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We continue to be concerned that your ablation is likely to have multifocal properties, which means that some light will be out of focus even at the best focal plane. It is possible that your proposed mesopic contrast sensitivity study will help resolve some of these concerns. Also, any claims you may wish to assert regarding advantages of multifocality may not be supported by your change in accommodation study.

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

Sincerely yours,

*Nancy C. Brogdon for*

A. Ralph Rosenthal, M.D.

Director

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Office of Device Evaluation

Center for Devices and Radiological Health

FDA C 0053