You indicated that you have performed hyperopic retreatments on your pre-IDE patients. Please provide any information you have on these patients regarding pre-retreatment visual acuity, amount of retreatment required, post-retreatment visual acuity and stability of manifest refraction, and any other information which would be appropriate in demonstrating that this procedure provides a stable retreatment of an overcorrected cornea.

We acknowledge your request in your original IDE (dated March 18, 1997) to conduct a study at one site with 400 eyes low myopia and 590 eyes high myopia for each of two investigators (single site total of 1980 eyes or 990 subjects). We will approve a request to expand to the full number of subjects for this study (990) after you have received approval of supplements addressing the following deficiency from our letter of October 3, 1997. No additional expansions of your IDE will be granted until supplements containing the following information are approved:

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 postoperative manifest refraction, graphs of dioptric power or radius of curvature as a function of distance from the center of the ablation, preoperative and postoperative 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.

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:
"Procedures to Request a Regulatory Hearing."

FDA 0 0041