3. Please provide narratives to further elaborate on each case reported as a complication, including the management and outcome, for eyes not included in the narratives above. Please group this information according to the 4 indications for treatment.

4. The adverse event previously reported in the last annual report, 1 case of a corneal infiltrate or ulcer at 1 month postoperatively, was not included in the tabulation of adverse events in this report. Please elaborate on this adverse event including the subject's preoperative visual status, management, and outcome.

5. Please provide tables (similar to those requested for initial treatments) and narrative summarizing the results of the IDE substudy of enhancements for 25 subjects/50 eyes that had undergone treatment prior to implementation of the IDE, and of the data from enhancements performed for eyes enrolled under the IDE. Please provide separate analyses for the first enhancement, second enhancement, etc.

Please address the following additional deficiencies related to the annual report:

6. Please report the rate of unintended overcorrections > 2 D at 3 months or later, a key safety variable.

7. Although page 38 of this annual report indicates that 188 eyes were enrolled in the contrast sensitivity substudy, Substudy NEV-98-002, page 4 states that a total of 184 eyes of 113 subjects have been enrolled in this substudy – 92 low myopia subjects and 21 high myopia subjects. Please resolve this apparent discrepancy.

8. Accountability is extremely poor. Please describe how you intend to improve accountability by assuring proper follow-up of subjects according to your protocol during your ongoing IDE study. Please be advised that aside from being a serious PMA concern, continued, improper follow-up of subjects may be reason for withdrawal of approval of an IDE study by the FDA.

9. You indicated to FDA, through your consultant Dr. Fant, that you are no longer enrolling subjects. However, it appears that you enrolled subjects up to at least December 19, 2001. As you have been advised previously, you are required to submit monthly accountability reports for each subject treated; these reports should include the investigator, the patient identifier, the eye treated, the date treated and the treatment performed.
   a. Please provide these monthly reports beginning with patients treated in January, 2002.
   b. The last monthly report we have on file is for January 1998. Please provide an accountability table for all eyes treated since January 20, 1998, in the format described in a., above.
   c. If you have ceased enrollment, please submit a request to FDA to cease enrollment. If this is the case, you still need to provide the information requested in b. above up to the date of cessation of enrollment.