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

Dr. Herbert Nevyas performs minor parts replacement and maintenance however, all major work is performed by Maintenance records observed during the inspection do indicate that is performing maintenance, repairs and calibrations.

The emission from the laser passes through a safety shutter, beam shaping optics, beam modulator, imaging optics and finally is reflected downward into the working region. The operation of the laser, shutter and beam shaping optics is controlled by a computer system. According to Barbara Fant, consultant, validation of the computer system is to be done by an outside firm and will be included with the submission

The desired lens correction information is entered into the computer which controls the laser beam size and delivered energy density during the ablation process. First a very thin corneal flap is created using an instrument called a popular correction. When the eye is properly positioned, the operator uses a foot pedal to activate the laser and ablate the corneal tissue to achieve the desired lens correction. The corneal flap is then repositioned to heal.

Dr. Nevyas's initial IDE submission was disapproved May 8, 1998. He was granted conditional approval on August 7, 1998. As Dr. Nevyas addressed various issues presented in letters from FDA CDRH/ODE he was granted more uses of the IDE laser. As of 11/2/98 his investigation is limited to 1 institution (333 City Av., Bala Cynwyd PA location) and

According to a letter from the FDA to Dr. Nevyas dated 1/20/99

EXHIBIT #1, the investigation is still limited to one location, listed in bold above however, the population has grown to subjects

and: