 330-420 days postoperative visit. Refer to **Table 4** below for subject accountability by each scheduled visit.

Table 4: Accountability of Subjects at Each Form Visit (All Enrolled)

Subject Status	Preop Exam n (%)	Op Report n (%)	Form 1 n (%)	Form 2 n (%)	Form 3 n (%)	Form 4 n (%)	Form 5 n (%)	Form 6 n (%)
Available for Analysis	229 (100.0)	229 (100.0)	227 (99.1)	223 (97.4)	219 (95.6)	219 (95.6)	215 (93.9)	212 (92.6)
Discontinued	0	0	2 (0.9)	3 (1.3)	3 (1.3)	3 (1.3)	5 (2.2)	10 (4.4)
Missing at scheduled visit but seen later	0	0	0	3 (1.3)	7 (3.1)	6 (2.6)	5 (2.2)	2 (0.9)
Not seen but accounted for	0	0	0	0	0	0	2 (0.9)	1 (0.4)
Lost to follow-up	0	0	0	0	0	1 (0.4)	2 (0.9)	4 (1.7)
Active	0	0	0	0	0	0	0	0
Percent Accountability			(100.0)	(98.7)	(96.9)	(96.9)	(96.0)	(96.8)

Notes: Percentages are based on the number of enrolled subjects.
Percent accountability = 100 x Available for Analysis / (Enrolled - Discontinued - Active)

The figure below displays a breakdown of the analysis populations used in this study: All Enrolled Cohort, Safety Cohort, Repositioned Lens Cohort, Effectiveness Cohort, Best Case Cohort, Not Best Case Cohort, and Consistent Cohort.



*A total of 41 subjects who reported 49 ocular or corneal pathologies were included in the Not Best Case Cohort.
Notes: n=Control/Toric 1.25 D/Toric 2.00 D/Toric 2.75 D IOL.

C. Study Population Demographics and Baseline Parameters

The demographics (**Table 5**) of the study population are typical for an IOL study performed in the US. In total, 106 subjects were male, and 123 subjects were female. The mean age for subjects in the Control Cohort was 69.8 years and the mean age for subjects in the All Toric Cohort was 70.1 years. The age range for all subjects was 47 to 89 years. With regard to gender, the majority for both cohorts were female, with 55.3% and 52.9% in the Control and All Toric Cohorts, respectively.

Table 5: Demographics (All Enrolled)

	Control IOL (N=76)	Toric IOL 1.25 D (N=82)	Toric IOL 2.00 D (N=47)	Toric IOL 2.75 D (N=24)	All Toric IOL (N=153)
Age (years)					
Total Non-Missing	76	82	47	24	153
Mean (SD)	69.8 (9.2)	69.9 (8.8)	70.4 (8.4)	70.4 (10.8)	70.1 (9.0)
Median	71.0	70.0	70.0	73.0	70.0
Min, Max	47, 89	48, 88	52, 89	51, 86	48, 89
< 60	13 (17.1%)	8 (9.8%)	3 (6.4%)	5 (20.8%)	16 (10.5%)
60 to 69	20 (26.3%)	32 (39.0%)	20 (42.6%)	5 (20.8%)	57 (37.3%)
70 to 79	34 (44.7%)	27 (32.9%)	15 (31.9%)	7 (29.2%)	49 (32.0%)
≥ 80	9 (11.8%)	15 (18.3%)	9 (19.1%)	7 (29.2%)	31 (20.3%)
Gender					
Total Non-Missing	76	82	47	24	153
Male	34 (44.7%)	35 (42.7%)	27 (57.4%)	10 (41.7%)	72 (47.1%)
Female	42 (55.3%)	47 (57.3%)	20 (42.6%)	14 (58.3%)	81 (52.9%)
Operative Eye					
Total Non-Missing	76	82	47	24	153
OD	42 (55.3%)	37 (45.1%)	25 (53.2%)	12 (50.0%)	74 (48.4%)
OS	34 (44.7%)	45 (54.9%)	22 (46.8%)	12 (50.0%)	79 (51.6%)

D. Safety and Effectiveness Results

1. Safety Results

   The analysis of safety was based on the Safety cohort of 227 implanted subjects and 2 not implanted subjects who underwent surgery for the implantation of a study lens (either test or control). The key safety outcomes for this study are presented in tables 2 and 3. Adverse effects are reported in **Tables 6 – 7** below.

Adverse effects that occurred in the PMA clinical study:

Table 6: ISO 11979-7 SAFETY AND PERFORMANCE ENDPOINTS (SPE) ADVERSE EVENTS REPORTED AT EACH POSTOPERATIVE VISIT, IMPLANTED SUBJECTS (SAFETY, CONTROL IOL)

Adverse Event	Unscheduled n/N (%)	Form 1 n/N (%)	Form 2 n/N (%)	Form 3 n/N (%)	Form 4 n/N (%)	Form 5 n/N (%)	Form 6 n/N (%)	Cumulative n/N (%)	ISO SPE (%)	p-value
Cumulative										
Endophthalmitis	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.1	>0.999
Hypopyon	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.3	>0.999
Lens Dislocated From Posterior Chamber	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.1	>0.999
Macular Edema	0/44	0/76	0/75	1/74 (1.4)	1/73 (1.4)	0/70	0/69	1/76 (1.3)	3.0	0.901
Pupillary Block	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.1	>0.999
Retinal Detachment	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.3	>0.999
Secondary Surgical Intervention	0/44	0/76	1/75 (1.3)	0/74	0/72	1/70 (1.4)	0/69	2*/76 (2.6)	0.8	0.124
Persistent										
Corneal Edema								0/69	0.3	>0.999
Iritis								0/69	0.3	>0.999
Macular Edema								0/69	0.5	>0.999
Raised IOP Requiring Treatment								0/69	0.4	>0.999

*Reason for secondary surgical intervention (SSI): 1) IOL reposition due to IOL malposition; 2) IOL Exchange.

Table 7: ISO 11979-7 SPE ADVERSE EVENTS REPORTED AT EACH POSTOPERATIVE VISIT, IMPLANTED SUBJECTS (SAFETY, ALL TORIC IOL)

Adverse Event	Unscheduled n/N (%)	Form 1 n/N (%)	Form 2 n/N (%)	Form 3 n/N (%)	Form 4 n/N (%)	Form 5 n/N (%)	Form 6 n/N (%)	Cumulative n/N (%)	ISO SPE (%)	p-value
Cumulative										
Endophthalmitis	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.1	>0.999
Hypopyon	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.3	>0.999
Lens Dislocated From Posterior Chamber	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.1	>0.999
Macular Edema	0/77	0/151	0/148	1/145 (0.7)	1/147 (0.7)	0/145	0/143	1/151 (0.7)	3.0	0.990
Pupillary Block	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.1	>0.999
Retinal Detachment	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.3	>0.999
Secondary Surgical Intervention	0/77	0/151	0/148	0/145	1/147 (0.7)	0/145	0/143	1*/151 (0.7)	0.8	0.703
Persistent										
Corneal Edema								0/143	0.3	>0.999
Iritis								0/143	0.3	>0.999
Macular Edema								0/143	0.5	>0.999
Raised IOP Requiring Treatment								0/143	0.4	>0.999
*Reason for SSI: Reposition of IOL (2.00 D Cohort) not related to lens axis misalignment or rotation.										

2. Effectiveness Results

The analysis of effectiveness was based on the 210 subjects who were implanted with a study lens (either Test or Control), whose lens was not repositioned, and who had no major protocol deviations. Key effectiveness outcomes are presented in tables 1 to 18.

The results achieved by 227 subjects followed postoperatively for six months provide data to support the conclusion that eyes implanted with a Trulign™ Toric IOL following cataract extraction achieve visual correction of aphakia and astigmatism.

The data support a reduction in absolute cylinder, rotational stability of the lens, and improvement of uncorrected visual acuity at distance following implantation of Trulign™ Toric IOL.

One of the primary effectiveness endpoints was the mean percent reduction in absolute cylinder. The percent reduction in absolute cylinder is defined as the difference between the postoperative magnitude of the subjective Manifest Refractive cylinder (converted to the corneal plane) and the preoperative magnitude of the keratometric cylinder, divided by the intended reduction in cylinder expressed as a percentage. The intended reduction in cylinder is the difference between the "intended" magnitude of the postoperative Manifest Refractive cylinder (converted to the corneal plane) and the magnitude of the preoperative keratometric cylinder. When comparing the mean (SD) for the Control Cohort 46.5% (43.8%) to that of the 1.25 toric Cohort 79.9% (31.8%), a statistically significant difference ($p < 0.001$) was demonstrated. The mean (SD) percent reduction of cylinder for the 2.00 toric Cohort was 88.0% (27.1%); for the 2.75 toric Cohort it was 97.4% (19.2%), and for the all toric cohort it was 85.0% (29.3%).

The percent of eyes within 0.50D and 1.00D of intended correction for the Trulign™ Toric Posterior Chamber Intraocular Lens was 78.4% and 95.5%, respectively. The minimum preoperative keratometric cylinder treated was 1.33 D. The results are shown in **Table 8**. Preservation of best-corrected visual acuity show 98.0% and 100.0% of eyes implanted with a toric lens reported a VA of 20/40 or better at six months at distance and near, respectively. All visual acuity results are presented in **Tables 9 - 17**. The rotational stability of the toric lens was demonstrated in a cohort of subjects across the Form 3 to Form 4 (1-2 months to 3-6 months) postoperative intervals. One hundred percent (122/122 eyes) of subjects demonstrated less than or equal to 5 degrees of rotation between

Consecutive Visits. Additionally, 96.1% of eyes exhibited rotation of less than or equal to 5 degrees between the day of surgery and the Form 4 visit, demonstrating rotational stability in the early postoperative period. The results are shown in **Table 18**. No eyes (0%, 0/20) in the highest available cylinder correction (2.75D) reported significant visual disturbances through Form 4. The results are shown in **Table 19**.

The data provided below includes all subjects enrolled in Clinical Trial 650, including 4 eyes with the control lens AT52, and 6 eyes with the test lens AT52T. Please note, the AT52T is not approved.

TABLE 8

PERCENT OF EYES WITH REDUCTION IN CYLINDER WITHIN 0.50 D AND 1.00 D OF INTENDED – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
Total Non-Missing	68	74	39	21	134
Within 0.50 D of Intended	30 (44.1%)	59 (79.7%)	31 (79.5%)	15 (71.4%)	105 (78.4%)
Within 1.00 D of Intended	49 (72.1%)	71 (95.9%)	36 (92.3%)	21 (100.0%)	128 (95.5%)

TABLE 9

PRESERVATION OF BCDVA AT EACH EXAMINATION (ALL TORIC IOLS, IMPLANTED SAFETY SUBJECTS)

	Preop	Form 3	Form 4	Form 5	Form 6	Unscheduled
20/40 or Better	108 (72.0%)	143 (99.3%)	144 (98.0%)	143 (98.6%)	141 (98.6%)	39 (97.5%)
Worse than 20/40	42 (28.0%)	1 (0.7%)	3 (2.0%)	2 (1.4%)	2 (1.4%)	1 (2.5%)

TABLE 10

PRESERVATION OF BEST CORRECTED NEAR VISUAL ACUITY (BCNVA) AT EACH EXAMINATION (ALL TORIC IOLS, IMPLANTED SAFETY SUBJECTS)

	Preop	Form 3	Form 4	Form 5	Form 6	Unscheduled
20/40 or Better	124 (89.2%)	141 (98.6%)	147 (100.0%)	142 (98.6%)	142 (99.3%)	30 (100.0%)
Worse than 20/40	15 (10.8%)	2 (1.4%)	0	2 (1.4%)	1 (0.7%)	0

TABLE 11

DISTANCE CORRECTED INTERMEDIAT VISUAL ACUITY (DCIVA) AT 32 INCHES (80 CM) – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
DCIVA (logMAR)					
Total Non-Missing	67	74	38	21	133
Mean (SD)	0.074 (0.142)	0.060 (0.107)	0.059 (0.149)	0.024 (0.139)	0.054 (0.125)
DCIVA (Snellen)					
20/40 or Better	64 (95.5%)	74 (100.0%)	38 (100.0%)	21 (100.0%)	133 (100.0%)
Worse than 20/41	3 (4.5%)	0	0	0	0

TABLE 12

DCNVA AT 16 INCHES (40 CM) – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
DCNVA (logMAR)					
Total Non-Missing	67	74	38	21	133
Mean (SD)	0.309 (0.138)	0.308 (0.130)	0.310 (0.154)	0.258 (0.172)	0.301 (0.144)
DCNVA (Snellen)					
20/40 or Better	42 (62.7%)	47 (63.5%)	22 (57.9%)	16 (76.2%)	85 (63.9%)
Worse than 20/41	25 (37.3%)	27 (36.5%)	16 (42.1%)	5 (23.8%)	48 (36.1%)

TABLE 13

DCNVA AT 16 INCHES (40 CM) WITH ADD – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
DCNVA with Add (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.045 (0.072)	0.039 (0.075)	0.031 (0.066)	0.038 (0.074)	0.036 (0.072)
DCNVA with Add (Snellen)					
20/40 or Better	68 (100.0%)	74 (100.0%)	39 (100.0%)	21 (100.0%)	134 (100.0%)
Add (D)					
Mean (SD)	1.599 (0.575)	1.473 (0.451)	1.423 (0.494)	1.405 (0.599)	1.448 (0.486)

TABLE 14

BCDVA WITHOUT GLARE – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
BCDVA (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.012 (0.094)	0.003 (0.073)	-0.003 (0.076)	0.019 (0.180)	0.004 (0.097)
BCDVA (Snellen)					
20/40 or Better	68 (100.0%)	74 (100.0%)	39 (100.0%)	20 (95.2%)	133 (99.3%)
Worse than 20/41	0	0	0	1 (4.8%)	1 (0.7%)

TABLE 15

UCDVA – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
UCDVA (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.189 (0.181)	0.099 (0.140)	0.082 (0.119)	0.091 (0.130)	0.093 (0.132)
UCDVA (Snellen)					
20/40 or Better	51 (75.0%)	71 (95.9%)	39 (100.0%)	21 (100.0%)	131 (97.8%)
Worse than 20/41	17 (25.0%)	3 (4.1%)	0	0	3 (2.2%)

TABLE 16

UCIVA – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
UCIVA (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.069 (0.153)	0.044 (0.116)	0.058 (0.155)	0.004 (0.117)	0.042 (0.129)
UCIVA (Snellen)					
20/40 or Better	64 (94.1%)	73 (98.6%)	37 (94.9%)	21 (100.0%)	131 (97.8%)
Worse than 20/41	4 (5.9%)	1 (1.4%)	2 (5.1%)	0	3 (2.2%)

TABLE 17

UCNVA – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
UCNVA (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.286 (0.137)	0.284 (0.155)	0.310 (0.142)	0.268 (0.149)	0.289 (0.150)
UCNVA (Snellen)					
20/40 or Better	49 (72.1%)	53 (71.6%)	24 (61.5%)	17 (81.0%)	94 (70.1%)
Worse than 20/41	19 (27.9%)	21 (28.4%)	15 (38.5%)	4 (19.0%)	40 (29.9%)

TABLE 18

ROTATIONAL STABILITY BETWEEN CONSECUTIVE VISITS – FORM 4 (CONSISTENT)

	Toric IOL 1.25 D (N=69)	Toric IOL 2.00 D (N=34)	Toric IOL 2.75 D (N=19)	All Toric IOL (N=122)
Absolute Value of Rotation (°)				
Total Non-Missing	69	34	19	122
Mean (SD)	1.074 (0.966)	1.166 (0.906)	1.537 (1.406)	1.172 (1.034)
Lenses Rotating ≤5° Since Last Visit	69 (100.0%)	34 (100.0%)	19 (100.0%)	122 (100.0%)

TABLE 19

Subjects Experiencing One or More Significant Visual Disturbances – Form 4

(Effectiveness, Subjects Whose Lens Was Not Repositioned)

	Control IOL (N=72) n(%)	Toric IOL 1.25 D (N=75) n(%)	Toric IOL 2.00 D (N=40) n(%)	Toric IOL 2.75 D (N=23) n(%)	All Toric IOL (N=138) n(%)
Total Non-Missing	66	74	39	20	133
Significant Visual Disturbance	6 (9.1)	0	1 (2.6)	0	1 (0.8)
No Significant Visual Disturbance	60 (90.9)	74 (100.0)	38 (97.4)	20 (100.0)	132 (99.2)

3. Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes device effectiveness across the range of preoperative corneal astigmatism (**Tables 20-24**). **Tables 25-26** provide information on the predictive error of the Trulign™ Toric IOL calculator. **Table 27** shows the dioptric change in cylinder (D) by IOL cylinder power including control.

TABLE 20

Percentage Reduction of Cylinder (ANSI) Stratified by Predicted Postoperative Corneal Cylinder

Predicted Postoperative Corneal Cylinder (D)	Percentage Reduction of Cylinder (ANSI)	
	Toric IOL 1.25 D (n) mean	Sphere IOL (n) mean
0.83 to 1.07	(45) 77.52	(51) 44.59
1.08 to 1.32	(29) 83.55	(17) 52.23

Notes: Percentage reduction of cylinder (ANSI) = percentage of intended reduction achieved from preoperative keratometric cylinder to postoperative manifest cylinder

TABLE 21

Percent Reduction of Preoperative Corneal Cylinder Stratified By Preoperative Keratometric Cylinder

	Percent Reduction of Cylinder	
Preoperative Keratometric Cylinder (D)	Toric IOL 1.25 D (n) mean	Sphere IOL (n) mean
1.33 to 1.57	(43) 71.12	(50) 41.23
1.58 to 1.82	(29) 65.50	(17) 41.33

Notes: Percent reduction of cylinder = (preoperative keratometric cylinder – postoperative refractive cylinder) / preoperative keratometric cylinder

TABLE 22

Refractive cylinder stratified by preoperative keratometric cylinder

	Magnitude of Refractive Cylinder (D)	
Preoperative Keratometric Cylinder (D)	Toric IOL 1.25 D n mean	Sphere IOL n mean
1.33 to 1.57	43 0.41	50 0.86
1.58 to 1.82	29 0.59	17 1.01

TABLE 23

logMAR uncorrected distance visual acuity (UCDVA) stratified by preoperative keratometric cylinder

	logMAR UCDVA	
Preoperative Keratometric Cylinder (D)	Toric IOL 1.25 D n mean	Sphere IOL n mean
1.33 to 1.57	43 0.10	50 0.20
1.58 to 1.82	29 0.11	17 0.16

TABLE 24

Change in absolute cylinder stratified by preoperative keratometric cylinder

Preoperative Keratometric Cylinder (D)	Change in Absolute Cylinder (D)	Toric IOL 1.25 D	Sphere IOL
1.33 to 1.57	Total Non-Missing	43	50
	Mean (SD)	-1.020 (0.407)	-0.573 (0.609)
	Median	-1.010	-0.610
	Min, Max	-1.52, 0.14	-1.56, 1.23
	< 0.50 D	43 100.0%	48 96.0%
	> 0.50 D	0	2 4.0%
	≤± 0.50 D	6 14.0%	21 42.0%
	>-0.50 D	6 14.0%	23 46.0%
	<-0.50 D	37 86.0%	27 54.0%
	<-0.75 D	33 76.7%	22 44.0%
	<-1.00 D	22 51.2%	11 22.0%
	Missing	0	0
1.58 to 1.82	Total Non-Missing	29	17
	Mean (SD)	-1.104 (0.454)	-0.679 (0.564)
	Median	-1.100	-0.780
	Min, Max	-1.81, 0.16	-1.69, 0.49
	< 0.50 D	29 100.0%	17 100.0%
	> 0.50 D	0	0
	≤± 0.50 D	3 10.3%	6 35.3%
	>-0.50 D	3 10.3%	6 35.3%

Preoperative Keratometric Cylinder (D)	Change in Absolute Cylinder (D)	Toric IOL 1.25 D	Sphere IOL
1.58 to 1.82 (Continued)	Total Non-Missing	29	17
	<-0.50 D	26 89.7%	11 64.7%
	<-0.75 D	25 86.2%	9 52.9%
	<-1.00 D	20 69.0%	4 23.5%
	Missing	0	0

Notes: Change in absolute cylinder = |postoperative refractive cylinder| - |preoperative keratometric cylinder|

TABLE 25

Error in the predicted postoperative keratometric astigmatism at 120 to 180 days after surgery

	Randomized Eyes (N=150)
Signed Bias versus Predicted (D)	
Total Non-Missing	141
Mean (SD)	0.132 (0.398)
Median	0.120
Min, Max	-0.78, 1.24
Absolute Error (D)	
Total Non-Missing	141
Mean (SD)	0.335 (0.250)
Median	0.270
Min, Max	0.01, 1.24

TABLE 26

Error in the predicted postoperative keratometric steep axis at 120 to 180 days after surgery

	Randomized Eyes (N=150)
Signed Bias versus Predicted (degrees)	
Total Non-Missing	141
Mean (SD)	-0.1 (17.9)
Median	-1.0
Min, Max	-49, 88
Absolute Error (degrees)	
Total Non-Missing	141
Mean (SD)	11.7 (13.6)
Median	7.0
Min, Max	0, 88

TABLE 27

Dioptric change in cylinder (D) by IOL cylinder power including control

	Sphere	Toric 1.25D	Toric 2.00D	Toric 2.75D
N	68	74	39	21
Mean (SD)	-0.61 (0.59)	-1.06 (0.42)	-1.61 (0.50)	-2.27 (0.45)
Median	-0.64	-1.07	-1.73	-2.37
Min, Max	-1.69, 1.23	-1.81, 0.16	-2.11, 0.46	-2.93, -1.34

Notes: Dioptric change in cylinder = |postoperative manifest cylinder| - |preoperative keratometric cylinder|

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 9 investigators, of which none were full-time or part-time employees of the applicant and 3 investigators had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Significant payment of other sorts: 3 investigators

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

A. Panel Meeting Recommendation

At an advisory meeting held on April 8, 2013. The Ophthalmic Devices Advisory Panel voted 10/0/2 that there is reasonable assurance the Trulign™ Toric IOL is safe, 10/1/1 that there is reasonable assurance that the device is effective, and 10/1/1 that the benefits of the device do outweigh the risks in subjects who meet the criteria specified in the proposed indication. The panel consensus was that the evidence supported device safety and the effectiveness of the lens in providing astigmatic correction and providing improved intermediate vision, as well as some benefit to near vision. However, in panel discussions regarding the accommodative ability of the lens, including published literature and clinical trial data, the panel did not believe that the data available supported the claim that this IOL provides approximately one diopter of accommodation.

B. FDA's Post-Panel Action

The panel discussed the evidence concerning the accommodative ability of the lens including published literature and clinical trial data. They did not believe that the data available supported the claim that this IOL provides approximately one diopter of accommodation. Therefore, statements related to "accommodation" were removed from the labeling.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Significant reduction of astigmatism was achieved for all models. The Trulign™ Toric IOL astigmatic correction combined with the incisional effects of the cataract surgery provided on average about 85% of the intended astigmatic correction.

For the randomized portion of the trial (subjects qualifying for the lowest cylinder power correction), the mean percent reduction in astigmatism (compared to the intended) was ~80% for the toric IOL arm compared to 46% for the control spherical IOL arm. It is important to note that part of this reduction was due to incisional effects of the procedure.

The percent of eyes within 0.50D and 1.00D of intended correction for the Trulign™ Toric Posterior Chamber Intraocular Lens was 78.4% and 95.5%, respectively.

Approximately 96% of eyes exhibited rotation of less than or equal to 5 degrees between the day of surgery and the 6 month visit.

In general, good best-corrected distance visual acuities and good uncorrected distance visual acuities were seen in all Trulign™ IOL cylinder powers studied.

B. Safety Conclusions

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

Potential AEs and complications accompanying cataract and IOL implantation surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), inflammation, retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, iris prolapse, hypopyon, elevated intraocular pressure (IOP) requiring treatment, and secondary surgical intervention. Because of the design of the Trulign™ Toric IOL, the device can vault forward and get stuck in a forward or tilted position.

The main serious AEs specifically related to use of a toric device, is the potential for secondary surgery to correct IOL misalignment (rotation). In addition, while not considered an AE, there is risk of a poor uncorrected acuity outcome, if there is significant IOL rotation. The secondary surgery generally provides improved uncorrected visual acuity in the event of IOL rotation. However, it is not required for ocular health or acceptable vision, as the eye can generally achieve good acuity with spectacle correction.

Visual distortion is a theoretical potential visual symptom related to toric IOL rotation. It can vary in perceived severity and is most likely to be of limited duration. If very severe and persistent, a patient might request secondary surgery to remove the IOL (a more serious adverse event), but this result was not seen. In addition, because of the small optic, there is potential for visual symptoms such as glare or halos from stray light.

Potential SSIs can include, but are not limited to, lens repositioning (due to vaulting, decentration, rotation, subluxation, etc.), lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, retinal detachment repair, corneal transplant, and lens replacement due to refractive error or severe inflammation.

All safety endpoints of Study 650 were met. The Trulign™ Toric IOL demonstrated preservation of BCDVA and BCNVA, and the incidences of complications and AEs reported for the All Toric population did not exceed the ISO 11979-7 SPE rates of historical controls or those reported with the parent Crystalens IOL, Model AT45 (PMA P030002). No SSIs were related to rotational instability.

C. Benefit-Risk Conclusions

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The results from Study 650 demonstrate that the Trulign™ Toric IOL is a safe and effective option for cataract patients with astigmatism who, with the counsel of their surgeon, select the Trulign™ Toric IOL. This may reduce the need for patients to pursue spectacle, contact lens, or other refractive correction. These findings support a favorable risk-benefit ratio for visual correction of aphakia and astigmatism with the Trulign™ Toric IOL.

In conclusion, given the available information above, the data support that for primary implantation in the capsular bag of the eye for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia who desire reduction of residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate and distance vision, the probable benefits 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 data and information provided in PMA P030002/S027 support the safety and effectiveness of the Trulign™ Toric IOL. Under controlled clinical investigation (Study 650), the Trulign™ Toric IOL met or exceeded the safety and effectiveness endpoints established for the trial. The Trulign™ Toric IOL demonstrated rotational stability with favorable effectiveness and safety compared with the Control IOL and

the historical control (ISO 11979-7 SPE) population. The Trulign™ Toric IOL provides correction of astigmatism in a single procedure. The Trulign™ Toric IOL provides distance and intermediate vision, and improved near vision. These findings support the safe and effective use of the Trulign™ Toric IOL in the proposed patient population.

XIII. CDRH DECISION

CDRH issued an approval order on May 20, 2013. The final conditions of approval cited in the approval order are described below.

Trulign™ Toric IOL New Enrollment Study: The study will be a single arm, multi-site, prospective study with a sample size of 500 eyes at the end of 3 year follow-up. The specific question to be answered is the incidence of IOL vaulting (i.e., position change such as clinically significant anterior vaulting, clinically significant tilt, and secondary surgical intervention related to such vaulting) up to three years post implant. Follow-up assessments will occur at 1 day, 1 week, 1 month, 6 month, 1 year, and then every year until the 3rd year of follow-up. Data collection will include observations, symptoms, diagnosis, treatment, sequelae, and resolution.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.