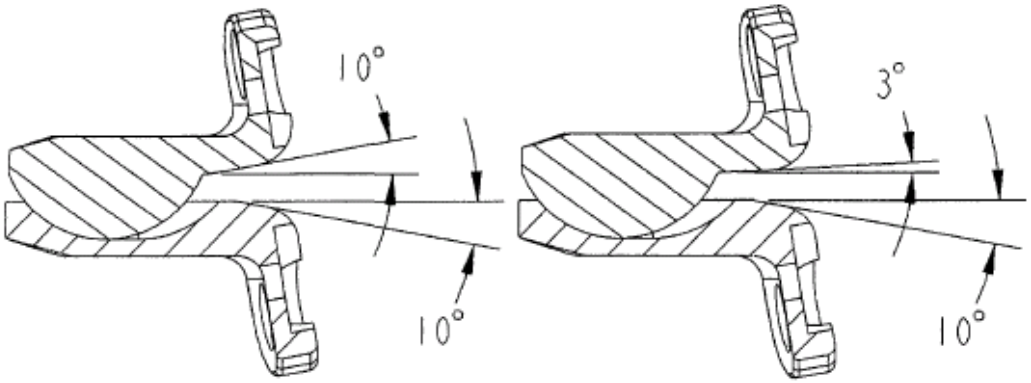
FDA Questions for the Panel:

1. Please discuss the adequacy of the preclinical testing as provided by the sponsor as an adequate assessment of the long term function and durability of the Prestige device. Are any additional tests recommended?

2. A modification of the cut angle has been made in the superior components since the clinical study. The cut angle has been modified from 10° to 3°. This change adds material to the superior component; however, the range of motion has also been slightly decreased. The sponsor does not intend to market the 10º cut angle device, although it was the only device used in the clinical trial. Please discuss the potential impact of such a design change on the potential for impingement/function of this device and then comment on the adequacy of the clinical data collected on the original device design in addressing the safety and effectiveness of the newly proposed device design.



3. Efficacy evaluations were performed on the first 250 patients (128 Investigational, 122 Control) that had complete overall success outcome information (without FSU). This represents about 46% of the total patient enrollment in the study. In addition, even fewer patients (95 investigational and 90 control, about 34%) had complete overall success outcome information with FSU. Please comment on the appropriateness of making study conclusions using this interim analysis based on the overall success criteria with and without FSU, i.e., 46% and 34% of enrolled patients.

4. There were five incidences of cancer in the treatment group as opposed to two incidences in the control group. Two of the patients developed cancer in the first 12 months of follow-up and the remaining three patients during the 12 to 24 month follow-up. Considering the concerns with metal on metal devices (e.g., particulate wear generation, particulate migration, etc.) and the metal ion testing, please discuss whether this raises safety concerns with the investigational device. Also, should there be a section in the labeling discussing this issue?

5. The package insert currently has no claims of the device maintaining range of motion. The sponsor does state in the PMA, however, that in the treatment group, the mean preoperative angular motion (flexion/extension) at the target segment was 7.55° while the mean angular motion values at 12 and 24 months were 7.59° and 7.87°,

respectively. Is this data adequate to demonstrate a possible claim that the device maintains motion? Please discuss how the labeling might be adjusted to reflect such information.

6. Please discuss the adequacy of the device labeling. Are there any special labeling suggestions related to the presentation of the Bayesian analyses?

7. Please discuss whether the clinical data in the PMA provide reasonable assurance that the proposed device is safe. If not, what additional data or analyses are needed?

8. Please discuss whether the clinical data in the PMA provide reasonable assurance that the proposed device is effective. If not, what additional data or analyses are needed?