4. The software allows the user to set 10 preferences such as fluence count & size; nitrogen on/off delay(s); laser frequency; wipe alert options, etc., and for manual positioning of the aperture doors and angle, and selection of iris size. Please specify which, among the selectable options in software, are selected for the study.

5. The naming convention for the software is confusing and inconsistent with the typical software practice. Typically, the higher software version would include everything in the lower version, as well as some additional features. Therefore, if Apollo version 3.66 were installed in the machine, there should be no need to install Apollo version 3.5. If 3.5 and 3.66 contain two distinct and separate routines, then different names should be given to them and their versions should each be 1.0.

The deficiencies identified above represent the issues that we believe need to be resolved before your IDE application can be approved. In developing the deficiencies, we carefully considered the relevant statutory criteria for Agency decision-making as well as the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center webpage at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If you submit information correcting the deficiencies, FDA will reevaluate the proposed change in the investigational plan. 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

Alternatively, you may request a regulatory hearing regarding the disapproval of your IDE supplement. The enclosure "Procedures to Request a Regulatory Hearing" describes how to submit such a request. The procedures governing a regulatory hearing are described in the regulations at 21 CFR Part 16.