

AGENDA

ORTHOPEDIC AND REHABILITATION DEVICES PANEL of the

MEDICAL DEVICES ADVISORY COMMITTEE

Holiday Inn

2 Montgomery Village Avenue

Gaithersburg, Maryland

July 27, 2010

Panel Chairperson

John Kelly IV, M.D.

Designated Federal Officer

Tracy Phillips, Ph.D.

**8:00 a.m. Call to Order
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
FDA Update**

AMPLIFY rhBMP-2 Matrix, PMA P050036.

8:30 a.m. Sponsor Presentation

10:00 a.m. Q & A

10:15 a.m. Break

10:30 a.m. FDA Presentation

12:00 a.m. Q & A

12:15 p.m. Lunch

1:00 p.m. Open Public Hearing*

2:00 p.m. Panel Deliberations

3:15 p.m. Break

3:30 p.m. FDA Questions

5:00 p.m. FDA and Sponsor Summations

5:20 p.m. Panel Vote

6:00 p.m. Adjournment

*** 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, the Chair may ask them to remain if the panel wishes to

question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.