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

3. All changes made to the protocol were documented by the investigator, dated, maintained with the protocol, however all changes were not approved by the IRB **(see FDA-483 observation #1 listed on page 4 of this report)**. Patient files were organized, in good condition, complete and legible.

SUBJECTS' RECORDS:

1. The clinical investigator's raw data files were easy to follow, in good condition, organized complete and legible.

2. According to documents reviewed all audited subjects did exist and were alive and available for the duration of their stated participation in the study.

3. Pre-surgical eye tests, as noted in the case report forms, was documented by the presence of completed test records among the raw data.
   a) Adverse reactions were reported in the case report forms and they were listed in the consent form
   b) All concomitant therapy and/or intercurrent illness was clearly indicated on the patient case report forms.
   c) The number and type of subjects entered into the study were confined to protocol limitations.

4. According to the records I reviewed, I observed each patient record contains:
   a) Observations, information, and data on the condition of the subject at the time the subject was entered into the clinical study;
   b) The identity of all persons and locations obtaining raw data or involved in the collection or analysis of such data.
5. According to records reviewed the clinical investigator did report all dropouts, and the reasons therefore, to the sponsor.

Consent of Human Subjects:

1. According to records reviewed, informed consent was obtained from all subjects prior to their entry into the study.