

AGENDA

*December 5, 2008, Emphasys Medical Inc. Zephyr Endobronchial Valve System
(P070025)*

Anesthesiology and Respiratory Therapy Devices Panel
Hilton Washington DC North
Gaithersburg, MD

Panel Chairperson
David J. Birnbach, MD

Executive Secretary
Neel J. Patel

- 8:00 a.m.** **Call to order**
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
- 8:15 a.m.** **1st Open public hearing***
- 8:45 a.m.** **Presentation by the Sponsor**
- 10:00 a.m.** **Sponsor Q & A**
- 10:15 a.m.** **Break**
- 10:30 a.m.** **Presentation by FDA**
- 11:45 p.m.** **FDA Q & A**
- 12:00 p.m.** **Lunch**
- 1:00 p.m.** **Panel Deliberations and FDA Questions**
- 3:00 p.m.** **Break**
- 3:15 p.m.** **2nd Open public hearing***
- 3:45 p.m.** **FDA and Sponsor Summation**
- 4:15 p.m.** **Panel Recommendation and Vote**
- 5:00 p.m.** **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. Birnbach will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.