8. You have not adequately addressed Deficiency #5 in our letter of May 8, 1997 regarding the beam path for the operating microscope and subsystems. Please provide a ray trace which also shows how the microscope is positioned in referen e to the subject's eye, the aiming laser, the treatment laser, the fixation lights, etc.

9. Although you indicate that the COMPex 201 laser engine has a divergence of 3 milliradians/meter, please provide the divergence for your laser system after the last focusing lens.

10. In your description of the operative procedure, please specify the thickness of the corneal flap that is cut and reflected prior to ablation.

11. Please correct your protocol, page 19, to reflect that soft contact lenses will be lef out for at least 3 days prior to examination and surgery.

12. Please provide additional *technical* information regarding the methods of obtainir g and maintaining both temporal and spatial beam homogeneity.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We acknowledge your request to conduct a study at one site with approximately 990 eyes f r each of two investigators. We believe that adequate safety information has been provided t allow the initiation of your study at one site with 100 subjects; however, issues remain whi h must be resolved prior to the expansion of your study for marketing approval. Prior to your request for expansion beyond 100 subjects, you should submit the results of this initial pha e after 50% of the subjects have achieved at least 3 months of follow-up. FDA 0 0019

We would like to point out that FDA approval of your IDE application does not imply th t this investigation will develop sufficient safety and effectiveness data to assure FDA appro l of a premarket approval (PMA) application for this device. You may obtain the guideline or the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," fro t