Institutional Review Board (IRB):

1. [redacted]

See **EXHIBIT #10** FOR IRB Membership.

According to records reviewed, the investigator maintains copies of all reports submitted to the IRB and reports of all actions by the IRB.

a) The investigator did submit reports of all deaths and adverse reactions to the IRB.

3. According to records reviewed, the investigator did submit and obtain IRB approval of the protocol, modifications to the protocol **(except as noted in FDA-483 OBSERVATION #1)**, report of prior investigations, materials to obtain human subject consent and media ads for patient/subject recruitment before subjects were allowed to participate in the study.

4. There was no indication that the investigator disseminated promotional material or otherwise represent that the device was safe and effective for the purpose for which it is under investigation.

Records Retention:

1. The clinical investigator maintains custody of the clinical study records. Study is ongoing.

ATTACHMENTS:

1. FDA-482, Notice of Inspection dated 4/19/2001
2. FDA-483, Inspectional Observations

EXHIBITS:

1. Letter from the FDA CDRH, Division of Ophthalmic Devices to Dr. Herbert J. Nevyas dated 1/20/99.