

AGENDA

GENERAL AND PLASTIC SURGERY DEVICES PANEL of the MEDICAL DEVICES ADVISORY COMMITTEE

Salons A, B, & C, Grand Ballroom
Gaithersburg Hilton Hotel
620 Perry Parkway, Gaithersburg, Maryland
February 28, 2003

Panel Acting Chair:

Robert L. McCauley, MD

Executive Secretary:

David Krause, PhD

- 8:00 am** **Call to Order**
- Conflict of Interest and Opening Remarks**
 David Krause, PhD, Executive Secretary
- Panel Introductions**
 Robert L. McCauley, MD, Acting Chairman
- Update Since the Last Meeting**
 Stephen P. Rhodes, MA, Branch Chief, Plastic and Reconstructive Surgery Devices
 Branch
- 8:30 am** **Open Public Comment** (up to 15 minutes)
- 8:45 am** **Applicant Presentation**
- 9:45 am** **FDA Presentation**
- 10:15 am** **Break**
- 10:30 am** **Panel Deliberations and Address FDA Questions**
- 11:30 am** **Open Public Comments** (up to 15 minutes)
- 11:45 am** **FDA Summation**
- Sponsor Summation**
- 12:00 pm** **Concluding Panel Deliberations and Vote**
- 12:30 pm** **Lunch**
- 1:15 pm** **Call to Order**
- Conflict of Interest and Opening Remarks**
 David Krause, PhD, Executive Secretary

Panel Introductions

Robert L. McCauley, MD, Acting Chairman

1:30 pm

General Topic Discussion

Clinical Issues in Regards to Medical Devices for the Treatment of Emphysema

FDA Presentation

Industry Presentations:

Broncus Technologies, Inc.

Closure Medical, Inc.

Emphasys Medical, Inc.

Spiration, Inc.

2:45 pm

Open Public Comments (up to 15 minutes)

3:00 pm

Open Panel Discussion and FDA Questions

3:30 pm

General Topic Discussion

Clinical Issues in Regards to Devices used to Ablate Lung Tumors

FDA Presentation

Industry Presentation:

RITA Medical Systems, Inc.

4:00 pm

Open Public Comments (up to 15 minutes)

4:15 pm

Open Panel Discussion and FDA Questions

5:00 pm

Adjournment