

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

All FDA correspondence should be addressed to Dr. Nevyas at the aforementioned Bala Cynwyd PA 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 Dr. Richard Sterling, Clinical Coordinator. He is not the most responsible individual at the firm however, Dr. Nevyas, who is the most responsible individual, was unavailable at the time. Dr. Nevyas is the founder and Medical Director of Nevyas Eye Associates. Dr. Nevyas stated Dr. Sterling would be able to answer my questions and be present throughout most of the inspection.

OPERATIONS:

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 and is conducting a clinical study, Correction of [REDACTED] under an approved Investigational Device Exemption (IDE). Dr. Nevyas is a Sponsor/Clinical Investigator. Dr. Anita Nevyas-Wallace is the Co-Investigator and the only other physician who performs LASIK surgical procedures with an excimer laser at the practice. The laser is identified as a [REDACTED] 8. It was built in the fall of 1995 by [REDACTED]. Dr. Nevyas provided [REDACTED] with the basic specifications for the laser and [REDACTED] then designed and built the laser indicating to Dr. Nevyas the components that were needed and where to order them. The laser beam generator is a [REDACTED], serial number [REDACTED] purchased from [REDACTED]. The housing and electrical/gas delivery system [REDACTED] source to produce the laser beam] was purchased from [REDACTED]. The other components were ordered from other various manufacturers.

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