SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

A. Premarket Approval Application (PMA) Number: P990013
Date Filed: March 5, 1999
Date Approved: APR - 2 2000

B. Generic Name of Device: Collamer ™ Ultraviolet-Absorbing Posterior Chamber Intraocular Lens Model CC-4203VF (IOL)

C. Trade Names of Device: Collamer ™ Intraocular Lens

D. Applicant's Name and Address:
Staar Surgical Company
1911 Walker Avenue
Monrovia, CA 93111

E. Good Manufacturing Practice (GMP) Inspection Dates:
Date of Inspection: 10/14/99 and 12/9/99
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

F. Ophthalmic Devices Panel (Panel): None

II. INDICATIONS

The COLLAMER™ Ultraviolet-Absorbing Posterior Chamber Intraocular Lenses are intended to correct aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by phacoemulsification cataract extraction. The lens is to be implanted in the posterior chamber and in the capsular bag through a tear-free capsulorhexis (circular tear anterior capsulotomy).

III. SUMMARY

The clinical study consisted of two phases. In the first phase, 125 cases were enrolled and followed through 4-6 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, 561 additional cases were enrolled for a total of 686 cases.

The clinical study design featured enrollment of eligible cases in a non-randomized fashion at

15 clinical sites with their results 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 U940A 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 60 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, August 17, 1998, 502 of the enrolled cases had completed the study (the "Cohort"). Of the remaining 184 cases, 133 had reported enough interim examinations to otherwise qualify for the Cohort but had not completed the Form 6 exam by the date of the database cut-off (Continuing group); 34 were lost-to-follow-up and 17 had deceased prior to completion of the Form 6 exam.

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 686 subjects was 72.5 years at the time of surgery; 59.9% of the 686 subjects were female and 40.1% were male. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology. The study population was 91.4% Caucasian; 4.1% African-American, and 4.5% other for the 686 subjects. In this study, which began in 1996, all patients who met the inclusion criteria were included in the study.

Most Collamer™ 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.

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)

	Collamer™ IOL Study	FDA Grid
Age < 59 Years	100.0% [25/25]	93.7%
Age 60-69 Years	97.1 % [134/138]	90.8%
Age 70-79 Years	95.5% [254/266]	88.6%
Age > 80 Years	91.8% [67/73]	75.2%
All Ages Combined	95.6% [480/502]	88.0%
♦Best Case, All Ages Combined	96.2% [325/360]	94.0%

Adverse Reactions

	Collamer™ IOL Study	FDA Grid
Hypopyon	0.0%[0]	0.4%
Intraocular Infection	0.1%[1]	0.1%
Acute Corneal Decompensation	0.0%[0]	0.2%
Surgical Reintervention	0.6%[4]	2.0%

Postoperative Complications

	Collamer™ IOL Study	FDA Grid
Cumulative Hyphema	0.0% [0]	1.0%
Cumulative Macular Edema	2.4% [12]	3.5%
Persistent Macular Edema	0.0% [0]	0.8%
Cumulative Pupillary Block	0.0% [0]	0.3%
Persistent Secondary Glaucoma	0.0% [0]	0.5%
Persistent Cyclitic Membrane	0.0% [0]	<0.1%
Persistent Vitritis	0.0% [0]	0.1%
Cumulative Retinal Detachment	0.0% [0]	0.5%
Cumulative Endophthalmitis	0.0% [0]	<0.1%
Persistent Corneal Edema	0.0% [0]	0.6%
Persistent Iritis	0.2% [1]	1.0%
Cumulative Lens Dislocation	0.0% [0]	0.4%

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

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 - 2 2000 and signed by the Director, Office of Device Evaluation.