

Nevyas Eye Assoc.
333 City Av.
Bala Cynwyd PA 19004
4/19,20,23-30, 5/1-
4,7,10/2001 RALS

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. Dr. Herbert J. Nevyas is the Medical Director and founder of Nevyas Eye Associates where he performs laser eye surgery on patients. Dr. Nevyas has an excimer laser, [REDACTED] and is conducting a clinical study, Correction of [REDACTED] under an approved Investigational Device Exemption (IDE). Dr. Nevyas is a Sponsor/Clinical Investigator and Dr. Anita Nevyas-Wallace 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 [REDACTED] 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 [REDACTED]. An FDA-483 was issued at the conclusion of the inspection.

HISTORY OF BUSINESS:

Dr. Herbert J. Nevyas is the founder, Chief of Staff as well as the most responsible individual of Nevyas Eye Associates/Delaware Valley Laser Surgery Institute, 2 Bala Plaza, 333 City Av., Bala Cynwyd PA 19004. There are six additional physicians and three other locations associated with the practice.