

P010018

QUESTIONS FOR PANEL DISCUSSION

1. What are the concerns regarding the incidence of induced cylinder with significant axis shift, and its consequent effect on efficacy?
2. Is 12-month follow-up sufficient to provide reasonable assurance of safety and efficacy? There are 21 eyes available at 24 months. Should data for these eyes also be required in the labeling?
2. Does the refractive correction obtained with this device, in light of the rate of change of mean MRSE over time and the incidence of over- and undercorrection, justify the potential risks?
4. Are there concerns regarding the increased incidence of visual symptoms from pre-op levels?
5. Do the safety and efficacy data presented in this PMA support approval of this device for the requested indication? Is the requested indication appropriate as worded, based on the study outcome?
6. What are your recommendations for labeling regarding regression of effect, induction of cylinder, and incidence of visual symptoms? Are there additional labeling recommendations?