

January 20, 2004

Dear Panel Member:

Please review the information in this package in preparation for the February 23, 2004 Neurological Devices Panel meeting. This cover letter provides an index of the contents of this package. You will find one binder containing FDA's reviews and information provided by the sponsor. The binder contains the following:

Tab 1	Device Review
Tab 2	Clinical Review
Tab 3	Statistics Review
Tab 4	FDA Questions
Tab 5	510(k) Document (provided by the sponsor)

Because this application is a 510(k) and not a PMA, there will be no vote on recommendation of its clearance. The meeting will revolve around discussion of the questions in Tab 4. We appreciate your valuable input.

If you have any questions please do not hesitate to call (301-594-3090 x 207) or email (RPF@CDRH.FDA.GOV) me. We look forward to working with you.

Richard P. Felten
Lead Reviewer
General Surgery Devices Branch