

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

Gaithersburg Holiday Inn, Gaithersburg, MD

June 2, 2006

Panel Chairperson

John S. Kirkpatrick, M.D.

Executive Secretary

Janet L. Scudiero, M.S.

- 8:15 am Call to Order**
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
Update since September 8 & 9, 2005, Neil R. P. Ogden, Chief, GSDB
- R.S. Medical Bone Reclassification Petition for the
Non-invasive Growth Stimulator, 2005P-0121***
- 8:45 am Open Public Hearing***
- 9:15 am Reclassification Overview**, Marjorie G. Shulman, Classification/Reclassification
Coordinator, POS, ODE
- 9:30 am Sponsor Presentation**
Bill Carroll, Vice President, Research and Development, RS Medical
Robert L. Sheridan, R. Sheridan Consulting, LLC
Cathy S. Carlson, D.V.M., Ph.D, Diplomat A.C.V.P., Professor, College of Veterinary
Medicine, University of Minnesota
Edmund Frank, M.D., F.A.C.S., Professor, Oregon Health and Sciences University
Christine Brauer, Ph.D. Brauer Device Consultants
Jeffrey Skinner, Vice President, Engineering, ControlTek, Inc.
- 10:30 am Break**
- 10:45 am FDA Presentation**, Michel D. Janda
- 11:15 pm Panel Deliberations**
- 12:00 pm Lunch**
- 1:00 pm Panel Deliberations and FDA Questions**
- 1:45 pm Open Public Hearing**
- 2:15 pm FDA and Sponsor Summations**
- 2:45 pm Reclassification Questionnaire**, Ms. Shulman
- 3:30 pm 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.