[redacted]
4/19,20,23-30, 5/1-
4,7,10/2001 [redacted]

From the date the first patient was treated under the IDE, August 28, 1997, until 11/2/98 [redacted] has treated 154 subjects (276 eyes) for high and low myopia and 24 subjects (23 eyes) for myopic enhancements.
According to [redacted] refractive log **EXHIBIT #2**, from December 29, 1999 until April 20, 2001 590 patients, 1080 eyes, have been treated for high and low myopia and 162 patients, 241 eyes, for myopic enhancements.

[redacted] surgery is performed at the aforementioned main address and at the office located at [redacted]

OBJECTIONABLE CONDITIONS OR PRACTICES:

At the conclusion of the inspection an FD-483 was issued and a discussion with management held. [redacted] Clinical Investigator and [redacted] Clinical Coordinator attended the meeting.

The following observations refer to the Investigational Device Exemption (IDE) Protocol# [redacted] for the indicated study, " [redacted]) with an [redacted] Laser in the Surgical Treatment of Refractive errors: Myopia with and without Astigmatism"

1. **There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements] prior to implementation.**

   For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until August 28, 2000, 20 months later.

[redacted] uses a national IRB, [redacted] Institutional Review Board [redacted] for his clinical research study.
EXHIBIT #1 is a letter from the FDA CDRH, Division of Ophthalmic Devices to [redacted] which among other things granted him an increase in the number of clinical research study subjects to 1,015.