

- e. Revision Level History: the revision history log, documenting all major changes to the software during its development cycle and a description of the version numbers and dates.

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. Please submit revised versions of the protocols, consent form, and any revised case report forms indicating deletions with strikethroughs and additions with underlines.

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.

Please take into consideration the following issues related to any future PMA submissions when revising your protocol:

33. The protocol indicates that the subject questionnaire will be administered 3 and 6 months postoperatively and at the final exam with optional administration at the other visits. Please be advised that subject questionnaire data are expected at the point of stability. We recommend you remove the option for administration of the questionnaire "at other visits" and consider adding this as a mandatory evaluation to other follow-up visits, if there is the possibility that the cohort (or a subgroup) may reach stability after 6 months.

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