SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

A. Premarket Approval Application (PMA) Number: P990014
Date Filed: March 4, 1999
Date Approved:

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

C. Trade Name of Device: Hydroview® Composite Hydrogel Foldable UV-Absorbing Posterior Chamber Intraocular Lens, Model H60M

D. Applicant's Name and Address: Bausch & Lomb Surgical, Inc.
21 Park Place Blvd., N.
Clearwater, FL 33759

E. Good Manufacturing Practice (GMP) Inspection Date: September 12, 1997
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

F. Ophthalmic Devices Panel (Panel):
Date Reviewed: July 23, 1999
Recommendation: Approvable

II. INDICATIONS

Bausch & Lomb Hydroview® Composite Hydrogel Foldable UV-Absorbing Posterior Chamber Intraocular Lens – Model H60M, is indicated for primary implantation for the visual correction of aphakia in patients 60 years of age or older where a cataractous lens has been removed by extracapsular extraction methods. The lens is intended for placement 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 387 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. The average age of the 387 cohort subjects was 74.3 years at the time of surgery; approximately 63% of the 387 cohort subjects were female and 37% were male. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology The cohort study population of 387 patients was

96.4% Caucasian, 2.3% Black, and 1.3% other. This study, which began in 1995, 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 Hydroview® patients achieved a visual acuity of 20/40 or better. The rates for both overall and 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 H60M		Grid
Age			
≤ 59	100.0%	[7/7]	93.7%
60-69	95.7%	[89/93]	90.8%
70-79	99.3%	[147/148]	88.6%
≥80	91.6%	[76/83]	75.2%
All Cases, All Ages	96.4%	[319/331]	88.0%
Best Case, All Ages	98.9%	[269/272]	94.0%
Cumulative Adverse Events			
Endophthalmitis	0.0%	0	<0.1%
Hyphema	0.3%	1	1.0%
Hypopyon	0.0%	0	0.4%
Lens Dislocation	0.0%	0	0.4%
Macular Edema	2.6%	10	3.5%
Pupillary Block	0.0%	0	0.3%
Retinal Detachment	0.0%	0	0.5%
Lens Epithelial Ongrowth (Anterior Surface)	1.0%	8	
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	0.0%	0	
• Other (Not Lens Related)	0.3%	1	

Persistent Adverse Events			
Corneal Edema	0.0%	0	0.6%
Hyphema	0.0%	0	1.0%
Iritis	0.3%	1	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)	0.6%	6	

V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) and the Panel 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 NOV 12 1999 and signed by the Deputy Director for Science and Regulatory Policy, Office of Device Evaluation.