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[REDACTED]

SUMMARY OF FINDINGS:

The inspection of this Sponsor/Clinical investigator was conducted per assignment from CDRH, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (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, [REDACTED] and is conducting a clinical study, Correction of Myopia with and without astigmatism Protocol [REDACTED] under an approved Investigational Device Exemption (IDE). [REDACTED] Sponsor/Clinical Investigator and [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 without an approved IDE.

A follow-up inspection on 6/30/97 of this facility revealed the firm continued to use the excimer laser to perform [REDACTED] eye surgery without an approved IDE, planned to use the excimer laser for new treatment procedures not included in the firm's disapproved IDE and verification 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 previous inspection conducted 11/2/1998 revealed procedures being performed on IDE patients prior to approval date, missing date on a consent form, consent forms signed after surgery date and procedures done on IDE patients which are outside the IDE with an unidentified laser at an unauthorized location.

The current inspection revealed the firm has corrected the deficiencies noted in the inspection of 11/2/1998 however, the Clinical Investigator did not notify the IRB of all changes or deviations from the protocol. There was an unexplained lapse in IRB approval/coverage for the protocol [REDACTED] for approximately one month. The inspection is classified VAI. An FDA-483 was issued at the conclusion of the inspection.

HISTORY OF BUSINESS:

[REDACTED] is the founder, Chief of Staff as well as the most responsible individual of [REDACTED]

[REDACTED] There are six additional physicians and three other locations associated with the practice.