Questions for Consideration

1. Please comment on the results of the wear debris testing and particulate analysis.

2. A higher incidence of the following adverse events occurred in the Charité group compared to the BAK group:

- Non-device related pain
- Wound infections
- Device-related additional surgery at index level

Please discuss the clinical significance of these and any other adverse events seen in the trial.

3. Although the Charité Artificial Disc was highly successful in relieving pain, there were a significant number of patients who did not obtain pain relief: 14% had no pain relief or had their pain worsen, and an additional 13% had only partial pain relief. The etiology of their unrelieved pain is unknown. Please comment on the interpretation of these findings.

4. Within the Charité group, the mean range of motion (ROM) in flexion/extension at the treated level at 3, 6, 12, and 24 months was 4.9º, 6.0º, 7.0º, and 7.4º, respectively. Lateral bending and axial rotation ROM were not reported in this investigation.

Please comment on the sponsor's claim that the Charité permits "near physiological segment movement with up to 15º bending in flexion/extension and a similar degree of lateral bending and axial rotation to the natural disc."

5. Do the clinical data in the PMA provide reasonable assurance that the device is safe?

6. Do the clinical data in the PMA provide reasonable assurance that the device is effective?

7. If you recommend approvability for this PMA, do you recommend a post-approval study? If so, please discuss what types of endpoints would be useful for an updated label and recommend the duration of such a study.