DATE ASSIGND: 10/98 [redacted]

CENTRAL FILE NO.: [redacted]

CITY: [redacted]

PRIORITY: 1

JD/TA: 11

STATE: [redacted]

1476,1,8,12,14,17,20,22,25,26,
DATE INSP: 27,30-11/2/98 GRP: 5

CNTY: [redacted] PHONE: [redacted]

STREET: [redacted]

ZIP: [redacted] DISTRICT: E

ENDORSEMENT

The routine inspection of this Sponsor/Clinical investigator was conducted per assignment from CDRH, Office of Compliance, Division of Bioresearch Monitoring, (HFZ-312) and in accordance with CP 7348.811. [redacted] is the Medical Director and founder of [redacted] where he performs laser eye surgery on patients. [redacted] has an excimer 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 and this is the initial inspection for the firm in that capacity. [redacted] is the Co-Investigator.

An inspection conducted on 12/2/96 revealed the firm had assembled a single excimer laser and was using it to perform [redacted] eye surgery on at least 120 patients

Previous inspection on 6/30/97 of this facility revealed the firm continued to use the [redacted] laser to perform [redacted] eye surgery without an approved IDE, planned to use the [redacted] laser for new treatment procedures not included in the firms disapproved IDE and verified that the firm had received a disapproval letter from CDRH/ODE notifying them that use of the laser to treat patients was a violation of the law.

The current inspection revealed the firm now does Myopic [redacted] surgical procedures under an approved IDE however, procedures are being performed on IDE patients prior to approval date, the date is missing on a consent form, consent forms were signed by patients after surgery date and procedures were performed on IDE patients which are outside the IDE with an unidentified laser at an unauthorized location.

Forward to CDRH HFZ-312 with Warning Letter Recommendation
Reinspect upon assignment from CDRH HFZ-312

VOLUNTARY CORRECTION DATA

PAC	PROBLEM TYPE	CORRECTIVE ACTION	EST. COST OF ACTION	DATE ACTION VERIFIED	CORRECTING UNIT	REPORTING DISTRICT
[redacted]						

SIGNATURE: [redacted] DATE: 11/19/98

DISTRIBUTION: ORIG + EVH - [redacted]
CC ORIG + EVH -
CC -

[redacted]

NOV 24 1998

FORM FDA 481(E)-CG (09/83)