

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
July 24, 2003

Panel Acting Chair:
Robert L. McCauley, MD

Executive Secretary:
David Krause, PhD

8:00 am **Closed Session**

Update Regarding Future Submissions
Neil R. P. Ogden, Branch Chief, General Surgery Devices Branch

8:30 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

Open Public Comment

9:00 am **Reclassification of Absorbable Hemostatic Agents and Dressings**

Industry Presentation
John D. Paulson, PhD, Vice President Quality Assurance and Regulatory Affairs,
Johnson & Johnson Wound Management a Division of Ethicon, Inc.

Ms. Lene Retb?ll Muller, Director of Quality Assurance, Medical Devices, Ferrosan A/S

Judith E. O'Grady, RN, MSN, RAC, Senior Vice President, Regulatory, Quality and Clinical Affairs, Integra LifeSciences Corporation

10:00 am **FDA Presentation**
David Krause, PhD, Division of General, Restorative & Neurological Devices/ODE

10:30 am **Break**

11:00 am **Open Public Comment**

11:15 am **Panel Deliberations and Address FDA Questions**

Reclassification Questionnaire and Vote
 Mr. Robert Gatling, Office of Device Evaluation

12:00 am **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

Open Public Comment

1:45 pm **General Topic Discussion**
 Clinical Issues in Regards to Medical Devices for the Percutaneous Removal of Breast Tumors

FDA Presentation
 Binita S. Ashar, MD, Division of General, Restorative & Neurological Devices

Industry Presentations:
 Kelsey, Inc.

3:00 pm **Open Panel Discussion and FDA Questions**

5:00 pm **Adjournment**