P980040

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

A. Premarket Approval Application (PMA) Number: P980040
Date Filed: October 1, 1998
Date Approved: FEB - 3 2000

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

C. Trade Name of Device: SENSAR™ Soft Acrylic UV Light-Absorbing Posterior Chamber Intraocular Lens, Model AR40

D. Applicant's Name and Address: Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92623

E. Good Manufacturing Practice (GMP) Inspection Date: September 24, 1999
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

F. Ophthalmic Devices Panel (Panel): N/A

II. INDICATIONS

Allergan, Inc, SENSAR™ Soft Acrylic UV Light-Absorbing Posterior Chamber Intraocular Lens, Model AR40, is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag.

III. SUMMARY

The applicant has performed nonclinical and clinical testing on the device, following the recommendations in the draft FDA guidance testing for intraocular lenses dated October 10, 1997. Data on 335 patients followed postoperatively for 12 months were evaluated against historical controls (Stark WJ, et al 1983. The FDA Report on Intraocular Lenses. Ophthalmology 90(4): 311-317).

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. For the cohort subjects at the time of surgery, 30.4 % of subjects were 60-69 years old; 54% of the subjects were 70-79 years old; and 14.6 % were at least 80 years old. Approximately 60% of the 335 cohort subjects were female and approximately 40% were male. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology. The cohort study

population of 335 patients was 97.6% Caucasian, 2.1% Black and 0.3% Asian. This study, which began in 1996, included all patients who met the inclusion criteria.

Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of this device, i.e., adverse events and visual acuity results, compares favorably with FDA's 1983 grid of historical data.

Most SENSAR™ patients achieved a visual acuity of 20/40 or better. The rates for best-case visual acuity for both genders exceeded FDA grid values.

IV. SAFETY AND EFFECTIVENESS DATA

A. Nonclinical Studies

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 for use in intraocular lenses. The adequacy of the manufacturing processes, including sterilization, was established through a review of the manufacturing information in the PMA as well as thorough on-site inspections. Non-clinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives.

B. Clinical Studies

Visual Acuity (% 20/40 or better)	Model AR40		Grid
Age			
≤ 59	100.0%	[2/2]	93.7%
60-69	100.0%	[102/102]	90.8%
70-79	98.4%	[179/182]	88.6%
≥80	95.7%	[45/47]	75.2%
All Cases, All Ages	98.5%	[328/333*]	88.0%
Best Case, All Ages	98.9%	[269/272*]	94.0%

* - Two subjects did not have their best corrected distance visual acuity measured at 1 year.

Cumulative Adverse Events			
Endophthalmitis*	0.3%	1	<0.1%
Hyphema	0.0%	0	1.0%
Hypopyon	0.3%	1	0.4%
Lens Dislocation	0.3%	1	0.4%
Macular Edema	0.8%	3	3.5%
Pupillary Block	0.0%	0	0.3%
Retinal Detachment	0.0%	0	0.5%
Lens Epithelial Ongrowth (Anterior Surface)**	9.2%	35	
Secondary Surgical Intervention	0.3%	1	2.0%
• Iridectomy for Pupillary Block	0.0%	0	
• Vitreous Aspiration for Pupillary Block	0.0%	0	
• Repositioning of Lens	0.0%	0	
• IOL Removal For Inflammation	0.0%	0	
• IOL Replacement	0.3%	1	

* - Incidence is not statistically different from grid rate

Persistent Adverse Events			
Corneal Edema	0.0%	0	0.6%
Hyphema	0.0%	0	1.0%
Iritis	0.0%	0	1.0%
Macular Edema	0.0%	0	0.8%
Secondary Glaucoma	0.0%	0	0.5%
Vitritis	0.0%	0	0.1%
Lens Epithelial Ongrowth (Anterior Surface)**	5.0%	14	

** - Includes 2 and 3 year reports of tissue ongrowth on the anterior lens surface through July 15, 1999. Adverse effect on these subjects' vision was not reported by the investigators. Tissue ongrowth has been previously reported in the literature on other IOL material types.

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. In accordance with the provisions of section 515 (c)(2) of the Federal Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel for review and recommendation because the information in the PMA substantially duplicates the information previously reviewed by this panel. CDRH approved this PMA in a letter to the PMA applicant dated FEB - 3 2000 and signed by the Deputy Director for Science and Regulatory Policy, Office of Device Evaluation.