Inspection Dates: 4/18/00 to 4/20/00

**FDA ITEM:**

2. *The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.*

**[redacted] RESPONSE:**

2. We disagree with the inspector's statement that we are not complying with the Investigator Agreement, which was signed on 3/28/97, prior to the start of the study. The Investigator Agreement states that:

> *As an investigator for this study, I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in the protocol after notifying the sponsor-investigator, except when necessary to protect the safety, rights, or welfare of subjects. I agree to personally conduct or supervise the described investigation. I agree to inform any patients, or any persons used as controls, that the device is being used for investigational purposes and I will ensure that the requirements relating to the informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.*
>
> *I agree to report to the sponsor-investigator adverse experiences that occur in the course of the investigation in accordance with 21 CFR Part 812. I have read an understood the information in the device manual and protocol, including the potential risks and adverse effects of using the device. I agree to ensure that all associates and colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments. I agree to maintain adequate and accurate records and to make those records available for inspection in accordance with 21 CFR Part 812.*
>
> *I will ensure that an IRB complies with the requirements of 21 CFR Part 56, will be responsible for the continuing review and approval of the clinical*