the event, date first observed, any action taken, and ultimate outcome will be recorded.

1. Complications: Postoperative events that are anticipated, occur at an expected rate, and are manageable with usual standard of care should be recorded as complications. LASIK complications could include, but are not limited to:
   - Corneal edema between one week and one month after the procedure
   - Peripheral corneal epithelial defect at 1 month or later (location of the defect to be identified as on, off, or across the flap)
   - Epithelium in the interface (with or without scraping of epithelial cells)
   - Foreign body sensation at 1 month or later
   - Pain at 1 month or later
   - Ghost or double images in the operative eye
   - Central islands, glare or other postoperative visual events at 1 month or later
   - Flap is not of the size and shape as initially intended or microtome stopped in mid-cut

2. Adverse Events: Postoperative complications that are serious in nature, are vision-or-life-threatening, and all unanticipated adverse device effects should be recorded as adverse events. LASIK adverse events could include, but are not limited to:
   - Corneal infiltrate or ulcer
   - Any corneal epithelial defect involving the keratectomy at one month or later
   - Lost, misplaced, or misaligned flap
   - Melting of the flap
   - Uncontrolled intraocular pressure with increase of >10 mm Hg above baseline and any reading above 25 mm Hg
   - Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA
   - Decrease in BSCVA of more than 10 letters not due to irregular astigmatism as shown by hard contact lens refraction at 6 months or later
   - Retinal detachment
   - Retinal vascular accidents

3. Serious and Unanticipated Adverse Device Effects: An unanticipated adverse device effect is defined as "any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device if that