

AGENDA

CIRCULATORY SYSTEM DEVICES PANEL

September 11, 2001

Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD

8:00 – 12:30

First PMA Discussion, Recommendations, and Voting

8:00 a.m.

Call to Order

Warren Laskey, M.D., Acting Chairperson

8:05 – 8:15 a.m.*

Open Public Hearing*

8:15 – 9:15 a.m.

**Sponsor Presentation: CryoLife, Inc
P010003, BioGlue® Surgical Adhesive**

James C. Vander Wyk, Ph.D., VP Regulatory Affairs and Quality Assurance,
CryoLife, Inc.

David M. Fronk, VP Clinical Research, CryoLife, Inc.

Joseph S. Coselli, MD, Baylor College of Medicine

Joseph E. Bavaria, MD, Hospital of the University of Pennsylvania

9:15 – 9:30 a.m.

FDA Presentation

Lisa Kennell, lead reviewer

9:30 – 12:15 p.m.

**Open Committee Discussion, Recommendations, Warren Laskey, M.D.
and Voting**

10:15 – 10:30 a.m.

Break

12:15 – 12:30 p.m.*

Open Public Hearing*

12:30 p.m.

Adjourn – Break for Lunch

1:30 – 6:00 p.m.

Second PMA Discussion, Recommendations, and Voting

1:30 p.m.

Call to Order

Warren Laskey, M.D.

1:35 – 1:45 p.m.*

Open Public Hearing*

1:45 – 2:45 p.m.

**Sponsor Presentation: Cohesion Technologies
P010022, CoSeal Surgical Sealant**

Frank DeLustro, Ph.D., President and CEO, Cohesion

John Martin, M.D., West Shore Surgical Associates, Annapolis, MD

Mark Glickman, M.D., Virginia Vascular Associates

Ross Erickson, M.D., VP of Regulatory and Clinical Affairs, Cohesion

2:45 – 3:00 p.m.

FDA Presentation

Jennifer Goode, lead reviewer

3:00 – 5:45 p.m.

**Open Committee Discussion, Recommendations, Warren Laskey, M.D.
and Voting**

3:45 – 4:00 p.m.

Break

5:45 – 6:00 p.m.*

Open Public Hearing*

6:00 p.m.

Adjourn

OPEN PUBLIC HEARINGS*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Moynahan will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Laskey will recognize unscheduled speakers as time allows.

There were no requests to speak during the Open Public Hearings on September 11.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.