

Your contrast sensitivity substudy submitted in supplement 8 adequately addresses only deficiency 14.b., in our letter of October 3, 1997. Please submit adequate responses to deficiency 14, page 7, regarding probable multifocal properties of your ablation profiles and the need for procedures for post operative manifest refraction, graphs of dioptric power or radius of curvature as a function of distance from the center of the ablation, preoperative and post operative topographic difference maps, and lensometer measurements of the PMMA profile.

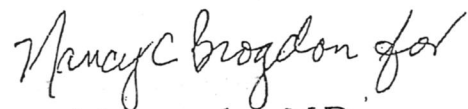
You also may want to consider incorporating into your laser system an additional algorithm to perform spherical ablations, so that you can compare in a clinical substudy your current ablation profile with a spherical ablation profile. We are available to meet with you to discuss our requirements for full approval, if you have any questions or wish further guidance.

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:

Deficiencies 5 through 16, excluding deficiency 14, in our letter of October 3, 1997.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure: Letter of October 3, 1997

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