

AGENDA

ORTHOPAEDIC AND REHABILITATION DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE
Hilton Washington, DC North
620 Perry Parkway
Gaithersburg, Maryland
September 9, 2005

Panel Chairperson
John S. Kirkpatrick, M.D.

Executive Secretary
Janet L. Scudiero, M.S.

8:00 a.m. Call to Order
Panel Introductions
Conflict of Interest

*Design of Clinical Studies for
Spinal Devices to Treat Mild to Moderate Low Back Pain*

8:30 a.m. Open Public Hearing*

Orthopaedic Surgical Manufacturers' Association

Sally Maher, Esq., President
Hal Matthews, M.D., title, affiliation

Spine Wave, Inc.

Ronald K. Smith, Director of Quality Systems & Regulatory Affairs
John Pafford, Chief Technical Officer

Zimmer Spine

Reginald Davis, M.D., Greater Baltimore Medical Center

Abbott Spine, Emerging Technologies Research & Development

Paul McAfee, M.D., Towson Orthopedics Association, Baltimore
Brent Blumenthal, Ph.D., TriArc Consulting, Seattle

Stryker Spine, Inc.

American Association of Neurological Surgeons

North American Spine Society

Marjorie Eskay-Auerbach, M.D., J.D.

St. Francis Medical Technologies, Inc.

Paul Anderson, M.D., University of Wisconsin

Spine Arthroplasty Society

*** Open Public Hearings:** During the open public hearings, 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.

9:45 a.m. Break

10:00 a.m. FDA Presentation
Jonathan H. Peck, Orthopedic Devices Branch

10:30 a.m. Panel Deliberation
Lead Discussant, Michael J. Yaszemski, M.D., Ph.D.

FDA Questions

1:00 p.m. Adjournment