

**PMA P030016**

**QUESTIONS FOR PANEL DISCUSSION**

**QUESTION 1**

Specular microscopy data is available for 205 eyes at 3 years and 67 eyes at 4 years. The mean endothelial cell loss at 3 years, as compared to preoperative measurement, was 8.9% for a cohort of 154 eyes. The mean loss at 4 years was 9.7% for a cohort of 57 eyes.

- A) The mean change between 3 years and 4 years in 57 eyes was a gain of 0.1%. A decrease in coefficient of variation and an increase in percentage of hexagonality were observed over time. **Is there sufficient data to support the sponsor's conclusion that losses in the first three years are reflective of the surgical trauma with prolonged remodeling, culminating in stabilization of cell loss after three years? If not, what is the minimum number of eyes and the minimum length of follow-up that you recommend for this assessment?**
- B) Eyes with Anterior Chamber Depth (ACD) of 2.80 to 3.00 mm experienced a mean loss of 12.2% of endothelial cells between the preoperative and three year visits, as compared to 8.4% for eyes with ACD > 3.00 mm. Endothelial cell percentage loss for the groups of eyes with ACD of 2.80 to 3.00 mm was statistically significantly larger than that of the ACD groups of >3.00 to 3.50 mm and >4.00mm. **Do the outcomes of the endothelial cell density analysis provide reasonable assurance of safety for this device for eyes with: 1) ACD of 2.8-3.00 mm; and 2) ACD > 3.00 mm?**

**QUESTION 2**

In the PMA cohort five eyes (0.9%) developed nuclear opacities >2+. There were a total of 14 cases of anterior subcapsular lens opacities (ASC) graded as trace or more.

- A) There were no new observations of ASC beyond 26 months of this three year trial. Nuclear opacities were first reported between two and three years. **Do you believe that three year follow-up is sufficient to establish a lens opacification profile associated with this device? If not, what is your recommendation?**
- B) In the PMA cohort, 11 of the 14 cases with ASC appeared at or before the 6 months visit, suggesting surgical trauma as the likely cause. When each investigator's surgical cases with V3 and V4 models were combined, 50% of early ASC cases occurred within the first 8 surgical cases. If site 15 is excluded, 87.5% of early ASC cases occurred within the first 8 cases.

In the Canadian Trial performed by 3 inexperienced surgeons, 22.5% of cases developed ASC. The Dominican Republic study, performed under supervision of the surgical proctor, demonstrated a rate of 4.8 % of ASC development

**In light of these findings, do you believe surgeon experience to be an important factor in ASC development secondary to surgical trauma? If yes, do you believe that future users of this lens should be required to undergo special training?**

- C) Three cases of ASC occurred between 12 and 26 months. All three ICLs had poor vault. The sponsor has demonstrated an association between poor vault and ASC development. However, the sponsor recommends replacement of the ICL only in cases of poor vault that exhibit early ASC in areas of ICL touch in subjects with UCVA worse than 20/50. **Do you agree with this recommendation? If not, what would you recommend?**

### **QUESTION 3**

All clinical investigations of STAAR ICL to date utilized the horizontal white-to-white and anterior chamber depth measurements for determination of the appropriate overall diameter.

In the PMA cohort, the ICL was replaced in 1.5% (8/526) of eyes due to surgeon's perception of inappropriate sizing.

There have been several reports in the literature, as well as presentations at the professional meetings, that indicate lack of correlation of white-to-white measurements and the sulcus-to-sulcus dimensions of the posterior chamber. None of the external measurements have been able to accurately predict internal ocular dimensions.

**Do you believe that the method currently recommended by the sponsor, for determination of the overall diameter of the ICL to be inserted, is appropriate? If not, what do you recommend?**

### **QUESTION 4**

There are currently no devices approved in the U.S. for correction of myopia greater than 15 D. STAAR ICL is requesting approval up to 20 D of myopia. There were 52 eyes treated with myopia > 15 D to 20 D. Three year data is available for 31 eyes. This data reveals:

- ?? At 6 months or later 3.8% of eyes had > 2 line loss of BSCVA, 5.8% had 2 line loss and 17.3% had 1 line loss (equivalent to 2 line loss due to magnification);
- ?? Clinically significant cataract occurred in 13.5% of eyes (5.8% with ASC and 7.7% with nuclear);
- ?? Retinal detachment occurred in 3.8% of eyes;

- ?? Predictability within 0.50 D was achieved in 23.3% and within 1.00 D in 53.3% of eyes;
- ?? Resultant MRSE was  $>-3D$  in 25.9% of eyes; and
- ?? 38.7% of all eyes (irrespective of preop BSCVA and postop target) achieved UCVA of 20/40 or better.

- A) Do the safety and efficacy data for eyes with preoperative myopia of greater than 15 D to 20 D support approval of this refractive range?**
- B) If approval for eyes with preoperative MRSE  $>15 D$  to  $20 D$  is recommended, is the term “correction of ” as it relates to this refractive range, appropriate in the indication statement? If not, what alternative term do you recommend?**

### **QUESTION 5**

**Do the safety and effectiveness outcomes support approval of STAAR ICL for the eyes with the following preoperative MRSE:**

- a)  $-3.00 D$  to  $-7.00D$ ; b)  $>- 7.00 D$  to  $-10.00 D$ ; and c)  $> - 10.00 D$  to  $-15.00 D$ ?**

### **QUESTION 6**

Management of acute IOP rises in the early postoperative treatment requiring repeat peripheral iridectomy or irrigation / aspiration was necessary in 20 patients (3.8%). IOP's measured in these cases were as high as 65 mm Hg. Time distribution of these occurrences was between 1 to 21 days postoperatively. **Do you believe that specific recommendations regarding early postoperative follow-up are needed in the labeling?**

### **QUESTION 7**

**Do you have any additional labeling recommendations?**