SUMMARY OF SAFETY AND EFFECTIVENESS (SSED)

I. GENERAL INFORMATION

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

Device Trade Name: Akreos™

Applicant's Name and Address: Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609

Date(s) of Panel Recommendation: Not Applicable

Premarket Approval Application (PMA) Number: P060022

Date of FDA Notice of Approval: September 05, 2008

Expedited: Not applicable

II. INDICATIONS FOR USE

The Akreos™ is a posterior chamber intraocular lens indicated for primary implantation for the visual correction of aphakia in adult patients where a cataractous lens has been removed by phacoemulsification by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag.

III. CONTRAINDICATIONS

Implantation is not advisable when the intraocular lens (IOL) may aggravate an existing condition, interfere with the diagnosis or the treatment of a pathology, or present a risk to the sight of the patient. These conditions are uncontrolled glaucoma, rubeotic cataract, retinal detachment, atrophy of the iris, microphthalmia, developing chronic eye infections, endothelial corneal dystrophy, perioperative complications (such as vitreous loss, hemorrhage, etc.), and foreseeable post-operative complications.

IV. WARNINGS AND PRECAUTIONS

Warnings

1. Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

   A. Recurrent severe anterior or posterior segment inflammation or uveitis.
   B. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
   C. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).

D. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
E. Circumstances that would result in damage to the endothelium during implantation.
F. Suspected microbial infection.
G. Children under the age of 2 years are not suitable candidates for intraocular lenses.
H. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.

2. Since the clinical study for the Akreos™ intraocular lens was conducted with the lens being implanted in the capsular bag only, there are insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.
3. YAG laser posterior chamber capsulotomies should be delayed until at least 12 weeks after the implant surgery. The posterior capsulotomy opening should be kept as small as possible. There is an increased risk of lens dislocation and/or secondary surgical reintervention with early or large capsulotomies.
4. Improper handling or folding techniques may cause damage to the haptic or optic portions of Akreos™ foldable lenses. If lenses are not folded according to directions, optic tears may result (see **DIRECTIONS FOR USE**). Physicians should not attempt to implant lenses that have radial optic tears or separations.
5. Use of folding instruments other than those validated and recommended in the labeling might result in IOL damage (optic tears, haptic damage) that might require IOL explantation.
6. To avoid the creation of permanent forceps marks in the central optic zone, exercise care during handling and insertion of the lens. Read and follow the folding and insertion instructions carefully.

Precautions

1. Do not attempt to resterilize these lenses.
2. Do not store the IOL package in direct sunlight or at temperatures below freezing (<0° C). Store at room temperature. Avoid high temperatures (>45°C).
3. Do not implant the IOL If the outer pouch or vial is opened or damaged.
4. Do not reuse the IOL.
5. Do not soak or rinse lenses in solutions other than balanced salt solution or equivalent.
6. A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and/or assisted in numerous surgical implantations and should have completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
7. As with any surgical procedure, there is risk involved. Potential adverse events and 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.

8. The IOL should be used in the shortest possible time after opening the vial.
9. Do not implant the IOL if the lens is not completely immersed in solution under in vial orientation
10. Akreos™ IOLs can absorb substances that they contact (disinfectant, drug…). Do not place the lens in contact with surfaces where such contamination can occur.
11. If a YAG laser posterior capsulotomy is performed, assure that the laser beam is focused slightly behind the posterior capsule.

V. DEVICE DESCRIPTION

Akreos™ manufactured by Bausch & Lomb Incorporated is a one-piece optical implant for the replacement of the human crystalline lens in the visual correction of aphakia.

The Akreos™ Advanced Optics Aspheric lens has aspheric surfaces and is designed to be free of spherical aberration. Clinical studies have not been conducted with the Akreos™ Advanced Optics Aspheric lens to assess the effect of the added aspheric surface to the parent lens model Akreos™ on spherical aberration, visual acuity and contrast sensitivity.

The lenses are lathe cut from a hydrophilic acrylic co-polymer material and contain a UV absorber. The lens is designed to be folded prior to insertion. The overall length varies by power. The characteristics specific to each IOL are listed on the carton label.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

A patient may decide not to have an intraocular lens implanted. There are three principal methods of restoring useful vision 1) Cataract spectacles (glasses), 2) hard or soft contact lenses, and 3) intraocular lenses made of rigid plastic, soft silicone, or other suitable material (some with supports made of polyimide, polypropylene, PMMA, or other suitable material).

VII. MARKETING HISTORY

The Akreos™ and the Akreos™ Advance Optics Aspheric Lenses are currently approved for sale in over 20 countries in North America, South America, the European Union and Asia.

The Akreos™ and the Akreos™ Advance Optics Aspheric Lens have not been withdrawn from any market for reasons relating to safety and effectiveness of the device.

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: 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 clinical studies, please see Section X below.

IX. SUMMARY OF PRECLINICAL STUDIES

Bausch & Lomb performed non-clinical studies on this device in accordance with the ISO 11979 standards for intraocular lenses.

Biocompatibility Studies

Bausch & Lomb conducted a battery of *in vivo* and *in vitro* acute and chronic toxicity tests that establish the biocompatibility of the lens materials. The biocompatibility studies were performed in accordance with the requirements in ISO 11979-5 to establish a complete profile for the IOL material. The ocular implant test was waived due to previous long-term foreign clinical experience. Summaries of the biocompatibility tests conducted are listed in Table 1.

Table 1: Biocompatibility Testing

Biocompatibility Test	Results and Conclusion
Cytotoxicity: Cell Inhibition	No significant evidence of cell growth inhibition
Cytotoxicity: Agar Diffusion Test (Direct Contact)	No evidence of cell lysis or toxicity in the treated cells
Cytotoxicity: Agar Diffusion (Indirect Contact)	No evidence of cell lysis or toxicity in the extract treated cells
Cytotoxicty: MEM Elution	No evidence of cell lysis or toxicity
Maximization Sensitization	The extractants showed no evidence of causing sensitization in guinea pigs.
Mutagenicity: Bacterial Reverse Mutation Assay	Did not cause a positive increase in the mean number of revertants per plate
Genotoxicity: Chromosomal Aberration:	Induced no clastogenic activity in the *in vitro* human lymphocyte metaphase analysis
Non-Ocular Irritation and Sensitization:	Non-irritant in tissue
Ocular Implant Test	Waived – Human evidence of IOL material and ocular tissue tolerance based on clinical data in 30 patients with 1 year follow up.
Nd: YAG Laser Test	Nothing related to the IOL material was identified in the saline
Test of Extractables by Exhaustive Extraction	Clinically insignificant levels of extractables were identified.
Hydrolytic Stability	The IOL material was found to be stable (clinically insignificant levels of extractables found) in an aqueous environment for 5 years.
Photostability	The IOL material is stable (no appreciative degradation) when exposed to UV for up to

	18 years.
Discoloration	No Evidence of discoloration or light scatter

Laboratory Studies and Manufacturing

Data from engineering analyses demonstrate the suitability of the material and overall device design for use in intraocular lenses; these studies are summarized in Table 2. The adequacy of the manufacturing processes, including sterilization, was established through review of the manufacturing information in the PMA, as well as through on-site inspections.

Table 2: Laboratory Studies

Laboratory Studies	Test and Results
Surface Analysis	Average silicone content ≤1%
Optical	Clear Optic Diameter, Dioptric Power, Imaging quality/resolution and spectral transmittance passed the acceptance criteria All lenses had an MTF of 0.34 or better at 100lp/mm.
Mechanical :Dimensions	All dimensions were within the designed acceptance criteria
Mechanical: Optic decentration	All lenses had a decentration at a 10mm compression diameter of 0.053mm or less
Mechanical: Optic Tilt	The average optic tilt at the compressed diameter was 0.27°
Mechanical: Loop pull strength	The force to pull the haptics exceeded 1N.
Mechanical: Fold and Recovery Testing	Lenses were free of cosmetic defects and any permanent changes to the optical properties of the lens when held in a folded state in the AI-28 inserter and in forceps for a minimum of 3 minutes.
Mechanical: Surface and Bulk homogeneity	No lenses exhibited cosmetic defects

Sterilization, Packaging, Shelf Life and Transport Stability

The objective of the sterilization, shelf-life, and transport stability studies was to establish a complete microbiological profile for the Akreos™ Lens. The IOL is packaged in a glass vial in a lens holder, immersed in balanced salt solution, sealed with a screw top and gasket. The sealed vial is packaged in a Tyvek pouch and then terminally sterilized with moist heat. These tests were conducted in accordance with the following standards and pharmacopoeial chapters: ISO 11134, Sterilization of Health Care Products-Requirements for validation and routine control-Industrial moist heat sterilization, ISO 11737-1:1995 Sterilization of medical devices-Microbiological methods- Part 1: Estimation of a population of microorganisms on products, USP 23, <71>, 1995, bacteriostasis and fungistasis testing) ,USP 23, <71>, 1995, Bacterial endotoxin testing, ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, ASTM F-1929-8 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye penetration, ASTM F 2096-04, Detecting Gross Leaks in Medical Packaging by Internal Pressurization, ISO 11979-6 Ophthalmic Implants-Intraocular lenses part 6: Shelf-life and transport stability, ISTA Procedure 2A, Packaged-Products weighing 150 lb (68 kg) or Less, Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration and shock testing.

Table 3 summarizes the tests conducted to establish the microbiological profile of the packaged Akreos™ Lens.

Table 3: Sterilization, Packaging, Shelf Life & Transport Tests

Sterilization, Packaging, Shelf Life & Transport Tests	**Test Conclusions**
Presterilization bioburden test	The bioburden percent recovery was within acceptable limits.
Post sterilization Sterility Test	No microbial growth was detected
Bacterial endotoxin testing	Endotoxin levels were below the agency's recommended limit for medical devices.
Bacteriostasis and Fungistasis	No bacteriostatic / fungistatic effect observed.
Whole package Integrity Testing	No air bubbles are seen in the package
Microbial Barrier package Integrity Testing	All test samples were negative for growth
Dye Penetration testing	No penetration of dye into the package (no tears or punctures).
Stability (Shelf Life)	Results were satisfactory to support 3 years shelf life
Transport Stability	The results showed lenses would not be damaged during shipping.

Conclusions:
The overall results of the preclinical tests were acceptable from biocompatible, physiochemical, optical, mechanical and microbiological perspectives.

X. SUMMARY OF PRIMARY CLINICAL STUDY

Bausch & Lomb performed a clinical study to establish a reasonable assurance of safety and effectiveness of intraocular implantation with the Akreos™ posterior chamber intraocular lens for the visual correction of aphakia in adult patients where a cataractous lens has been removed by phacoemulsification in the US under IDE #G040035. 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

Patients were treated between 11/23/04 and 04/19/05. The database for this PMA reflected data collected through 04/25/06 and included 352 patients. There were 14 investigational sites.

The Akreos™ lens was evaluated in a 12-month, prospective, multi-center, clinical investigation to establish safety and effectiveness compared to historical literature controls, specifically the FDA "Grid" of cataract surgery results. In the past, the data reported in Stark, W. J., et al., The FDA Report on Intraocular Lenses, Ophthalmology, 90(4):311-317, 1983 has been used as an historical control. These data have been updated from recent PMA approved IOL experience for adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models.

Clinical studies have not been conducted with the Akreos™ Advanced Optics Aspheric lens to assess the effect of the added aspheric surface to the parent lens Model Akreos™ on spherical aberration, visual acuity and contrast sensitivity.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the **Akreos™** Posterior Chamber IOL study was limited to patients who met the following inclusion criteria:

   - Patients had a clinically documented diagnosis of age-related cataract (cortical, nuclear, subcapsular, or a combination) that was considered amenable to treatment with standard phacoemulsification/ extracapsular cataract extraction.
   - Patients were adults (≥ 18 years of age).
   - Patients were eligible to undergo primary intraocular lens implantation for the correction of aphakia following continuous curvilinear anterior capsulotomy and phacoemulsification cataract extraction.
   - Patients were willing and able to provide written consent on the IRB approved Informed Consent form.
   - Patients were willing and able to return for scheduled follow-up examinations for 330 to 420 days following surgery.
   - Patients required a lens power from 15 to 30 diopters.
   - Patients had a visual potential of 20/40 or better in the study eye.

   Patients were not permitted to enroll in the Akreos™ posterior chamber IOL study if they met any of the following exclusion criteria:

   - Patients who had best-corrected distance visual acuity of 20/200 or less in the fellow eye.
   - Patients with any 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 Fuchs' dystrophy, clinically significant anterior membrane dystrophy, etc.).
   - Any inflammation or edema (swelling) of the cornea, including but not limited to the following: keratitis, keratoconjunctivitis, and keratouveitis.
   - Patients with uncontrolled glaucoma or glaucoma under current treatment in the eye to be implanted.
   - Patients with previous retinal detachment.
   - Patients with diabetic retinopathy (proliferative or non-proliferative).
   - Patients with rubella, bilateral congenital, traumatic, or complicated cataract.
   - Patients with marked microphthalmos or aniridia.
   - Patients who have had previous ocular surgery in the planned operative eye.
   - Patients who have already received an Akreos™ lens in the fellow eye.
   - Females of childbearing potential (those who are not surgically sterilized or postmenopausal) are excluded from participation in the investigation if they meet any one of the following conditions:

- They are currently pregnant.
- They are breast-feeding.
- Irregular corneal astigmatism.
- Amblyopia.
- Clinically significant retinal pigment epithelium/Macular changes.
- Iris neovascularization.
- Recurrent severe anterior or posterior segment inflammation due to unknown etiology.
- Optic atrophy.
- Patients with immunodeficiency conditions.
- Patients with chronic use of systemic steroids or immunosuppressive medications.
- Patients concurrently participating in another clinical trial.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 1-2 days, 7-14 days, 30 to 60 days, 120-180 days, and 330 to 420 days postoperatively.

Preoperatively, patients scheduled to undergo cataract extraction and intraocular lens implantations were screened for eligibility, and eligible patients were evaluated to obtain a medical history and to establish a baseline for ocular condition.

Patients underwent small incision surgery, continuous curvilinear anterior capsulorhexis, extracapsular cataract extraction via phacoemulsification, and in-the-bag implantation of the Akreos™ intraocular lens. For each patient, only one eye had an IOL implanted as part of this investigation.

Postoperatively, patients 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. Adverse events and complications were recorded at all visits.

3. Clinical Endpoints

The safety endpoints were adverse event rates compared to historical controls, specifically the FDA "Grid" of cataract surgery results. In the past, the data reported in Stark, W. J., et al., The FDA Report on Intraocular Lenses, Ophthalmology, 90(4):311-317, 1983 has been used as an historical control. These data have been updated from recent PMA approved IOL experience for adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models.

The effectiveness endpoints were overall Best-Corrected Distance VA (% achieving 20/40 or better) and Best-Case Best-Corrected Distance VA (% achieving 20/40 or better) compared to historical controls.

B. Accountability of PMA Cohort

At the time of database lock, of 356 patients enrolled in PMA study, 92.4% (329) subjects are available for analysis at the completion of the study, the 12 month post-operative visit (Form 5). The patient accountability is detailed in Table 4.

Table 4: Patient Accountability Total Enrolled Patients

Total Enrolled = 395, Total With Operative Visit = 356

		Form (Days)				
Status	Op	1 (1-2)	2 (7-14)	3 (30-60)	4 (120-180)	5 (330-420)
Discontinued	39 (9.9%)	43 (10.9%)	43 (10.9%)	43 (10.9%)	48 (12.2%)	58 (14.7%)
Death	0	0	0	0	4 (1.0%)	8 (2.0%)
Retreated	0	0	0	0	0	0
Voluntary Withdraw	19 (4.8%)	19 (4.8%)	19 (4.8%)	19 (4.8%)	19 (4.8%)	23 (5.8%)
Screen Failure	17 (4.3%)	17 (4.3%)	17 (4.3%)	17 (4.3%)	17 (4.3%)	17 (4.3%)
Illness	2 (0.5%)	2 (0.5%)	2 (0.5%)	2 (0.5%)	3 (0.8%)	5 (1.3%)
Study Stopped Enrollment	1 (0.3%)	1 (0.3%)	1 (0.3%)	1 (0.3%)	1 (0.3%)	1 (0.3%)
Study IOL Not Implanted	0	4 (1.0%)	4 (1.0%)	4 (1.0%)	4 (1.0%)	4 (1.0%)
Not Eligible for Interval	0	0	0	0	0	0
Unavailable for Visit	0	0	16 (4.1%)	15 (3.8%)	19 (4.8%)	8 (2.0%)
Overdue	0	0	0	0	0	0
Missed Visit	0	0	16 (4.1%)	15 (3.8%)	19 (4.8%)	1 (0.3%)
Lost to Follow-up	0	0	0	0	0	7 (1.8%)
Available for Analysis	356 (90.1%)	352 (89.1%)	336 (85.1%)	337 (85.3%)	327 (82.8%)	329 (83.3%)
% Accountability		100.0%	95.5%	95.7%	94.2%	97.6%

% Accountability = Available for Analysis / (Number Enrolled – Discontinued – Not Eligible for Interval)

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an IOL study performed in the US. The population at risk for developing visually-disabling cataracts and needing cataract surgery is typically the elderly; the elderly population has a slightly higher proportion of females to males. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology; patients with pre-existing macular degeneration accounted for 2.25%, while patients with other pre-existing conditions accounted for 12.36%. In this study, all patients who met the inclusion criteria were included in the study.

Table 5: Patient Population Model Akreos™
N=356

Demographics	**n**	**%**
Age: mean +/- SD, Range	**70.9 ± 8.8 (35.0, 94.0)**	
< 60	31	8.71%
60 to 69	117	32.87%
Age		
70 to 79	152	42.70%
>= 80	56	15.73%
Total	**356**	**100.0%**
Sex		
Male	141	39.61%
Female	215	60.39%
Total	**356**	**100.0%**
Race		
White	329	92.42%
Black	13	3.65%
Asian	2	0.56%
Other	12	3.37%
Total*	**356**	**100.0%**
* Other included HISPANIC (n= 12).		

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on adverse event rates compared to historical controls, specifically the FDA "Grid" of cataract surgery results. In the past, the data reported in Stark, W. J., et al., The FDA Report on Intraocular Lenses, Ophthalmology, 90(4):311-317, 1983 has been used as an historical control. These data have been updated from recent PMA approved IOL experience for adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models. The key safety outcomes, cumulative and persistent adverse events, for this study are presented below in tables 6 and 7.

Adverse effects that occurred in the PMA clinical study:

Table 6: Cumulative Adverse Events [1]

Cumulative Adverse Event	Akreos™ Incidence (%) N=353	FDA Grid (%)
Hyphema	0.0	2.2
Macular Edema	1.4	3.0
Retinal Detachment	0.0	0.3
Pupillary Block	0.0	0.1
Lens Dislocation	0.0	0.1
Endophthalmitis	0.0	0.1
Hypopyon	0.0	0.3
Surgical Reintervention	0.0	0.8

[1] Cumulative: Occurring at any time during the study (for 353 patients)

Table 7: Persistent Adverse Events [2]

Persistent Adverse Event	Akreos™ Incidence (%) N=353	FDA Grid (%)
Macular Edema	0.3 (6[3])	0.5
Corneal Edema	0.9(3)	0.3
Iritis	0.3(1)	0.3
Raised IOP Requiring Treatment	0.6(2)	0.4

[2] Persistent: Present at the 1-year study visit (for 329 patients)
[3] One patient was counted for both cumulative and persistent macular forms.

2. Effectiveness Results

The analysis of effectiveness was based on visual acuity at the twelve-month time point. Key effectiveness outcomes are presented in tables 8 to 11. Of those patients implanted with the Akreos™ IOL 97.1% achieved a best corrected visual acuity and 96.4% overall visual acuity of 20/40 or better as compared to the FDA historical controls of 96.7% and 92.5% respectively. The rates for both overall and best-case 20/40 or better visual acuity for the cohort population exceed the FDA grid values.

Table 8: Best Corrected Visual Acuity at One Year
Best Case Patients[3,4]
Model Akreos™
N=329

				20/20 or better		20/21 to 20/25		20/26 to 20/30		20/31 to 20/40		20/40 or Better		20/41 to 20/80		20/81 to 20/100		20/101 to 20/200		Worse than 20/200		
Age Group	Total	Not Reported	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	P-val for H0
<60	23	0	23	15	65.2	5	21.7	1	4.3	1	4.3	22	95.7	1	4.3	0	0.0	0	0.0	0	0.0	0.5873
60 to 69	100	0	100	52	52.0	33	33.0	9	9.0	5	5.0	99	99.0	1	1.0	0	0.0	0	0.0	0	0.0	0.2625
70 to 79	117	0	117	53	45.3	32	27.4	19	16.2	10	8.5	114	97.4	3	2.6	0	0.0	0	0.0	0	0.0	>0.9999
80 & older	39	0	39	12	30.8	13	33.3	8	20.5	3	7.7	36	92.3	3	7.7	0	0.0	0	0.0	0	0.0	0.6621
Total	279	0	279	132	47.3	83	29.7	37	13.3	19	6.8	271	97.1	8	2.9	0	0.0	0	0.0	0	0.0	0.8522

[3]Best Case: Excludes patients with preoperative ocular pathology, or macular degeneration at any time.
[4]Manifest refractions were performed at 14 feet rather than 20 feet for all patients at 1 study site (25 patients). After Form 3 (30-60 days post-op), a correction of -0.25D was added to the manifest refraction to ensure that measured BCVA was not impacted by this procedural deviation. BCVA at visits through Form 3 may be lower than actual BCVA achieved.

Table 9: Best Case Visual Acuity 20/40 or better best corrected

Age Group	Model Akreos™	FDA Grid
<60	95.7	98.5
60 to 69	99.0	96.5
70 to 79	97.4	97.5
Age 80 & Older	92.3	94.8
Total	97.1	96.7

Table 10: Best Corrected Visual Acuity at One Year
All Enrolled Patients[4,5]
Model Akreos™
N=329

				20/20 or better		20/21 to 20/25		20/26 to 20/30		20/31 to 20/40		20/40 or Better		20/41 to 20/80		20/81 to 20/100		20/101 to 20/200		Worse than 20/200		
Age Group	Total	Not Reported	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	P-val for H0
<60	25	0	25	15	60.0	6	24.0	1	4.0	1	4.0	23	92.0	1	4.0	0	0.0	1	4.0	0	0.0	0.1926
60 to 69	110	0	110	54	49.1	36	32.7	10	9.1	7	6.4	107	97.3	3	2.7	0	0.0	0	0.0	0	0.0	0.5981
70 to 79	142	0	142	61	43.0	39	27.5	27	19.0	11	7.7	138	97.2	4	2.8	0	0.0	0	0.0	0	0.0	0.0776
80 & older	52	0	52	16	30.8	15	28.8	13	25.0	5	9.6	49	94.2	3	5.8	0	0.0	0	0.0	0	0.0	0.1331
Total	329	0	329	146	44.4	96	29.2	51	15.5	24	7.3	317	96.4	11	3.3	0	0.0	1	0.3	0	0.0	0.0057

[5]24 patients had YAG capsulotomies, 5 occurring before Form 4 (120-180 days post-op). YAG capsulotomy is expected to produce an improvement in visual outcome compared to the pre-YAG visual acuity.

Table 11: Overall Visual Acuity 20/40 or better, best corrected

Age Group	Model Akreos™	FDA Grid
<60	92.0%	97.9%
60 to 69	97.3%	95.7%
70 to 79	97.2%	93.4%
Age 80 & Older	94.2%	86.5%
Total	96.4%	92.5%

XI. 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 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.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety Conclusions

The Akreos™ cumulative and persistent adverse event rates at 12 months are lower than the FDA historical control grids in all areas except macular edema, corneal edema, and raised IOP requiring treatment, but these rates are not statistically significantly different from the FDA grid rates.

B. Effectiveness Conclusions

Patients implanted with the Akreos™ IOL achieved a visual acuity of 20/40 or better. The rates for both overall and best-case 20/40 or better visual acuity for the cohort population exceed the FDA grid values.

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 for the visual correction of aphakia in adults in whom a cataractous lens has been removed by phacoemulsification by extracapsular cataract extraction.

The risks associated with eye surgery and implantation of this intraocular lens included corneal and macular edema, iritis, and increased intraocular pressure.

Yet there is an important benefit of restoring sight using a biocompatible permanent implant in an eye, previously obstructed by a cataractous lens. It is reasonable to conclude that the benefits of use of the lens for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use.

XIII. CDRH DECISION

CDRH issued an approval order on September 05, 2008. The final conditions of approval cited in the approval order are described below.

Add the conditions of approval – change to 3rd person.

The applicant's manufacturing facility(ies) was/were inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

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.

XV. REFERENCES

1. Barrett GD. A new hydrogel intraocular lens design. J Cataract Refract Surg. 1994; 20: 18-25
2. Dick HB. Capsular bag diameter: effect on IOL design. Symposium on cataract, IOL and refractive surgery. April-May 2001, abstract 604.
3. Hayashi H, Hayashi K, Nakao F, Hayashi F. Quantitative comparison of posterior capsule opacification after polymethylmethacrylate, silicone and soft acrylic intraocular lens implantation. Arch Ophthalmol. 1998; 116 : 1579-82

4. Lim JS. Analysis of zonular-free zone and lens size in relation to axial length of eye with age. J Cataract Refract Surg. 1998 ; 24 : 390-6
5. Oshika T, Suzuki Y, Hirofumi K, Yaguchi S. Two year clinical study of a soft acrylic intraocular lens. J Cataract Refract Surg. 1996 Jan/Feb ; 22 : 104-9
6. Vass C. Prediction of pseudophakic capsular bag diameter based on biometric variables. J Cataract Refract Surg. 1999;25 : 1376-81