

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

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES:

On 10/6/98 I presented my credentials and issued a FD-482 to [REDACTED] Clinical Coordinator. He is not the most responsible individual at the firm however, [REDACTED], who is the most responsible individual, was unavailable at the time. [REDACTED] is the founder and Medical Director of [REDACTED]. [REDACTED] stated [REDACTED] would be able to answer my questions and would be present throughout most of the inspection.

OPERATIONS:

[REDACTED] is the Medical Director and founder of [REDACTED] where he performs laser eye surgery on patients. [REDACTED] has an [REDACTED] and is conducting a clinical study, Correction of Myopia with and without astigmatism Protocol [REDACTED] under an approved Investigational Device Exemption (IDE). [REDACTED] is a Sponsor/Clinical Investigator and this is the initial inspection for the firm in that capacity. [REDACTED] is the named Sub-Investigator and the only other physician at the firm who performs [REDACTED] surgical procedures with an [REDACTED] laser. The IDE laser is identified as a [REDACTED]. It was built in the fall of 1995 by [REDACTED] a laser scientist and President of [REDACTED] provided [REDACTED] with the basic specifications for the laser and [REDACTED] then designed and built the laser indicating to [REDACTED] the components that were needed and where to order them. The laser system consists of a Laser beam generator, optical lens system, beam shaping apparatus, computer control system and patient treatment chair.

The laser beam generator is a [REDACTED] as halogen source to produce the laser beam; serial number [REDACTED] purchased from [REDACTED]. The housing and electrical/gas delivery system was purchased from [REDACTED]. The other components were ordered from other various manufacturers. [REDACTED] of [REDACTED] performs all maintenance, repairs and calibrations.

Prior to Myopic [REDACTED] surgery the patient is given a patient information and consent form, **EXHIBIT #2**, to read and sign.