been studied by the FDA, and the FDA does not regulate LASIK, only the devices used for the procedure.

22. Question 8 of the Informed Consent Quiz states, "TRUE OR FALSE: There is a good chance that my eyes will regress to the refractive error as before the surgery," and the Correct Answers and Explanation states, "FALSE There is practically no chance that your vision will regress completely." Since this is the subject of your IDE study, please remove this question from your consent form.

23. Please submit the intra-operative/day of surgery case report form for review.

24. Please be advised that until preliminary safety, efficacy, and stability are demonstrated in a sufficient number of eyes, we cannot allow fellow eye treatment or re-treatment. In addition, subject enrollment should occur in stages in an IDE study for a new technology, new refractive laser device, or a new indication. FDA will evaluate the subject data from each stage prior to expansion of the study. You may request a protocol modification to include fellow eye treatment, re-treatment, and an increase in the number of subjects by submitting data demonstrating satisfactory stability, safety and efficacy. Please revise your protocol and informed consent document accordingly. We recommend for the early subjects to be contact-lens tolerant in the fellow eye. These subjects should be advised that six or more months may elapse before fellow-eye treatment is allowed.

25. Please confirm that subjects with mixed astigmatism will not be enrolled into either protocol.

26. Please verify that there will only be 2 investigators involved in this study.

27. Please provide your agreement that all co-managing doctors that collect data on the study subjects will be considered sub-investigators, and, therefore, they will need to follow the same SOP's under the protocol and sign the investigator's agreement prior to their participation in the study.

28. There are discrepancies in the way you refer to the protocols throughout the submission. For example, in the Introduction you refer to the new protocols as NEV-97-002 (Myopia/Myopic Astigmatism) and NEV-97-003 (Hyperopia/Hyperopic Astigmatism). However, the myopia protocol itself has been labeled with the protocol number NEV-01-002. To avoid confusion, please make all necessary revisions in any future submission to correct such discrepancies.

Please respond to the following engineering concerns:

29. In Section 2.2 (Page 8-9), the total cumulative number of pulses (shown in Figure 2.2-1) for each area in a selected 1.33 mm zone does not match your narrative. Based on your description, the pulses are delivered to a diamond shaped area (not a slot area). It