

**DRAFT**  
**ORTHOPAEDIC AND REHABILITATION DEVICES PANEL**  
of the  
**MEDICAL DEVICES ADVISORY COMMITTEE**

Gaithersburg Marriott  
Salons A, B, C, and D  
9751 Washingtonian Boulevard  
Gaithersburg, Maryland  
June 3, 2004

**Panel Chairperson**

Michael J. Yaszemski, M.D., Ph.D.

**Executive Secretary**

Janet L. Scudiero, M.S., acting

**8:00 am Call to Order**  
**Conflict of Interest and Deputization to Voting Member Status Statements**  
**Panel Introductions**

***Reclassification of the Total and Unicompartmental Mobile Bearing  
Knee Joint Prostheses***

**8:15 am Open Public Hearing\***

**8:45 pm Industry Presentation**  
Orthopedic Surgical Manufacturers Association

**9:30 am FDA Presentation**

**10:00 am Break**

**10:15 am Panel Deliberation**  
Reclassification Questionnaire, Supplemental Data Sheet, and Vote

**12:15 am Lunch**

***Draft Hip Joint Prostheses Guidance: Performance Criteria***

**1:15 pm Open Public Hearing\***

**1:45 pm Industry Presentation**  
Orthopedic Surgical Manufacturers Association

**2:30 pm FDA Presentation**

**3:15 pm Break**

**3:30 pm Panel Deliberation and Recommendation**

**5:00 pm Adjournment**

**Open Public Hearings:** During the open public hearing, interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, Dr. Yaszemski may ask them to remain if the panel wishes to question them. Then Dr. Yaszemski will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing