Calibration:

5. Your description of the beam calibration is inadequate. Specifically, you should provide:

   a. description of the method, technical specifications of any substrates used, validation procedures for the tests, and passing criteria for energy (fluence), homogeneity, beam alignment, and any other calibration procedures;

   b. information on how instrument measurement precision was determined, and a calibration schedule;

   c. a diagram of the measurement set up (i.e., for opening the "beam shaping aperture") and test firing;

   d. the technical specifications of the Chiron substrate used for measurements so that the number of pulses and the irradiance level(s) that provide for breakthrough and complete removal for the substrate material can be verified;

   e. a statistical analysis used for the determination of energy stability;

   f. a technical description of the transparent substrate used for beam homogeneity determination and a description of how the scientific accuracy and validity of the test was determined;

   g. descriptions of any differences between the output beam measurement and homogeneity tests using a substrate of known thickness and ablation characteristics; and,

   h. a description of how the device software determines the energy output needed during the calibration process.

Laser Characteristics:

6. The energy output of your aiming lasers, each at 1 mW, is high relative to the other aiming lasers that we have encountered. Please determine the exposure hazard per CFR 1040.10 and specify the maximum exposure time.

7. Does your laser system have the capabilities to treat other refractive conditions that are not described in this application and which are not disabled for this clinical trial? If the answer is "yes", then please indicate the steps taken to ensure that the device will not be used outside the approved protocol(s).