

[REDACTED]
10/6,7,8,13,14,15,20
22,23,26,27,30-
11/2/98 RALS

EXHIBITS:

1. Current letterhead for [REDACTED] that lists doctors associated with the practice [REDACTED] and other office locations.
2. Current patient information and consent form for patients enrolled in clinical study: Treatment of refractive errors, myopia with and without astigmatism.
3. Letter form IRB to [REDACTED] which indicates [REDACTED] as Clinical Research Consultant for [REDACTED]
4. Monitors Log for site visit made to [REDACTED]
5. Monitoring Report for site visit made to [REDACTED]
6. Investigator Agreement signed by Sub-Investigator. [REDACTED] dated 3/18/97
7. Investigator Agreement signed by Primary-Investigator. [REDACTED] dated 3/18/97
8. IRB [REDACTED] approval of clinical study protocol and consent form dated 8/27/97
9. IRB membership list
10. Conditional approval letter dated 1/14/98 for simultaneous bilateral [REDACTED] procedure from CDRH/ODE to [REDACTED]
11. [REDACTED] laser log/intra-operative forms for [REDACTED] indicating simultaneous bilateral [REDACTED] and accompanying consent form
12. [REDACTED] laser log/intra-operative forms and accompanying consent form for [REDACTED] indicating simultaneous bilateral [REDACTED]
13. [REDACTED] dated March 18, 1997 was part of his initial IDE submission