

AGENDA

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

Salons D&E, Grand Ballroom
Gaithersburg Hilton Hotel
620 Perry Parkway, Gaithersburg, Maryland
July 17, 2001

Panel Acting Chair:
Susan Galandiuk, MD

Executive Secretary:
David Krause, PhD

10:00 am **Closed Session**

10:30 am **Call to Order**

Conflict of Interest and Opening Remarks
David Krause, PhD, Executive Secretary

Panel Introductions
Susan Galandiuk, MD, Acting Chairman

Update Since the Last Meeting
Stephen P. Rhodes, MA, Branch Chief, Plastic and Reconstructive Surgery Devices
Branch

11:00 am **Open Public Comment** (up to 30 minutes)

11:30 am **Applicant Presentation, Ortec International, Orcel™ Composite Cultured Skin**

Introduction/Product Indication
Costa Papastephanou, PhD, President,

Product Technology/Manufacturing
Mel Silberklang, PhD, VP Research and Development

Summary of Clinical Safety
Steven Peltier, VP Clinical and Regulatory Affairs

Clinical Discussion on Donor Sites
John Griswold, MD, Clinical Investigator

Protocol Overview
Steven Peltier

Clinical Results
Paul Glat, MD, Clinical Investigator

Statistical Results
Kazem Kazempour, PhD, Consultant

Summary and Conclusions

Steven Pelteir

12:30 pm

Lunch

1:30 pm

FDA Presentation

Preclinical and Technical

Sam Arepalli, PhD, Lead Reviewer, Division of General and Restorative Devices

Clinical

Roxolana Horbowyj, MD, Division of General and Restorative Devices

FDA Questions

Dr. Sam Arepalli

2:30 pm

Panel Deliberations and Address FDA Questions

Panel Lead Reviewers

Clinical: Joseph V. Boykin, Jr., MD

Statistical: David L. DeMets, PhD

3:00 pm

Additional Open Public Comments (up to 30 minutes)

3:30 pm

FDA Summation

Sponsor Summation

4:00 pm

Concluding Panel Deliberations and Vote

5:00 pm

Adjournment