

OPHTHALMIC DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE
One Hundred and Twelfth Meeting

March 27, 2009

OPEN SESSION

Panel Chairperson (Acting)
Jayne S. Weiss, M.D.

Executive Secretary (Acting)
James P. Swink

AGENDA*

8:00 AM Call to Order
Conflict of Interest Statement
Introductory Remarks

FDA Updates

8:15 AM Malvina B. Eydelman, M.D., Director
Division of Ophthalmic and Ear, Nose and Throat Devices

Kesia Y. Alexander, Ph.D.
Chief, Intraocular and Corneal Implants Branch

Kwame O. Ulmer
Chief, Diagnostic and Surgical Devices Branch

Danica Marinac-Dabic, M.D., Ph.D.
Chief, Epidemiology Branch
Office of Surveillance and Biometrics
Post Approval Study Program Update

Committee Deliberations
IMT™ Implantable Miniature Telescope (P050034)

9:00 AM Open Public Hearing**

9:30 AM Break

9:40 AM Sponsor Presentation

11:10 AM Panel Questions for the Sponsor

11:30 AM FDA Presentation

1:00 PM Panel Questions for FDA

1:15	PM	Lunch
2:00	PM	Panel Discussion of PMA P050034, FDA Questions
3:15	PM	Break
3:30	PM	Open Public Hearing**
4:00	PM	FDA and Sponsor Closing Comments
4:30	PM	Voting Options Read and Panel Recommendation taken by Vote Comments from Consumer and Industry Representatives
5:00	PM	Meeting Adjourned

*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. Weiss will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearings.