differences with 80% power (e.g., if the standard deviation is 0.3 log unit, about 80 subjects would be needed to meet this target). Postoperative testing should be conducted after visual function has stabilized.

c. If contrast sensitivity testing shows decreased sensitivity under mesopic conditions, it may be possible that better results could be obtained using a different spectacle correction. Knowing the dioptric powers of your ablation could help in choosing appropriate spectacle correction, or provide a basis for adjusting your algorithm. As an aid to documenting the degree of multifocal performance predicted for corneas treated with your ablation algorithms, please provide graphs of either dioptric power or radius of curvature as a function of distance from the center of the ablation for representative myopic, elliptical and astigmatic ablation profiles.

d. Please obtain preoperative and postoperative (after achieving refractive stability) corneal topographic measurements, and provide difference maps and difference profiles showing the change in the contour of the corneal surface resulting from your LASIK procedure for a subset of your subjects treated under this IDE.

e. Please provide data to support your statement (page 8 of supplement 4) that lensometer measurement of the PMMA ablation profile verified the desired dioptric correction. Please provide data to show whether or not lensometer measurement shows more than one possible dioptric reading for the same ablation.

Homogeneity:

15. Your beam appears to be inhomogeneous with varying hot spots and cool spots across the treatment area of the beam. Although you stated in supplement 4 that you are exploring options for adding a beam homogenizer onto your laser, the question regarding homogeneity remains a deficiency. In addition, since calibration is a part of maintaining beam homogeneity, you should address the questions above regarding beam calibration. Please provide additional technical details regarding your methods of obtaining (i.e., conditioning optics) and maintaining (e.g., calibration and maintenance) temporal and spatial beam homogeneity, including the range (tolerances) of acceptable values for homogeneity and data to support your findings.

You should also give serious consideration to the following items which are considered essential for the analysis of your data for the purposes of determining safety and effectiveness for a future PMA application:

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