SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

A. Premarket Approval Application (PMA) Number: P990080
Date Filed: January 13, 2000
Date Approved: APR - 5 2001

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

C. Trade Names of Device: CeeOn™ Edge Foldable Ultraviolet Light Absorbing Posterior Chamber Intraocular Lens - Model 911A

D. Applicant's Name and Address:
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, Michigan 49001-0199

E. Good Manufacturing Practice (GMP) Inspection Dates:
Date of Inspection: July 11, 1999
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

F. Ophthalmic Devices Panel (Panel): None

II. INDICATIONS

CeeOn Edge foldable intraocular lenses are indicated for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by phacoemulsification. The lens is intended to be placed in the capsular bag.

III. SUMMARY

The clinical study consisted of two phases. In the first phase, 62 subjects were enrolled and followed through 3-6 months postoperative after which their results were assessed by FDA to determine whether the study should be allowed to expand into its second phase. In the second phase, 363 additional subjects were enrolled for a total of 425 subjects.

The clinical study design featured enrollment of eligible cases in a non-randomized fashion at 15 clinical sites with their results at 1 year compared to literature controls, namely the FDA "Grid" of cataract surgery results. In 1983 Stark et. al. (Ophthalmology, 90(4): 311-317)

published a grid of historical clinical data established from review of 45,543 eyes implanted with IOLs PMA-approved before 1982. FDA adopted the grid, which includes adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models. Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of Model 911A compares favorably with the grid of historical data (refer to Section IV.B. Safety and Effectiveness Data).

Criteria for inclusion in the study were male or female aphakic patients age 50 years or older who underwent primary cataract extraction via phacoemulsification after successful circular tear anterior capsulotomy and whose posterior capsule remained intact.

As of the date of database cut-off, September 29, 2000, 344 (81%) of the enrolled subjects had completed the study (the "1-Year Cohort"). Of the remaining 81subjects, none remained active (i.e., not yet reached the 1-year/Form 5 exam); 42 were lost-to-follow-up; 18 died prior to completion of the Form 5 exam; and 21 missed the Form 5 exam, but were seen at a later visit.

The population at risk for developing visually-disabling cataracts and needing cataract surgery is typically elderly; the elderly population has a slightly higher proportion of females to males. The average age of the 425 subjects was 74 years at the time of surgery; 58% of the subjects were female and 42% were male. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology. The study population was 93% Caucasian, 5% African-American, 2% "Mixed" and 0.2% "Other." In this study, all patients who met the inclusion criteria were included in the study. The study began on December 17, 1996, and the last subject was enrolled on September 15, 1998.

Most Model 911A IOL patients 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.

The sponsor has agreed to provide, with each lens shipped, an Intraocular Lens Identification Card for the patient and a Lens Accountability Form for the implanting surgeon. The Lens Accountability Form is returned to the company so that they have a record of each implanting surgeon and patient that received a particular IOL serial number.

IV. SAFETY AND EFFECTIVENESS DATA

A. Nonclinical Studies

The applicant has performed nonclinical studies on this device that are consistent with the FDA draft guidance document for testing intraocular lenses dated October 14, 1999. The applicant conducted a battery of *in vivo* and *in vitro* acute and chronic

toxicity tests that establish the biocompatibility of the lens materials. These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the material and overall device design for use in an intraocular lens. 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. Nonclinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives.

B. Clinical Studies

Overall Visual Acuity (20/40 or better, best corrected)

	Model 911A		FDA Grid
Age <60 Years	100.0%	[14/14]	93.7%
Age 60-69 Years	98.7%	[77/78]	90.8%
Age 70-79 Years	97.6%	[162/166]	88.6%
Age >79 Years	91.9%	[57/62]	75.2%
All ages Combined	96.9%	[310/320]	88.0%
*Best Case, All Ages Combined	98.9%	[272/275]	94.0%

Overall Visual Acuity (20/20 or better, best corrected)

	Model 911A	
Age <60 Years	57.1%	[8/14]
Age 60-69 Years	61.5%	[48/78]
Age 70-79 Years	49.4%	[82/166]
Age >79 Years	33.9%	[21/62]
All ages Combined	49.7%	[159/320]
*Best Case, All Ages Combined	51.3%	[141/275]

*Best Case: Excludes patients with preoperative ocular pathology, or macular degeneration at any time.

Cumulative Adverse Events ♦

	Model 911A		FDA Grid
Hyphema	0.0%	[0]	1.0%
Macular Edema	3.8%	[16]	3.5%
Retinal Detachment	0.0%	[0]	0.5%
Pupillary Block	0.0%	[0]	0.3%
Lens Dislocation	0.0%	[0]	0.4%
Endophthalmitis	0.0%	[0]	<0.1%
Hypopyon	0.0%	[0]	0.4%
Corneal Decompensation	0.2%	[1]	0.2%
Surgical Reintervention	0.9%	[4]	2.0%
- Lens repositioning	(0.2)	[1]	
- Wound leak repair	(0.2)	[1]	
- Focal laser therapy	(0.5)	[2]	

Persistent Adverse Events ♦

	Model 911A		FDA Grid
Macular Edema	0.9%	[3]	0.8%
Corneal Edema	0.0%	[0]	0.6%
Iritis	0.0%	[0]	1.0%
Raised IOP Requiring Treatment	0.0%	[0]	0.5%
Cyclitic Membrane	0.0%	[0]	<0.1%
Vitritis	0.0%	[0]	0.1%

♦ Cumulative: Occurring at any time during the study (for 425 subjects)
Persistent: Present at the 1-year study visit (for 326 subjects)

V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. CDRH approved this PMA in a letter to the PMA applicant dated APR - 5 2001 and signed by the Director, Office of Device Evaluation.

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Draft: Joel Glover 3/21/01
Edit: Donna Lochner 3/23/01
Edit: Eva Rorer 3/27/01
Final: Joel Glover 4/5/01