investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make changes to the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects. I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements of 21 CFR Part 812.

We believe that we have complied fully with the Investigator's Agreement, except for the deviations noted in Item #1 above and Item #3 below. Specifically:

- We are conducting our investigation in accordance with the relevant, current protocol. The protocol has not been revised since July 8, 1998 (Version 1.2).
- Only two investigators have used the [redacted] (Dr. [redacted] and Dr. [redacted]). All use of the laser has been under the auspices of clinical protocol [redacted] and no unauthorized use of the laser has been permitted.
- Informed consent has been obtained from all subjects participating in the study and applicable substudies using an IRB-approved consent form. Copies of the signed informed consent documents are retained in the investigator's files for all subjects participating in the clinical study and applicable substudies.
- All adverse experiences have been reported to the sponsor-investigator, FDA, and IRB in accordance with 21 CFR Part 812.
- The clinical investigators have read and understand the laser manual and the protocol and have assured that their staff are informed about their roles and responsibilities with regards to the clinical study. Subinvestigators who perform followup examinations are provided with standardized forms to assure that they perform the required study procedures and report the data in a timely fashion.
- Adequate and accurate records of the investigation are maintained and all records were available for inspection during the recent FDA audit, including consent forms