

4/19,20,23-30, 5/1-
4,7,10/2001

All FDA correspondence should be addressed to [REDACTED] at the
aforementioned [REDACTED] address. The firm operates Monday
to Friday, 8:00am - 5:00pm.

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES:

On 4/19/01 I presented my credentials and issued a FD-482 to [REDACTED]
[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]
[REDACTED] is the founder and Medical Director of [REDACTED]
[REDACTED] stated [REDACTED] would be able to
answer my questions and 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 [REDACTED] laser 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.
[REDACTED] is the Co-Investigator and the only other
physician who performs [REDACTED] surgical procedures with an excimer
laser at the practice. The laser is identified as a [REDACTED]
[REDACTED] model [REDACTED]. It was built in the
fall of [REDACTED] 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 beam generator is a
[REDACTED] serial number [REDACTED] purchased from [REDACTED]
[REDACTED]. The housing and electrical/gas delivery system
[argon fluoride (ArF) as halogen source to produce the laser beam]
was purchased from [REDACTED]. The
other components were ordered from other various manufacturers.

Previously [REDACTED] of [REDACTED] performed all
maintenance, repairs and calibrations on the [REDACTED] laser.
Currently [REDACTED] a subsidiary of [REDACTED]
[REDACTED] performs
all maintenance, repairs and calibrations on the [REDACTED]
laser.