

## **Meeting of the Dental Products Panel**

*August 22, 2002*

*Gaithersburg Holiday Inn, Gaithersburg, Maryland*

*Issue: Review of Premarket Approval Application*

*Sponsor: Biomet, Incorporated*

*Product: Walter Lorenz Total Temporomandibular Joint Replacement System*

### **Draft Discussion Questions for the Dental Products Panel**

1. Can the results for jaw pain intensity, interference with eating, and maximal incisal opening for the cases presented with 3 year data, which represent 25% of the implanted population, adequately represent the expected outcomes for the total study group at 3 years?
2. 132/180 cases were treated at Site 1, 40/180 cases at Site 2, and 8/180 cases at Sites 3, 4, and 5 combined. Does the fact that that 96% (172/180) of the cases were treated at only 2 sites present a potential for bias in the clinical outcomes?
3. 52 patients of the 168 implanted patients had reports of adverse events. Of these 52 patients 8 required permanent device removal. Please discuss the rate of adverse events in this patient population.
4. The company plans to market the device as a non-cemented fossa or as a cemented fossa. In the clinical data set, some of the cases are with cement and some cases are without cement. Please discuss the data in light of these two different methods. Are there differences in outcomes?
5. The sponsor has provided engineering test data and a protocol for testing on both the new fossa design without a post and the fossa with the post removed using a rongeur. Do the engineering test data and protocol as presented give adequate safety and effectiveness information on the device?
6.
  - a. Draft labeling has been submitted by the sponsor and reviewed by FDA. Please discuss the draft labeling as presented.
  - b. Please discuss the need for training and the type of training protocol that may be necessary for safe and effective use of this device?
  - c. The Sponsor intends to complete their pivotal PMA study following all patients for 3 years. Please discuss the need for any additional post-market studies and issues that should be addressed were those studies to be required.