Agenda
Radiological Devices Panel Meeting

May 23, 2006

Purpose of the Meeting - To discuss, make recommendations and vote on the reclassification of full field digital mammography systems.

Closed Session

9:30 – 10:00	**Briefing on Current Investigational Devices** - Robert A. Phillips, Ph.D. and RADB Staff

Open Session

10:15 – 10:25	**Call to order and the Panel Introduction** – Elizabeth A. Krupinski, Ph.D., *Acting* Panel Chair **FDA Introductory Remarks** – Nancy G. Wersto, Executive Secretary **Update on FDA Radiology Activities** - Robert A. Phillips, Ph.D.
10:25 – 10:40	**Critical Path Initiative in Medical Devices** Sousan S. Altaie, Ph.D., Scientific Policy Advisor, Office of *In Vitro* Diagnostic Device Evaluation and Safety
10:40 – 10:55	**Condition of Approval Studies: Recent Changes in CDRH** Thomas P. Gross, M.D., MPH, Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics
10:55 – 11:55	**FDA Presentations**

Open Public Hearing

11:55 – 12:25	**Open Public Hearing**: interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.
12:25 – 1:25	**Lunch**

Open Committee Discussion

1:25 – 1:30 **Call to order**– Elizabeth A. Krupinski, Ph.D.

1:30 – 2:30 **Panel Discussion and FDA Questions**

Open Public Hearing

2:30 – 3:00 **Open Public Hearing**: interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

General Device Reclassification Recommendation

3:00 – 4:00 **Classification Questionnaire and Vote** – Marjorie G. Shulman, ODE

4:00 – 4:10 **Meeting Adjournment and Final Remarks** – Elizabeth A. Krupinski, Ph.D.