This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiencies.

1. Your device does not have a fail-safe mechanism for automatically shutting down your laser in the event of inappropriate energy output from the laser. Please submit an engineering plan and time-table for retrofitting your device with an adequate fail-safe mechanism. This mechanism should include a safe means to complete the treatment.

2. You agree to submit monthly reports of the subjects treated with your investigational laser identifying them by a unique subject identifier, date treated, and indication for treatment.

3. You agree that you will not perform retreatment procedures for subjects initially treated under this IDE. Retreatment (enhancement) for subjects initially treated under this IDE is appropriate only after your preliminary data demonstrate safety and indicate the time point of stability of the procedure. You may begin retreatment procedures only after FDA has approved your retreatment study plan and data to support stability.

This information 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

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We acknowledge your request to conduct a study at one site with approximately 990 eyes for each of two investigators. We believe that adequate safety information has been provided to allow the initiation of your study at one site with 150 subjects; however, issues remain which must be resolved prior to the expansion of your study for marketing approval. Prior to your request for expansion beyond 150 subjects, you should submit the results of this initial phase after 50% of the subjects have achieved at least 3 months of follow-up.

Prior to your request for expansion beyond 150 subjects, you should submit adequate responses to the following deficiencies. Incremental expansions beyond 150 subjects may be granted prior to fully satisfactory responses, based on the adequacy of your responses. We are aware that some of the deficiencies below have not been asked previously