

DRAFT
Agenda
Radiological Devices Panel Meeting

December 10, 2002

Purpose of the Meeting - To discuss, make recommendations and vote on a premarket approval application (PMA P010035) for a device that produces a computerized thermal image of the breast of women recommended for biopsy.

8:30 - 8:45 Call to order and the Chair's Introduction – Minesh P. Mehta, M.D.

Update on FDA Radiology Activities - Robert A. Phillips, Ph.D.
FDA Introductory Remarks - Robert J. Doyle, Executive Secretary

8:45 - 9:15 Development of Amendments to the U.S. Radiation Safety Standard for Diagnostic X-Ray Computed Tomography - Stanley Stern, Ph.D.

Open Public Hearing

9:15 – 9:45 Open Public Hearing

Open Committee Discussion

9:45 - 9:50 Charge to the Panel - Minesh P. Mehta, M.D.

9:50 - 11:10 Presentations on P010035 by sponsor

- Introduction - John Brenna
- Clinical Use - Yuri Parisky, M.D.
- Engineering and Technical - Lynn Satterthwaite
- Clinical Trial and Results - Karleen Callahan, M.D.
- Statistics - Steve Rust, Ph.D.
- Clinical Results and Use - Elizabeth Nelson
- Clinical Use - Kevin Hughes, M.D.

11:10 - 12:00 Presentations on P010035 by FDA

- PMA Overview - John Monahan
- Clinical Review - William Sacks, Ph.D., M.D.
- Statistical Analysis - Harry Bushar, Ph.D.
- Clinical Review continued - William Sacks, Ph.D., M.D.

12/6/2002

12:00 - 1:00 Lunch

Closed Session

12:30 - 1:00 Closed Session, Branch Actions - Robert A. Phillips, Ph.D.

Open Committee Discussion

1:00 - 3:00 Panel Discussion

3:00 - 3:15 Break

Open Public Hearing

3:15 - 3:45 Open Public Hearing

Open Committee Deliberations

3:45 – 5:00 Panel Recommendation(s) and vote

5:00 Adjourn