We also want you to know that if FDA approves your IDE application, you would be able to use your laser to perform only specific procedures on a limited number of subjects to demonstrate the safety and effectiveness of your laser for those procedures. Studies conducted under such an IDE would be subject to all IDE regulations. See 21 C.F.R. Part 812. For example, you would be prohibited from promoting and commercializing the laser, and from representing that the device is safe and effective. The IDE process is designed to investigate the safety and effectiveness of devices either for research or for market authorization, and is not itself a means of market authorization for the commercial treatment of patients. Once studies under your IDE were complete, you would not be able to use your laser unless you were to seek a PMA and FDA were to approve it.

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

Sincerely,

Nancy C Brogdon for

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure