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

is not identified in the protocol.

During the examination of patient records there were no non-indicated procedures performed on IDE patients with a laser that was not indicated in the study at a location which was not identified in the Protocol [redacted]

7. 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]

Same as prev 483

This observation was carried forth to the current listing of objectionable conditions or practices. **See FDA-483 observation #1 listed above on page #4 of this report.**

Questions from Compliance Program CP 7348.811:

Authority and administration:

1. [redacted] of [redacted] visits the clinical site to monitor the clinical research according to the monitor's log examined during the inspection.

2. [redacted] is the principal investigator and [redacted] is the Co-Investigator, they retain control and knowledge of the study.

3. The study was not discontinued before completion and is currently ongoing.

4. A review of file records revealed pre-surgical eye tests for study patients are performed at [redacted]

Protocol:

1. Protocol for study is included as **EXHIBIT #9.**

2. There were no major changes to the protocol with reference to subject selection, frequency of subject observations, dosage, route of administration, frequency of dosage and blinding procedures, however there was an increase in the number of subjects.