

Page 3 - Herbert J. Nevyas, M.D.

- Ed iv. Please provide scientific documentation that a final aperture opening of 2 mm does not adversely affect the quality of the ablation profile and whether or not it could induce complications.
- Ed d. Please provide the etch rate and the precision of the etch rate for your laser.
- Ed e. The Spiricon beam analysis provided in Attachment 2.1.B-1 does not appear to be from your laser but, possibly, from a laser similar to yours. Please provide one of the following: (1) a detailed Spiricon beam analysis from your laser; (2) certification from Spiricon that the data presented are from your laser; (3) some other measurement of beam homogeneity performed on your laser; or, (4) appropriate manufacturing information demonstrating that your device is the same (in terms of all components comprising the laser and optics generating the beam, method of manufacture, and GMP compliance) as the device measured in the Spiricon beam analysis. The beam homogeneity measurements should be performed on the beam at the treatment plane at maximum diaphragm opening.
- Ed f. Please provide additional details regarding methods for obtaining and maintaining both temporal and spatial beam homogeneity.
- Ed g. Please provide the nomogram you will be using to produce the patterns of ablation.
- ✓ 3. Please explain the low effectiveness and safety outcomes achieved in your prior clinical studies and specify what steps you are taking to improve your results. Your refractive and visual outcomes were reported at one month as: MSRE for low myopes, < 57% were within 1D and < 35% were within 0.5D; less than 60% achieved BUCVA > 20/40; complication and adverse events occurred in > 2% of the cases.
- Ed 4. Please indicate what Operating System your computer is using.
- Ed 5. Please provide a beam path and narrative description (with diagrams) of the subsystem and components of the operating microscope subsystem, including geometry and eye illumination levels (provide microscope lamp specifications and whether or not illumination is changed for different indications).
- Ed 6. On page 62 you indicate that the beam divergence is 4°. This seems quite large, since beam divergence for these types of refractive lasers is usually on the order of fractions of a degree. Please specify in milliradians what the beam divergence is following the last focussing lens and explain any large divergence (> 50 milliradians).

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