8. The electrical safety information provided applies only to the Lambda Physik excimer laser, not the complete device as required by FDA. Also, the standards cited are German standards which to date have not been accepted by FDA. You are reminded that you should provide electrical certification for the *entire system*, including the laser, motors, other electrical devices which connect to the laser, electrically operated chairs, etc. Please provide certification that the device conforms to a recognized national or international electrical safety standard for medical devices (e.g., Underwriters Laboratories, UL544 76, UL-2601 for Medical Equipment Systems; Canadian Standards Association, C22.2 No.125-M1984; British Standards Institute, BS 5724; International Electrotechnical Commission, IEC 601-1; Japanese Industrial Standard, JIS T1001; or, equivalent).

9. Although you provided the ray trace for the microscope section, the ray trace diagram in tab 3.4.1.3.B-2 (original IDE) does not show how the optics along the delivery path condition the beam, and the beam imaging module is not adequately depicted or described in the submission. Please provide more detailed information on both of these items and address the comments below:

   a. The optic diagram (3.4.2.2_A.4 on page 78) needs a ray trace to show how all the components function to condition the beam from the raw beam output to projection onto the corneal surface.

   b. The beam imaging module has not been adequately described. Please describe the components of the beam imaging module, their specifications, a diagram with ray trace diagram to illustrate the optical design, and the manner in which the intended functions are attained.

10. Please provide the following information about your laser system:

    a. please specify the cavity type for your laser: stable or non-stable; and,

    b. please specify the stability of the pulse through the gas lifetime and indicate how this was determined.

Ablation Algorithms and Profilometry:

11. You stated in supplement 4 that the etch rate curve is being generated; therefore, this remains a deficiency. Please provide the etch rate *curve*, showing the laser energy per pulse versus the PMMA removed, for energy levels above and below your treatment energy level. Provide the expected etch rate in tissue and provide data or documentation to support your expected tissue etch rate.