# SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

## I. GENERAL INFORMATION

Device Generic Name: Monofocal, Aspheric Posterior Chamber Intraocular Lens (IOL)

Device Trade Name: EC-3 IOL, (Models EC-3 IOL and EC-3 Precision Aspheric Lens (PAL) IOL)

Applicant's Name and Address:

Aaren Scientific Inc. – (formerly Ophthalmic Innovations International, Inc. (Oii))
4290 East Brickell St., Bldg. A
Ontario, CA 91761 USA

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P100016

Date of FDA Notice of Approval: October 19, 2010

Expedited: Not Applicable

## II. INDICATIONS FOR USE

The EC-3 Intraocular Lenses (IOL) are indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.

## III. CONTRAINDICATIONS

Outside of general contraindications for ocular surgery, the following specific contraindications apply: Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal detachment, corneal decompensation, diabetic retinopathy, iris atrophy, perioperative complications, potential foreseeable post operative complications and other conditions which an ophthalmic surgeon might identify based on their experience.

## IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Aaren Scientific EC-3 IOL labeling.

## V. DEVICE DESCRIPTION

The Aaren Scientific EC-3 three-piece, foldable, hydrophobic acrylic posterior chamber intraocular lens (IOL) with ultraviolet (UV) absorber is designed to be implanted in the capsular bag through a small incision following extracapsular cataract extraction. The optic is made from a clear, UV-absorbing hydrophobic acrylic material. The haptics are of a modified C loop design and are formed from polyvinylidene fluoride (PVDF) monofilament. The haptics are bonded within the optic using a medical-grade epoxy adhesive. The lens has an optic diameter of 6.0mm and an overall diameter of 13.0mm. There is a 5° haptic vault angle.

This lens is also manufactured with an aspheric optic design (EC-3 Precision Aspheric Lens (PAL) IOL).

The EC-3 and EC-3 PAL are provided in the dioptric power range from +4.00D to + 34.00D in 0.50D increments.

## VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

1. Other approved IOLs may be used for visual correction after cataract surgery.

2. The following are non-surgical alternatives to implantation of an IOL following cataract extraction:

    a. Spectacles: Spectacles, or eyeglasses, are the safest means for improving vision after cataract surgery. However, they are rarely used after modern cataract surgery as the lenses are required to be thick, which causes distorted vision and may be uncomfortable or cosmetically unappealing to the patient.

    b. Contact lenses: Contact lenses are rarely prescribed for patients after cataract extraction, although they may provide excellent vision. Contact lenses have risks associated with their use including infection.

## VII. MARKETING HISTORY

The EC-3 is approved for marketing in Europe with approximately 100,000 EC-3 lenses distributed since February 2005. The EC-3 has not been withdrawn from any market for reasons related to the safety or effectiveness of the device.

## VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device. Potential adverse events and complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma and secondary surgical intervention. Secondary surgical interventions include, but are not limited to, lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, and retinal detachment repair. Amongst those directly related to the IOL are decentering and subluxation, precipitates on the surface of the IOL. Silicone oil, particularly when used in the surgical treatment of detached retina, may stick to the IOL if the posterior capsule of the crystalline lens is not intact.

For the specific adverse events that occurred in the EC-3 IOL clinical study, please see Section 7 below.

## IX. SUMMARY OF PRECLINICAL STUDIES

Nonclinical laboratory testing was performed in accordance with the requirements established in ISO 11979 and where appropriate, in accordance with the Good Laboratory Practice Regulations.

### A. Biocompatibility Studies

Aaren Scientific conducted a series of *in vitro* and *in vivo* tests, acute and chronic, to demonstrate the biocompatibility of the EC-3 lenses, including all lens components. Testing was conducted under the Good Laboratory Practice Regulations, where applicable, and in accordance with the requirements established in the ISO 11979-5 *Ophthalmic Implants – Intraocular lenses – Part 5: Biocompatibility.* Results are summarized in Table 1:

Table 1: Biocompatibility Testing

| Test | Results |
|---|---|
| Cytotoxicity (ISO Agarose Overlay – extract) | No cell lysis reported in any samples |
| ISO Maximization Sensitization (Extract) | No evidence of delayed dermal contact sensitization |
| ISO Muscle Implantation Study | Non-irritant |
| In Vitro Inhibition of Cell Growth (ICG) – | Non-toxic |

| | |
|---|---|
| One Point Assay | |
| Intracutaneous Reactivity | Non-irritant |
| Intraocular Irritation Study | Non-toxic |
| Six-Month Intraocular Implantation Study | Non-irritant<br>Non-toxic |
| Mouse Bone Marrow Micronucleus Study | Non-genotoxic |
| In Vitro Chromosomal Study in Mammalian Cells (extract) | Non-genotoxic |
| Bacterial Reverse Mutation Study<br>(Saline Extract)<br>(DMSO Extract) | Non-mutagenic |
| Systemic Injection Test | Non-toxic |
| Exhaustive Extraction | No appreciable extractables originating from the test article when the test article is subjected to exhaustive extraction conditions |
| Leachables Testing | Safe as long-term implants |
| Hydrolytic Stability Testing | Stable for accelerated equivalent of 5 years |
| Photostability Testing | The results show no additional leachable substances from the EC-3 after UV-A exposure and no significant loss of UV absorption properties over the 20 year test period. |
| Nd:YAG Laser Exposure Stability Testing | The results show no additional peaks from the Test leachate were detectable in the UV-Vis absorption spectra. No additional peaks from the Test leachate were detectable in HPLC or GC/FID chromatograms. |
| Insoluble Inorganic Residuals Testing | All inorganic insoluble residuals were below 0.2µg/lens |

**B. <u>Laboratory Studies and Manufacturing</u>**

Optical and mechanical testing were performed per ISO 11979-2 *Ophthalmic Implants – Intraocular lenses – Part 2: Optical Properties and Test Methods*, and ISO 11979-3 *Ophthalmic Implants – Intraocular lenses – Part 2: Mechanical Properties and Test Methods*. Results are summarized in Table 2.

Table 2: Laboratory Studies

| Laboratory Studies | Test Results |
|---|---|
| Dioptric Power | Meets standard |
| Imaging Quality | > 63% |
| Spectral Transmission | % T > 90% at 600nm;<br>% T=10% at 383nm |
| Dimensions | Meets ISO Standard |
| Compression Force | Mean = 0.178g |
| Axial Displacement | Mean = 0.457mm |
| Optic Decentration | Mean + 2s =<br>0.334mm < 0.48mm<br>(10% clear optic) |
| Optic Tilt | Mean + 2s = 3.36° < 5° |
| Angle of Contact | Mean 90° |
| Compression Force Decay | Before: Mean = 0.210<br>After: Mean = 0.151 |
| Dynamic Fatigue Durability | No broken loops following 250K cycles of haptic compression (n=60) |
| Loop Pull Strength | Mean = 0.98 ± 0.10N |
| Surface and Bulk Homogeneity | Lenses inspected under 10x magnification for defects |
| Lens Foldability | Not adversely affected following 3 minutes in a folded state. |

**C. <u>Sterilization, Packaging, Shelf Life & Transport Tests</u>**

The objective of the sterilization, shelf life and transport stability studies was to establish a complete microbiological profile for the finished IOL. The EC-3 IOL is packaged in a lens tray that is sealed with a cap. The tray is then placed in a Tyvek pouch and is shipped sterile (via ethylene oxide) to the end user. The tests conducted in support of the sterilization validation, package integrity, shelf life, and transport stability studies for the device are summarized in Table 3.The device in its packaging is validated for a shelf life of 5 years.

Table 3: Sterilization, Packaging, Shelf Life & Transport Tests

| Test | Test Result |
|---|---|
| Sterilization Validation | Performed per ISO 11135, "Sterilization of health care products-Ethylene Oxide," and EN 550, "Sterilization of Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization" |
| Sterilant Residuals | Ethylene Oxide (EO) - meets requirements of 1.25 µg per lens<br>Ethylene Chlorohydrin (ECH) – meets requirements of 5 µg/lens |

| | |
|---|---|
| Bioburden test | Pre-sterilization bioburden levels were within acceptable limits |
| Bacterial Endotoxin | Endotoxin levels were below the Agency's recommended limit for intraocular lenses |
| Sterility Test | No microbial growth was detected |
| Bacteriostasis/fungistasis test | No bacteriostatic/fungistatic effect was observed |
| Package Evaluation – Dye migration | No leaks were detected in the package seals |
| Package Evaluation – Bubble Emission | No leaks were detected in the packaging |
| Transport Stability | The results showed that the lenses would not be damaged during shipping. |

The overall results of the preclinical tests were acceptable from biocompatibility, physicochemical, optical, mechanical, and shelf-life perspectives.

## X. SUMMARY OF PRIMARY CLINICAL STUDY

Aaren Scientific performed a clinical study to establish a reasonable assurance of safety and effectiveness of intraocular implantation with the EC-3 posterior chamber intraocular lens (IOL) for the visual correction of aphakia when the cataractous lens was removed by phacoemulsification with a continuous curvilinear capsulorhexis under IDE # G060107. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

### A. Study Design

Patients were treated in one eye only between April 2007 and January 2008. The database for this PMA reflected data collected through January 2009 and included 324 subjects. There were 14 investigational sites.

The Aaren Scientific EC-3 IOL was evaluated in a 12-month, prospective, non-randomized multi-center clinical investigation to establish safety and effectiveness compared to historical literature controls, specifically, the FDA "Grid" of cataract surgery results. In the past, the data reported in Stark, W.J., et al, The FDA Report on Intraocular Lenses, Ophthalmology 90(4):31 1-317, 1983 have been used as an historical control. These data have been updated from recent FDA approved IOL experience for adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models, with a Study endpoint of 1 year. Post-operative safety and effectiveness outcomes were compared against "FDA Grid" values (ISO 11979-7: 2006).

Clinical studies have not been conducted with the EC-3 PAL IOL to assess the effect of the added aspheric surface on spherical aberration, visual acuity, and contrast sensitivity.

## 1. Clinical Inclusion and Exclusion Criteria

Enrollment in the EC-3 clinical study was limited to patients who met the following inclusion criteria:

- Patients must be undergoing primary intraocular lens implantation for the correction of aphakia following cataract extraction by an extracapsular method (e.g., small incision phacoemulsification).
- Patients must be at least 50 years of age at the time of implant surgery.
- Patients must be able to return for scheduled follow-up examinations for one year after surgery.
- The patient must sign an Informed Consent Form.
- Best Corrected Visual Acuity (BCVA) is poorer than 20/40 with the potential for correction to 20/20.
- Clear intraocular media other than cataract.

Patients were not permitted to enroll in the EC-3 clinical study if they met any of the following exclusion criteria:

- Patients with corneal astigmatism of greater than 1.50D in the operative eye.
- Patients with any anterior segment pathology (chronic uveitis, iridocyclitis, rubeosis iridis, corneal dystrophy, poor pupil dilation in the operative eye, etc.).
- Patients with uncontrolled glaucoma or under current treatment for glaucoma in either eye.
- Patients with previous retinal detachment or retinal pathology in the operative eye.
- Patients with systemic disease that could increase operative risk or confound the outcome.
- Subjects with ocular disorders such as macular degeneration or other retinal disorders that could possibly cause future acuity losses or require retinal laser treatment.
- Patients with congenital bilateral cataract.
- Patients with marked microphthalmos or aniridia in either eye.
- Patients with any other serious ocular pathology, serious ocular complications at the time of cataract extraction (e.g., capsule rupture, anterior capsule tear during continuous curvilinear capsulorhexis, vitreous loss, zonular dis-insertion or other surgical complications that would compromise IOL stability), or underlying serious medical conditions, based on the Investigator's medical judgment. These patients should NOT be implanted with the device.
- Patients in whom secure placement of the IOL in the capsular bag cannot be achieved (as determined pre-operatively), or in whom zonular rupture may affect the postoperative centration or tilt of the lens, should NOT be enrolled in the study and implanted with this device.

- Patients using systemic medications with significant ocular side effects or any medications that could confound the outcome or increase the risk to the subject.
- Patients with only one eye with potentially good vision, (i.e., expected to achieve 20/40 (6/12; 0.5) or better).
- Patients who have had previous ocular surgery in the operative eye, including Lasik.
- Patients with corneal abnormalities or disease.
- Patients participating in any other clinical trial or who have participated in a clinical trial within past 30 days.
- Abnormal angle as shown by gonioscopy.

**2. Follow-up Schedule**

All patients were scheduled to return for follow-up examinations at 1-2 days, 7-14 days, 30-60 days, 120-180 days, and 330-420 days postoperatively.

Preoperatively, patients scheduled to undergo cataract extraction and IOL implantation were screened for eligibility, and eligible patients were evaluated to obtain a medical history and establish a baseline for ocular condition.

Postoperatively, patients underwent a complete ophthalmic evaluation at regularly scheduled intervals to assess the condition of their eyes and visual function for 12 months after their cataract surgery. Postoperatively, the objective parameters measured during the study included adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

**3. Clinical Endpoints**

The safety endpoints were adverse event rates compared to historical controls, specifically the FDA "Grid" of cataract surgery results. In the past, the data reported in Stark, W. J., et al., The FDA Report on Intraocular Lenses, Ophthalmology, 90(4):311-317, 1983 has been used as an historical control. These data have been updated from recent PMA approved IOL experience for adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models.

The effectiveness endpoints were overall Best-Corrected Distance visual acuity (VA) (% achieving 20/40 or better) and Best-Case Best-Corrected Distance VA (% achieving 20/40 or better) compared to historical controls.

## 4. Accountability of PMA Cohort

At the time of database lock, of 354 subjects enrolled in PMA study, 91.5% (324) subjects were available for analysis at the completion of the study, the 12 month post-operative visit. The patient accountability is detailed in Table 4.

A total of 354 male and female subjects between the ages of 50 and 95 were implanted with the EC-3 IOL. Of these 91.5% (324/354) completed the one year study with the percent accountability of 96.7%. At one year 19 subjects (5.4%) were discontinued and 11 (3.1%) were lost-to-follow-up. The following table shows the subject accountability at each follow-up visit.

Table 4: Patient Accountability by Postoperative Visit

| Total Subjects (N) = 354 | 1 Day | 1 Week | 1 Month | 6 Months | 1 Year |
|---|---|---|---|---|---|
| Available for Analysis n/N (%) | 353/354 (99.7%) | 347/354 (98.0%) | 341/354 (96.3%) | 330/354 (93.2%) | 324/354 (91.5%) |
| Discontinued* n/N (%) | 0/354 (0.0%) | 0/354 (0.0%) | 0/354 (0.0%) | 2/354 (0.6%) | 19/354 (5.4%) |
| Lost to Follow-up† n/N (%) | 0/354 (0.0%) | 2/354 (0.6%) | 7/354 (2.0%) | 10/354 (2.8%) | 11/354 (3.1%) |
| Missed Visit‡ n/N (%) | 1/354 (0.3%) | 5/354 (1.4%) | 6/354 (1.7%) | 12/354 (3.4%) | 0/354 (0.0%) |
| % Accountability = Available for Analysis / Enrolled - Discontinued | 99.7% | 98.0% | 96.3% | 93.8% | 96.7% |

N = Total number of subjects enrolled.

* Discontinued

† Lost to follow-up: Subjects unable to be contacted for 12-Month Visit.

‡ Missed visit: Subjects were not examined at the scheduled visit, however, were examined at a subsequent visit.

## 5. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an IOL study performed in the US. Approximately 62% of the population was female (219/354) with 38% male (135/354). Nearly all subjects were Caucasian (351/354), 1 Black, 1 self-reported as of "mixed" ethnicity and 1 reported as "Other." The mean age for all subjects was 73.5 years old with a range of 50 to 95 years. The subjects ranged in age from 50 to 95 years with half of the subjects in the 70 to 80 year old age group. The study population demographics are summarized in Table 5.

Table 5: Patient Population

N=354

| NUMBER OF SUBJECTS | | 354 Enrolled Subjects |
|---|---|---|
| **Gender** | n | % |
| Female | 219 | 61.9% |
| Male | 135 | 38.1% |
| **Race** | | |
| Asian | 0 | 0.0% |
| Black | 1 | 0.3% |
| Caucasian | 351 | 99.1% |
| Mixed | 1 | 0.3% |
| Other | 1 | 0.3% |
| **Age** (Years) | | |
| <60 | 20 | 5.6% |
| 60 to < 70 | 76 | 21.5% |
| 70 to < 80 | 177 | 50.0% |
| ≥ 80 | 81 | 22.9% |
| **Age** (Years) | | |
| Mean (±SD), N | 73.5 (±8.0), 354 | |
| Range | 50.0 – 95.0 | |

Age: 3 subjects were 50 years old; 1 subject was 95 years old

## 6. Safety and Effectiveness Results

### a. Safety Results

The analysis of safety was based on the cohort of 324 patients available for the 12-month evaluation. The analysis of safety was based on adverse event rates compared to historical controls, specifically the FDA "Grid" of cataract surgery results. In the past, the data reported in Stark, W. J., et al, The FDA Report on Intraocular Lenses, Ophthalmology, 90(4):311-317, 1983 has been used as an historical control. These data have been updated from recent PMA approved IOL experience for adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models. The key safety outcomes, cumulative and persistent adverse events, for this study are presented below in Tables 6 and 7. All complications and adverse events reported for patients in this study are consistent with those seen for patients in this age group and who have been implanted with a posterior intraocular lens.

Table 6: Cumulative Adverse Events*

| Cumulative Adverse Events | EC-3 % | Historical % |
|---|---|---|
| Secondary Surgical Intervention | 2.0 | 0.8 |
| Open operative side-port (incision to relieve elevated IOP) | 0.6 | N/A |
| Lens removal | 0.6 | N/A |
| Repair Retinal Detachment | 0.3 | N/A |
| "Piggyback" procedure | 0.3 | N/A |
| Epi-retinal membrane removal | 0.3 | N/A |
| Cystoid Macular Edema | 1.1 | 3.0 |
| Hyphema | 0.3 | 2.2 |
| Retinal Detachment | 0.3 | 0.3 |
| Endophthalmitis | 0.0 | 0.1 |
| Hypopyon | 0.0 | 0.3 |
| IOL Dislocation | 0.0 | 0.1 |
| Pupillary Block | 0.0 | 0.1 |

* Cumulative: Occurring at any time during the study.

Table 7: Persistent Adverse Events*

| Persistent Adverse Events | EC-3 % | Historical % |
|---|---|---|
| Cystoid Macular Edema | 0.3 | 0.5 |
| Corneal Edema | 0.0 | 0.3 |
| Iritis | 0.0 | 0.3 |
| Elevated IOP Requiring Treatment | 0.0 | 0.4 |

* Persistent: Present at the One-Year Visit for any subject.

**b. Effectiveness Results**

The analysis of effectiveness was based on visual acuity on 324 patients at the twelve-month time point. Key effectiveness outcomes are presented in Tables 8 and 9. Of those patients implanted with the Aaren Scientific EC-3 IOL, 99.1% achieved a best corrected visual acuity of 20/40 or better , and 99.3% a best case best corrected visual acuity of 20/40 or better, as compared to the FDA historical controls of 92.5% and 96.7% respectively. The rates for both overall and best-case 20/40 or better visual acuity for the cohort population exceed the FDA grid values.

Table 8: **Best Corrected Visual Acuity by Age: All Patients**

| Visual Acuity One Year | Age (in Years) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | < 60 | | 60 to < 70 | | 70 to < 80 | | ≥80 | |
| | n | % | n | % | n | % | n | % |
| 20/20 or better | 14 | 73.7 | 45 | 67.2 | 114 | 68.3 | 38 | 53.5 |
| 20/25 or better | 17 | 89.5 | 59 | 88.1 | 152 | 91.0 | 57 | 80.3 |
| 20/32 or better | 18 | 94.7 | 63 | 94.0 | 164 | 98.2 | 68 | 95.8 |
| 20/40 or better | 18 | 94.7 | 66 | 98.5 | 166 | 99.4 | 71 | 100 |
| *FDA Grid for % of 20/40 or better* | *97.9%* | | *95.7%* | | *93.4%* | | *86.5%* | |
| ***$\chi^2$ test p-value for H0: p=FDA Grid*** | P=0.8625 | | P=0.4062 | | P=0.003 | | P=0.0016 | |
| ***Fisher's exact test for comparing %s of 20/40 or better among the age groups*** | P=0.1556 | | | | | | | |
| 20/41 to 20/63 | 0 | 0.0 | 1 | 1.5 | 1 | 0.6 | 0 | 0.0 |
| 20/64 to 20/100 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 20/101 to 20/200 | 1 | 5.3 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Worse than 20/200 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| N[1] | 19 | | 67 | | 167 | | 71 | |
| N (missing)[2] | 0 | | 0 | | 0 | | 0 | |
| Total[3] | 19 | | 67 | | 167 | | 71 | |

1 N = Number of available subjects with 1-Year VA for the corresponding age group.
2 N (missing) = Number of available subjects with missing 1-Year VA for the corresponding age group.
3 Total = Number of available subjects at 1-Year for the corresponding age group.

Table 9: Best Corrected Visual Acuity by Age: Best Case Patients

| Visual Acuity One Year | Age (Years) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | < 60 | | 60 to < 70 | | 70 to < 80 | | ≥80 | |
| | n | % | n | % | n | % | n | % |
| 20/20 or better | 13 | 72.2 | 43 | 68.3 | 110 | 68.8 | 37 | 56.1 |
| 20/25 or better | 16 | 88.9 | 57 | 90.5 | 148 | 92.5 | 54 | 81.8 |
| 20/32 or better | 17 | 94.4 | 61 | 96.8 | 158 | 98.8 | 65 | 98.5 |
| 20/40 or better | 17 | 94.4 | 62 | 98.4 | 160 | 100 | 66 | 100 |
| *FDA Grid for % of 20/40 or better* | *98.5%* | | *96.5%* | | *97.5%* | | *94.8%* | |
| ***$\chi^2$ test p-value for H0: p=FDA Grid*** | P=0.6547 | | P=0.6242 | | P=0.0764 | | P=0.1042 | |
| ***Fisher's exact test for comparing %s of 20/40 or better among the age groups*** | P = 0.0274 | | | | | | | |
| 20/41 to 20/63 | 0 | 0.0 | 1 | 1.6 | 0 | 0.0 | 0 | 0.0 |
| 20/64 to 20/100 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 20/101 to 20/200 | 1 | 5.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Worse than 20/200 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| N[1] | 18 | | 63 | | 160 | | 66 | |
| N (missing)[2] | 0 | | 0 | | 0 | | 0 | |
| Total[3] | 18 | | 63 | | 160 | | 66 | |

1 N = Number of available subjects with 1-Year VA for the corresponding age group.
2 N (missing) = Number of available subjects with missing 1-Year VA for the corresponding age group.
3 Total = Number of available subjects at 1-Year for the corresponding age group.

## XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Aaren Scientific conducted a multicenter, international, clinical study in Italy, France and Germany using the EC-3 IOL. A total of 96 eyes were implanted and the patients were followed for 6 months post implantation. A total of 49 of these eyes implanted with the EC-3 IOL were followed at twelve months and later following the implant procedure. Subsequently, a 15-subject study was also performed in Columbia, South America under a clinical protocol similar to that used for the European trial and the IDE clinical investigation. Results of these studies where 160 EC-3 IOLs were implanted demonstrated the same safety and effectiveness profile as that shown in the pivotal clinical investigation.

## XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmology Devices Advisory Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

## XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

### A. Safety Conclusions

The adverse effects of the device are based on data collected in a clinical study conducted to support PMA approval as described above. The Aaren Scientific EC-3 IOL cumulative and persistent adverse event rates at 12 months are lower than the FDA historical control grids for all adverse events assessed.

### B. Effectiveness Conclusions

The effectiveness of the device is based on data collected in a clinical study conducted to support PMA approval as described above. The rates for both overall and best-case 20/40 or better visual acuity for the cohort population exceed the FDA grid values.

### C. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use: primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed. It is recommended that the use of the intraocular lens be initially limited to one eye. Use of the lenses is especially appropriate in patients who cannot tolerate contact lenses,

those who would not be candidates for cataract spectacles, or for patients requiring an intraocular lens for occupational or other reasons.

The risks associated with eye surgery and implantation of this intraocular lens included corneal and macular edema, iritis, and increased intraocular pressure.

Yet there is an important benefit of restoring sight using a biocompatible permanent implant in an eye, previously obstructed by a cataractous lens. It is reasonable to conclude that the benefits of use of the lens for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use.

## XIV. CDRH DECISION

CDRH issued an approval order on October 19, 2010. The final conditions of approval cited in the approval order are described below.

The applicant's manufacturing facility was inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

## XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.