SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

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

Device Trade Name: LENSTEC Softec HD Aspheric Posterior Chamber Intraocular Lens

Applicant's Name and Address:

Lenstec Inc.
1765 Commerce Ave N
St. Petersburg, Florida 33716

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P090022

Date of FDA Notice of Approval: April 12, 2010

Expedited: Not applicable

II. INDICATIONS FOR USE

The LENSTEC Softec HD Aspheric Posterior Chamber Intraocular Lens (IOL) is intended for the replacement of the human crystalline lens following phacoemulsification cataract removal in adults over the age of 21. The lens is indicated for capsular bag placement.

III. CONTRAINDICATIONS

Outside of general contraindications for ocular surgery, the following specific contraindications apply: Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal detachment, corneal decompensation, diabetic retinopathy, iris atrophy, perioperative complications, potential foreseeable post operative complications and other conditions which an ophthalmic surgeon might identify based on their experience.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Softec HD Aspheric Posterior Chamber IOL labeling.

V. DEVICE DESCRIPTION

The Softec HD Posterior Chamber Intraocular Lens (Softec HD IOL) is a single piece lens with "modified C Loop" haptics. The Softec HD IOL can be inserted through a small (2.5 mm to 3.0 mm) clear corneal incision and is manufactured completely from medical grade Hydroxyethylmethacrylate (HEMA, 26% water content) and a polymerizable UV blocker.

The overall length of the lens is 12.0 mm. The lens optic is an equal conic biaspheric optic with square edges, 5.75 mm in length and is designed for placement in the capsular bag.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of aphakia after cataract surgery. 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.

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 Softec HD IOL has been marketed in 25 countries, including Australia, Barbados, Belgium, Brazil, Canada, Chile, China, Czech Republic, Dominican Republic, England, France, Germany, Greece, Hungary, Hong Kong, India, Italy, Malaysia, Pakistan, Poland, Portugal, Romania, Slovak Republic, South Africa, Spain, Switzerland, Turkey, Venezuela and the United Arab Emirates. The Softec HD IOL has 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

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device. 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 specific events that occurred in the clinical studies, please see Section X below.

IX. SUMMARY OF PRECLINICAL STUDIES

Lenstec Incorporated performed non-clinical studies on this device in accordance with the ISO 11979 standards for intraocular lenses.

A. Biocompatibility Studies

Lenstec Incorporated 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. Summaries of the biocompatibility tests conducted are listed in Table 1.

Table 1: Biocompatibility Testing

Title/Test Description	Results/Conclusions
Cytotoxicity Study: ISO Elution Method (solid)	No cell lysis caused by test sample, nontoxic
Cytotoxicity Study: ISO Agarose Overlay Method (solid)	No cell lysis caused by test sample, nontoxic
Cytotoxicity Study: ISO Agarose Overlay Method (liquid)	No cell lysis caused by test sample, nontoxic
Cytotoxicity Study: ISO Elution Method (liquid)	No cell lysis caused by test sample, nontoxic
In Vitro Inhibition of Cell Growth	No evidence of cell growth inhibition
Genotoxicity: Bacterial Reverse Mutation Study	Non-mutagenic
Genotoxicity: *In Vitro* Chromosomal Aberration Study	Not genotoxic
Genotoxicity: Mouse Bone Marrow Micronucleus Study	Not genotoxic

Title/Test Description	Results/Conclusions
ISO Maximization Sensitization	No delayed dermal contact sensitization
ISO Intracutaneous Study	Nonirritant
USP and ISO Systemic Toxicity Study	Nontoxic
ISO Muscle Implantation – 2 Week Study	Nonirritant
Intramuscular Implant and Scanning Electron Microscopy Assessment of Possible Material Surface Changes to Intraocular Lens Device	Both control and test samples showed little difference with respect to material changes after 28 days of implantation
One Year Intraocular Implantation Study in the Rabbit	Test sample showed no evidence of abnormal local effects. Also, there were no signs of significant irritation or toxicity to ocular tissues that were considered to be directly related to the test or control articles
Nd:Yag Laser Exposure, Cytotoxicity Study	No cell lysis caused by test sample, nontoxic
Test for Hydrolytic Stability	No known leachables detected by GC/MS, HPLC or liquid chromatography; No appreciable difference between spectral transmittance or dioptric power of test and control samples
Test for Photostability	No significant component migration, no significant loss of UV absorption properties over the 20 year test period
Test for Extractables	No appreciable extractables originating from the test article when the test article is subjected to exhaustive extraction conditions
Insoluble Inorganics/ICP Spectroscopy	All detectable metals/elements were acceptably low
Determination of Total Aluminum in Acrylic Lenses	All samples had acceptably low levels of aluminum
In Vitro Hemolysis Study (Modified ASTM-Direct Contact Method)	Non-hemolytic

B. 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. The following optical and mechanical testing was performed in accordance with ISO 11979-2 and ISO 11979-3, respectively.

Table 2: Laboratory Studies

Laboratory Studies	Test and Results
Optical	Dioptric power, imaging quality/resolution and spectral transmittance passed the acceptance criteria. All lenses had an MTF value of greater than 0.43
Mechanical: Dimensions	All dimensions were within the designed acceptance criteria
Mechanical: Compression force	All compression forces were within the designed acceptance criteria
Mechanical: Axial displacement	All lenses had an average axial displacement of 0.1 mm
Mechanical: Optic decentration	All lenses had an average decentration of 0.152mm
Mechanical: Optic tilt	The average optic tilt at the compressed diameter was 1.58°
Mechanical: Angle of contact	All angles of contact were within the designed acceptance criteria
Mechanical: Compression force decay	All compression force decay measurements were within the designed acceptance criteria
Mechanical: Dynamic fatigue durability	All haptics withstood 250,000 cycles of near sinusoidal deformation
Mechanical: Surgical manipulation	The force to pull the haptics exceeded 1N.
Mechanical: Surface and bulk homogeneity	No lenses exhibited cosmetic defects

Laboratory Studies	Test and Results
Mechanical: Recovery of properties following simulated surgical manipulation	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 various Lenstec inserters and in forceps for 2 minutes.*

*Lenstec's labeling reflects that the use of less than two minutes of manipulation time is optimal, as the hydrophilic nature of the lens could cause it to dehydrate and become brittle

C. Sterilization, Packaging, Shelf Life and Transport Stability

The objective of the sterilization, packaging, shelf-life, and transport stability studies was to establish that the properties of the Softec HD IOL remain within their specified limits over the course of the proposed shelf-life. The IOL is shipped sterile (via steam sterilization) in a white plastic delivery system, which is located in a glass vial containing 0.9% saline. The vial is sealed using a silicone stopper, which is finally closed by a 'twist' cap. These items are sealed and sterilized in a Tyvek pouch which is validated for a shelf life of 3 years.

Table 3 summarizes the tests conducted to establish the shelf-life of the packaged Softec HD IOL.

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

Sterilization, Packaging, Shelf Life & Transport Tests	Test Conclusions
Sterilization annual requalification	The annual requalification was performed according to EN ISO 17665: 2006 Sterilization of health care products—Moist heat—part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
Pre-sterilization bioburden test	The bioburden percent recovery was within acceptable limits
Bacterial endotoxin testing	Endotoxin level were below the Agency's recommended limit for intraocular lenses
Visual inspection to determine integrity	Both lens vial labeling and seal integrity met the requirements of ASTM F1886- Standard Test

Sterilization, Packaging, Shelf Life & Transport Tests	Test Conclusions
	Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
Sterility test	No microbial growth was detected; Met the requirements of USP <71> Sterility
Bacteriostasis/ fungistasis test	No bacteriostatic/ fungistatic effect was observed
Package evaluation- burst test	Aged packages performed equivalently to un-aged packages, per ASTM F1140- Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
Microbial challenge- dust drum test	All samples were found negative for growth of indicator organism
Product functionality test/stability	Results were satisfactory to support a 3 year shelf life per ISO 11979-6- Ophthalmic implants— Intraocular lenses—Shelf-life and transport stability
Transport stability	The results showed that the lenses would not be damaged during shipping; Met the requirements of ISO 2233- Packaging — Complete, filled transport packages and unit loads — Conditioning for testing, 8318- Packaging — Complete, filled transport packages and unit loads — Sinusoidal vibration tests using a variable frequency and 2248- Packaging — Complete, filled transport packages — Vertical impact test by dropping

Conclusions:

The overall results of the preclinical tests were acceptable from biocompatible, physiochemical, optical, mechanical and shelf-life perspectives.

X. SUMMARY OF PRIMARY CLINICAL STUDY

Lenstec Inc. performed a clinical study to establish a reasonable assurance of safety and effectiveness of intraocular implantation with the Softec HD IOL for the replacement of the human crystalline lens following phacoemulsification cataract removal in adults over the age of 21 under IDE #G060058. 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 December 13, 2006 and June 9, 2008. The database for this PMA reflected data collected through July 29, 2009 and included 390 patients. There were 8 investigational sites.

The Softec HD IOL was evaluated in a 12-month, prospective, non-randomized 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 have been used as an historical control. These data have been updated from recent FDA approved IOL experience for adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models, with a Study endpoint of 1 year. Post-operative safety and effectiveness outcomes were compared against "FDA Grid" values (ISO 11979-7: 2006).

Clinical studies have not been conducted with the Softec HD IOL to assess the effect of the added aspheric surface on spherical aberration, visual acuity and contrast sensitivity.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the Softec HD IOL study was limited to patients who met the following inclusion criteria:

- Male or Female
- Any race
- Patient's age at time of surgery to be 21 years or older
- Presence of cataract requiring cataract extraction
- Clear intraocular media other than cataract
- Patients with best spectacle-corrected visual acuity < 20/40 or cataract with glare acuity worse than 20/30
- Patient is able and willing to comply with follow-up
- Patient is able to provide written informed consent
- Understanding that only 1 eye can be implanted with study lens; fellow eye if, requiring an IOL will be implanted with an approved IOL

Patients were not permitted to enroll in the Softec HD study if they met any of the following exclusion criteria:

- Patients who are monocular.
- Presence of an ocular infection.
- Previous intraocular surgery in either eye (except for cataract extraction with IOL implantation or correction of retinal detachment in other eye; or treatment for retinal holes).
- Patients with a pre-existing ocular condition/disease that could limit potential acuity to worse than 20/40.
- Previous serious corneal disease.
- An acute or chronic disease or illness that would increase the operative risk or confound the outcome(s) of the investigation (e.g., immunocompromised, connective tissue disease, clinically significant atopic disease, diabetes, etc.).
  Clarification: "Non-clinically Significant Diabetes" for the Softec HD IDE Clinical Investigation is defined as diabetes that in the opinion of the Clinical Investigator would not increase the operative risk or confound the outcome(s) of the investigation AND the patient has no history or evidence of any more than mild background diabetic retinopathy. Proliferative diabetic retinopathy is a clear exclusion. Therefore, "Clinically Significant Diabetes" would in the opinion of the Clinical Investigator, increase the operative risk or confound the outcome(s) of the investigation AND/OR patient has a documented history of diabetic eye disease (more than mild background diabetic retinopathy).
- Ocular condition that may predispose for future complications, for example:
  - history or current evidence of severe corneal disease (e.g., herpes simplex, herpes zoster Keratitis, etc.); with the exception of old corneal scars.
  - evidence of retinal vascular disease.
  - uncontrolled glaucoma.
    Clarification: "Uncontrolled glaucoma" for the Softec HD IDE Clinical Investigation is defined as an inability to maintain IOP within a desired range (= 20 mmHg) on maximal medications. Patients may be enrolled with controlled glaucoma on topical medical therapy
- Previous intraocular or corneal surgery that might confound the outcome of the investigation or increase the risk to the subject. Subjects who may be expected to require retinal laser treatment.
- Patients requiring administration of topical ophthalmic medications other than the study medications. Systemic medications that may confound the outcome of the investigation or increase the risk to the subject, including, but not limited to, steroids, anti-metabolites, etc.
  Clarification: Systemic steroids and anti-metabolites are absolute exclusion criteria. All prescription topical medications, with the exception of ocular hypertensive agents for patients with controlled glaucoma, are to be excluded from the Softec HD Clinical Investigation.
- Allergy to anesthetics or other postoperative medications.

- Pregnant or lactating women or who plan to become pregnant over the course of this clinical investigation.
- Persons who, in the determination of the investigator, are not competent to understand the procedure, the actions asked of them as research subjects.
- Participation in a previous clinical trial within the 30 days prior to the start of the study.
- Persons who may not be able to complete the requirements of returning to the investigator's clinic over the period of the study, or who may be difficult to locate or contact on short notice. This does not preclude vacations or travel.

2. Follow-up Schedule

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

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

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.

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

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 visual acuity (VA) (% achieving 20/40 or better) and Best-Case Best-Corrected Distance VA (% achieving 20/40 or better) compared to historical controls.

4. Accountability of PMA Cohort

At the time of database lock, of 390 patients enrolled in PMA study, 95% (366) patients were available for analysis at the completion of the study, the 12 month post-operative visit. The patient accountability is detailed in Table 4.

Table 4: Patient Accountability

	Form 1 (1-2 days) n/N (%)	Form 2 (7-14 days) n/N (%)	Form 3 (30-60 days) n/N (%)	Form 4 (120-180 days) n/N (%)	Form 5 (330-420 days) n/N (%)	Form 6 (630-780 days) n/N (%)
Available for Analysis	386 / 390 (99%)	365 / 390 (94%)	370 / 390 (95%)	350 / 390 (90%)	366 / 390 (94%)	122 / 390 (31%)
Missing Subjects:						
Discontinued (Deceased)	0 / 390 (0%)	0 / 390 (0%)	0 / 390 (0%)	0 / 390 (0%)	5/390 (1%)	9/390 (2%)
Missed visit but seen later	4 / 390 (1%)	25 / 390 (6%)	20 / 390 (5%)	35 / 390 (9%)	7 / 390 (2%)	0 / 390 (0%)
Lost to follow-up	0 / 390 (0%)	0 / 390 (0%)	0 / 390 (0%)	4 / 390 (1%)	12 / 390 (3%)	12 / 390 (3%)
Active	0 / 390 (0%)	0 / 390 (0%)	0 / 390 (0%)	0 / 390 (0%)	0 / 390 (0%)	243 / 390 (62%)
% Accountability	99%	94%	95%	90%	95%	88%

5. 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. Mean age was 70.8 years. Patients were included from both genders and any race. The proportion of patients with pre-existing macular degeneration was 3.1%; with pre-existing preoperative conditions in general excluding macular degeneration 30.5%.

Table 5: Patient Population
N=366

Patient Population	Population Description
Mean Age (years)	70.8 yrs ± 8.7 (24-90 yrs)
Patients with Pre-existing Macular Degeneration	3.1%
Other Patients with Pre-existing Conditions	30.5%
Gender	
Female	58.2%
Male	41.8%
Race	
Caucasian	85.6%
Black	2.8%
Asian	1.5 %
Mixed	1.0 %
Other	9.0%

6. Safety and Effectiveness Results

a. Safety Results

The analysis of safety was based on the cohort of 366 patients available for the 12 month evaluation. 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	Softec HD Incidence (%) N=366	FDA Grid (%)
Hyphema	0.0	2.2
Macular Edema	0.8	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 366 patients)

Table 7: Persistent Adverse Events [2]

Persistent Adverse Event	Softec HD Incidence (%) N=366	FDA Grid (%)
Macular Edema	0.8	0.5
Corneal Edema	0.0	0.3
Iritis	0.3	0.3
Raised IOP Requiring Treatment	0.6	0.4

[2] Persistent: Present at the 1-year study visit (for 366 patients)

b. Effectiveness Results

The analysis of effectiveness was based on visual acuity on 366 at the twelve-month time point. Key effectiveness outcomes are presented in tables 8 and 9. Of those patients implanted with the Softec HD 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 by Age: All Patients

				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	36	0	36	26	72.2	7	19.4	3	8.3	0	0.0	36	100.0	0	0.0	0	0.0	0	0.0	0	0.0	<0.001
60 to 69	128	0	128	85	66.4	25	19.5	15	11.7	2	1.6	127	99.2	0	0.0	0	0.0	0	0.0	0	0.0	<0.001
70 to 79	155	0	155	78	50.3	43	27.7	22	14.2	9	5.8	152	98.1	1	0.6	0	0.0	0	0.0	0	0.0	<0.001
80 & older	47	0	47	22	46.8	11	23.4	11	23.4	4	8.5	45	95.7	2	4.3	0	0.0	0	0.0	0	0.0	<0.001
Total	366	0	366	211	57.7	86	23.5	51	13.9	15	4.1	345	98.4	3	0.8	0	0.0	0	0.0	0	0.0	<0.001

Table 9: Best Corrected Visual Acuity by Age: Best Case Patients

				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	32	0	32	29	90.6	1	3.1	2	6.3	0	0.0	32	100.0	0	0.0	0	0.0	0	0.0	0	0.0	<0.001
60 to 69	118	0	118	91	77.1	9	7.6	15	12.7	2	1.7	117	99.2	0	0.0	0	0.0	0	0.0	1	0.8	<0.001
70 to 79	135	0	135	72	53.3	36	26.7	19	14.1	5	3.7	132	97.8	0	0.0	3	2.2	0	0.0	0	0.0	<0.001
80 & older	42	0	42	23	54.8	8	19.0	8	19.0	3	7.1	42	100.0	0	0.0	0	0.0	0	0.0	0	0.0	<0.001
Total	327	0	327	215	65.7	54	16.5	44	13.5	10	3.1	323	98.8	0	0.0	0	0.0	0	0.0	0	0.0	<0.001

c. Subgroup Analyses

Additional safety analyses were conducted to look for trends that may not be apparent from the overall analysis of the adverse event and best spectacle

corrected visual acuity (BSCVA) rates. The following clinical data were evaluated, as recommended by ISO 11979-7:2006:

- BSCVA by age
- Best-case BSCVA
- BSCVA by adverse event
- BSCVA by pre-operative ocular pathology
- BSCVA 20/40
- BSCVA by Investigator

Best Corrected Distance Visual Acuity - Stratified by Age (All Eyes)
Best corrected distance visual acuity at the Form 5 Study Endpoint postoperative follow-up visit; stratified by age (Age Groupings: < 60 years; 60 to < 70 years; 70 to < 80 years and ≥ 80 years). As would be anticipated, the proportion of eyes with BCVA ≥ 20/40 decreased with age: < 60 years (100%); 60 to < 70 years (99.2%); 70 to < 80 years (98.1%) and ≥ 80 years (95.7%).

Best Corrected Distance Visual Acuity - Stratified by Age (Best Case)
Best corrected distance visual acuity at the Form 5 Study Endpoint in the Best Case cohort, stratified by age (Age Groupings: < 60 years; 60 to < 70 years; 70 to < 80 years and ≥ 80 years). The proportion of eyes with BCVA ≥ 20/40 was no less than 97.8% for any age category: < 60 years (100%); 60 to < 70 years (99.2%); 70 to < 80 years (97.8%) and ≥ 80 years (100%).

Best Corrected Distance Visual Acuity - Stratified by Adverse Event
The sponsor performed an analysis of the best corrected distance visual acuity stratified by the presence of any adverse event, or specifically for the presence of a haptic break respectively.

The BCVA of subjects who experienced and adverse event as compared to those who did not have an event was worse with regard to proportion of cases seeing 20/40 or better. At 1 year (Form 5), 87.5% in the adverse event group compared to 98.9% in the non-adverse event group had BCVA of ≥20. 100% of cases in the adverse event group could see 20/50 or better compared to 98.9% in the non-adverse event group. For those 6 study subjects who experienced a haptic break at the time of the Softec HD implantation and then received a Softec PCIOL, the 1 year (Form 5) BCVA is actually better compared to the total study subject population in the Softec HD Cohort that did not experience a haptic break; 100% haptic break group; 98.4% non-haptic break group seeing 20/40 or better. The occurrence of a haptic break had *no* impact on visual acuity.

Best Corrected Distance Visual Acuity - Stratified by Preoperative Ocular Pathology
Best corrected distance visual acuity clinical outcomes (BCVA ≥ 20/40) are lower in those study subjects *with* preoperative ocular pathology (94.1%)

compared to the group of study subjects with *no* preoperative ocular pathology (98.8%) at the Form 5 Study Endpoint.

Best Corrected Distance Visual Acuity – Decrease of 2 or More Lines
Forty-two (42) subjects were included in a dateline listing of a decrease of 2 or more lines of BCVA. The distance BCVA was 20/40 or better in 34 of the 42 subjects (81.0%). A clinical diagnostic explanation for the decrease in BCVA of 2 or more lines was identified by the sponsor. Thirty-seven (37) of 42 subjects (88.1%) had a definitive clinical diagnosis that affected visual acuity. In the 5 cases with no definitive clinical explanation, the decreases in BCVA were as follows: 20/10 to 20/20 (preop 20/30), 20/20 to 20/30 (preop 20/25); 20/20 to 20/30 (preop 20/50), 20/25 to 20/40 (preop 20/50) and 20/25 to 20/40 (preop 20/50).

Best Corrected Distance Visual Acuity – Stratified by Investigator
There was no statistically significant difference among sites with regard to BCVA 20/40 or better at 12 Months (Form 5) (p=0.24).

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

The applicant's original protocol stipulated a 3-year postoperative follow-up because of potential safety concerns regarding possible lens opacification. However, the clinical data at 1 year, and the nonclinical biocompatibility data mitigated these concerns, and the applicant received FDA approval to truncate the study at 1-year follow-up. At the time of truncation of the study, the applicant had collected 2-year data on 122 patients. At the 2-year timeframe, 95.9% (117/122) patients had a BCVA of 20/40 or better, and 96.4% (107/111) of the "best case" patients had a BCVA of 20/40 or better. The only adverse event reported at 2 years was one case of cystoid macular edema. These results are consistent with the results provided in X.

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 Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety Conclusions

The Softec HD cumulative and persistent adverse event rates at 12 months are lower than the FDA historical control grids in all areas except macular 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 Softec HD 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.

XIV. CDRH DECISION

CDRH issued an approval order on April 12, 2010. The final conditions of approval cited in the approval order are described below.

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).

XV. 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.