

## SUMMARY OF SAFETY AND EFFECTIVENESS DATA

### I. GENERAL INFORMATION

- A. Premarket Approval Application (PMA) Number: P010027  
Date Filed: June 18, 2001  
Date Approved: November 21, 2001
- B. Generic Name of Device: Anterior Chamber Intraocular Lens (IOL)
- C. Trade Name of Device: Allergan, Inc. Model AC21B Ultraviolet-Absorbing PMMA Anterior Chamber Intraocular Lens
- D. Applicant's Name and Address: Ophthalmic Innovations International, Inc.  
4290 East Brickell Street  
Ontario, CA 91761
- E. Good Manufacturing Practice (GMP) Inspections: November 20, 2000 (applicant) and  
March 16, 2001 (sterilizer)
- F. Ophthalmic Devices Panel: April 21, 1988

### II. INDICATIONS

Anterior chamber lenses are used for the replacement of the human lens in the visual correction of aphakia. These anterior chamber intraocular lenses are to be used in patients 60 years of age and older where a cataractous lens has been removed by primary intracapsular cataract extraction (ICCE); or by primary extracapsular cataract extraction (ECCE) where there is a structural reason that the anterior chamber lens is the preferred one; or other primary ECCE provided that this be performed only after the physician has compared the published results of the anterior chamber lens with posterior chamber lenses; or in a secondary implant procedure.

### III. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH) DECISION

The application includes by reference the data in PMA P860034 for the Allergan Medical Optics (now Allergan, Inc.) Model AC-21B Anterior Chamber IOL, which was approved by FDA on September 29, 1989. Allergan, Inc. has authorized Ophthalmic Innovations International, Inc. (OII) to incorporate by reference the information contained in its approved PMA to manufacture the lenses. OII will use the manufacturing process previously approved under P970034 for Ultraviolet-Absorbing PMMA Posterior Chamber IOLs and has incorporated information from that application by reference. Preclinical validation studies, including optical, dimensional, and physicochemical testing, were submitted to support the equivalence of OII- and Allergan-manufactured Model AC21B IOLs. The device's shelf life has been established as five years.

CDRH approval of the Ophthalmic Innovations International PMA is based on (1) the safety and effectiveness data contained in PMA P860034, (2) preclinical studies demonstrating equivalence between OII- and Allergan-manufactured lenses, and (3) the results of the FDA inspection of the manufacturing facility. A summary of safety and effectiveness data for the Allergan, Inc. Model AC21B Anterior Chamber IOL appears in Attachment A.

On April 21, 1988, the Ophthalmic Devices Panel reviewed the PMA for the Allergan Medical Optics AC-21B anterior chamber IOL (P860034) and recommended approval. CDRH concurred with the Panel recommendation and approved this application (P860034) and final labeling on September 29, 1989. In accordance with CDRH's announced policy (4/18/86 PMA Guidance Memorandum #86-4), this licensing PMA was not taken to the Panel. CDRH approved this application (P010027) and final labeling on November 21, 2001. In an on-site inspection on November 20, 2000, the manufacturing facility was found to be in compliance with the device Good Manufacturing Practice regulations.

Attachment

## Attachment A

### SUMMARY OF SAFETY AND EFFECTIVENESS DATA

#### I. GENERAL INFORMATION

- A. Premarket Approval Application (PMA) Number: P860034  
Date Filed: July 6, 1987  
Date Approved: September 29, 1989
- B. Generic Name of Device:  
Anterior Chamber Intraocular Lenses (IOLs)
- B. Trade Name of Device: Models AC—21 Non—Ultraviolet—Absorbing  
and AC—21B Ultraviolet—Absorbing Anterior Chamber  
Intraocular Lenses
- D. Applicant's Name and Address: Allergan Medical Optics  
9701 Jeronimo Road  
Santa Aria, California 92799-5155
- E. Good Manufacturing Practice (GIP) Inspections:  
Date of Inspections:  
Irvine, California Facility: July 10, 1987  
Puerto Rico Facility: April 4 — 12, 1988  
Conclusion: All manufacturing sites were determined to be in  
compliance with all device GZIP requirements.
- F. Ophthalmic Devices Panel (Panel):  
Date Reviewed: April 21, 1988  
Recommendation: Approval

#### II. INDICATIONS

These devices are indicated for the visual correction of aphakia in patients 60 years of age and older where a cataractous lens has been removed by primary intracapsular cataract extraction (ICCE); or primary extracapsular cataract extraction (ECCE), where there is a structural reason that the anterior chamber lens is the preferred one; or other primary ECCE provided that this be performed only after the physician has compared the published results of the anterior chamber lens with posterior chamber lenses; or in a secondary implant procedure.

#### III. SUMMARY

The applicant has performed nonclinical and clinical testing on these devices in accordance with the FDA guidance document for testing intraocular lenses dated June 9, 1980. Non-clinical testing demonstrates the safety and effectiveness of these devices from microbiology, toxicology, chemistry, engineering, and manufacturing perspectives. Data on 722 patients followed postoperatively for 12—14 months were clinically and statistically evaluated against historical controls. The clinical performance of these devices, i.e., certain complications and adverse reactions and visual acuity

results, is consistent with the overall clinical performance of anterior chamber IOLs. While certain aspects of the clinical performance of these devices fall below that contained in FDA’s 1981 IOL “grid” of historical data and below the clinical performance of posterior chamber IOLs in general, the detailed data presented in the PMA demonstrate that the benefits outweigh the risks when the devices are implanted in accordance with the indications described above in Section II and in the approved labeling.

IV. SAFETY AND EFFECTIVE24ESS DATA

A. The applicant conducted a battery of *in-vivo* and *in-vitro* acute and chronic toxicity tests that establish the biocompatibility of the lens materials. Additionally, data from chemistry and engineering analyses further 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 manufacturing information in the P14k as well as through on-site inspections.

B. Clinical Studies

[Numbers in brackets represent numbers of patients in category.]

|  | Primary<br>ICCE<br>(N=474) | Primary<br>ECCE<br>(Planned)<br>(N=110) | Primary<br>ECCE<br>(Backup)<br>(N=43) | Secondary<br>Surgery<br>(N=94) | All<br>Cohort<br>(N=722 <sup>+</sup> ) |
|--|----------------------------|---|---------------------------------------|--------------------------------|--|
| <u>Visual Acuity</u>                     |                            |   |                                       |                                |  |
| 20/40 or better<br>Grid = 84%            | 83.3%<br>[395]             | 79.1%<br>[ 87]                          | 65.1%<br>[ 28]                        | 75.5%<br>[ 71]                 | 80.5%<br>[581]                         |
| 20/41 to 20/200<br>Grid = 2-7%           | 13.1%<br>[62]              | 17.3%<br>[19]                           | 23.3%<br>[10]                         | 22.3%<br>[21]                  | 15.7%<br>[112]                         |
| Worse than 20/200<br>Grid = 2 - 8%       | 3.6%<br>[ 17]              | 3.6%<br>[ 4]                            | 11.6%<br>[ 5]                         | 2.1%<br>[ 3 <sup>+</sup> ]     | 3.9%<br>[29 <sup>+</sup> ]             |
| Best Case* 20/40 or better<br>Grid = 87% | 91.2%<br>[322/353]         | 91.8%<br>[67/73]                        | 70.0%<br>[21/30]                      | 84.9%<br>[62/73]               | 89.2%<br>[472/529]                     |

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

|   | Primary<br>ICCE<br>(N=474) | Primary<br>ECCE<br>(Planned)<br>(N=110) | Primary<br>ECCE<br>(Backup)<br>(N=43) | Secondary<br>Surgery<br>(N=94) | All<br>Cohort<br>(N=722 <sup>+</sup> ) |
|---|----------------------------|---|---------------------------------------|--------------------------------|--|
| <u>Adverse Reactions</u>  |                            |   |                                       |                                |  |
| Acute Corneal Decompensation<br>Grid = 1.0 - 1.5%                     | 0.4%<br>[2]                | 0.0%<br>[0]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.3%<br>[2]                            |
| Hypopyon<br>Grid = 1.5%   | 0.2%<br>[1]                | 0.0%<br>[0]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.1%<br>[1]                            |
| Intraocular Infection<br>Grid = 0.3%                                  | 0.2%<br>[1]                | 0.0%<br>[0]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.1%<br>[1]                            |
| Surgical Reintervention<br>Grid = --                                  | 0.0%<br>[0]                | 1.8%<br>[2]                             | 2.3%<br>[1]                           | 2.2%<br>[2]                    | 0.7%<br>[5]                            |
| <u>Postoperative Complications</u>                                    |                            |   |                                       |                                |  |
| Corneal Edema (Persistent)<br>Grid = 1.4%                             | 1.9%<br>[9]                | 0.9%<br>[1]                             | 2.3%<br>[1]                           | 1.1%<br>[1]                    | 1.7%<br>[12]                           |
| Iritis (Persistent)<br>Grid = 2.0% (ICCE),<br>3.0% (ECCE)             | 0.0%<br>[0]                | 0.9%<br>[1]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.1%<br>[1]                            |
| Lens Dislocation (Cumulative)<br>Grid = 2.5%                          | 0.0%<br>[0]                | 0.0%<br>[0]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.0%<br>[0]                            |
| Hyphema (Cumulative)<br>Grid = 1.0%                                   | 2.7%<br>[13]               | 0.9%<br>[1]                             | 2.3%<br>[1]                           | 1.1%<br>[1]                    | 2.2%<br>[16]                           |
| Secondary Glaucoma (Persistent)<br>Grid = 1.0 - 1.5%                  | 1.3%<br>[6]                | 1.8%<br>[2]                             | 0.0%<br>[0]                           | 2.1%<br>[2]                    | 1.4%<br>[10]                           |
| Macular Edema (Cumulative)<br>Grid = 7.0% - 9.0%                      | 8.4%<br>[40]               | 4.5%<br>[5]                             | 25.6%<br>[11]                         | 7.4%<br>[7]                    | 8.7%<br>[63]                           |
| Macular Edema (Persistent)<br>Grid = 2.0 - 3.0%                       | 2.5%<br>[12]               | 1.8%<br>[2]                             | 9.3%<br>[4]                           | 3.2%<br>[3]                    | 2.1%<br>[21]                           |
| Pupillary Block (Cumulative)<br>Grid = 0.5%                           | 0.2%<br>1                  | 0.0%<br>[0]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.1%<br>[1]                            |
| Cyclitic Membrane (Persistent)<br>Grid = 0.1%                         | 0.0%<br>[0]                | 0.0%<br>[0]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.0%<br>[0]                            |
| Viritis (Persistent)<br>Grid = 3.0%                                   | 0.0%<br>[0]                | 0.9%<br>[1]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.1%<br>[1]                            |
| Endophthalmitis (Cumulative)<br>Grid = 0.3%                           | 0.2%<br>[1]                | 0.0%<br>[0]                             | 0.0%<br>[0]                           | 0.0%<br>[0]                    | 0.1%<br>[1]                            |
| Retinal Detachment (Cumulative)<br>Grid = 2.5% (ICCE),<br>2.0% (ECCE) | 0.4%<br>[2]                | 0.0%<br>[0]                             | 0.0%<br>[0]                           | 1.1%<br>[1]                    | 0.4%<br>[3]                            |

+ Includes one patient whose type of surgery is unknown. This patient's final visual outcome was 20/200.

V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) and the Panel reviewed the PMN and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the devices under the prescribed indications for use. CDRH approved this PMA in a letter to the PMA applicant dated September 29, 1989 and signed by the Director, Office of Device Evaluation.