You should also give serious consideration to the following items which are considered important for the analysis of your data for the purposes of determining safety and effectiveness for a future PMA application.

1. Please note that, based on the stability analyses you have provided in this submission, we do not agree that the time point of stability is at 12 months postoperatively as you have indicated, and, in fact, may be earlier for some of the indications. However, the eyes treated for high myopic astigmatism (high astigmatic group) appear to remain unstable throughout the follow-up period. If PMA approval were requested for all of these indications in one submission, a decision regarding approval would be significantly affected by the inability to confirm stability at the same time point for each of the indications under consideration.

2. As previously stated in FDA's letter of April 10, 2001, you have indicated that only subjects treated with the "new centration technique" will be included in the PMA, and that you have selected the eyes treated between 2/19/98 and 11/22/99 as the cohort to support the safety and effectiveness of the device. We would like to clarify that data from all subjects treated under the IDE should be included in the PMA. The main PMA cohort on which the decision of the safety and effectiveness of the device will mainly rest may be limited to all eyes treated with the new centration technique, but not to only those enrolled during a given period of time, as you appear to have suggested. Data from all eyes treated prior to the adaptation of the new centration technique may be analyzed separately from the main PMA cohort, but must be submitted as supportive evidence.

3. As indicated above, your follow-up accountability is very low. Seventy-five to 80% of total eyes treated should have reached the point of stability and, of those, about 80% should have been seen and accounted for at the stability time point.

This information must be submitted to FDA within 45 days from the date of this letter. It should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850