

Sixty-Ninth Meeting of the
Obstetrics and Gynecology Devices Panel

Tuesday, May 17, 2005
Holiday Inn, Gaithersburg, Maryland

MediSpectra LUMA™ Cervical Imaging System (P040028)
DRAFT Agenda*

- 8:30-8:35 Call to order
- 8:35-8:50 Office of Surveillance and Biometrics (OSB) presentation – Role of OSB in the review of postmarket study designs
- Susan Gardner, Ph.D.
- 8:50-9:00 Introductory remarks
- Colin Pollard, Chief, Obstetrics and Gynecology Devices Branch
- 9:00-9:30 Open public hearing**
- 9:30-10:30 Sponsor presentation
- Theresa Wingrove, Ph.D., Senior Director Regulatory & Clinical, MediSpectra
 - J. Thomas Cox, M.D., Director Gynecology Services, University of California, Santa Barbara
 - Ross Flewelling, Ph.D., Chief Technical Officer, MediSpectra
 - Joan L. Walker, M.D., Chief, Gynecologic Oncology, University of Oklahoma
 - Thomas C. Wright, Jr., M.D., Director of Gynecologic Pathology, Columbia University, Consulting Medical Director, MediSpectra
 - Warner K. Huh, M.D., Gynecologic Oncologist, University of Alabama, Birmingham
 - Brent Blumenstein, Ph.D., TriArc Consulting
- 10:30-10:45 Break
- 10:45-11:45 FDA presentation
- Joyce Whang, Ph.D.
 - Julia Carey-Corrado, M.D.
 - Gene Pennello, Ph.D.
- 11:45-12:00 Questions and Answers
- 12:00-1:00 Lunch
- 1:00-3:15 Panel discussion
- 3:15-3:30 Break
- 3:30-4:00 Open public hearing**
- 4:00-5:00 Panel deliberations and vote
- 5:00 Adjourn

** all times are approximate*

**** Open Public Hearings** – Interested persons may present data, information, or views, orally or in writing, on the meeting agenda. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, Dr. Noller will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.