

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL

March 4, 2002

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

10:00 – 4:00	PMA Supplement Discussion, Recommendations, and Voting
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10:00 a.m. **Call to Order** **Warren Laskey, M.D., Acting Chairperson**

10:05 – 10:15 a.m.* **Open Public Hearing***

10:15 – 11:15 a.m. **Sponsor Presentation: Thoratec Corporation**

P910014/S016, HeartMate VE LVAS

Donald A. Middlebrook, Vice President Regulatory Affairs and Quality Assurance

Victor Poirier, Chief Technology Advisor

Eric Rose, MD, REMATCH Principal Investigator, Chairman Department
of Surgery Columbia-Presbyterian Medical Center, NY

Lynne W. Stevenson MD, REMATCH Medical Management Committee

Chair & Director Cardiomyopathy and Heart Failure Brigham & Woman's Hospital,
Boston

11:15 – 12:00 p.m. **FDA Presentation**

Michael Berman, PhD, lead reviewer

Julie Swain, MD, clinical reviewer

12:00 p.m. **Adjourn – Break for Lunch**

1:00 p.m. **Call to Order : Open Discussion**

Warren Laskey, M.D.

2:15 – 2:30 p.m. **Break**

2:30 – 3:15 p.m. **Open Panel Discussion, Recommendations
and Voting**

Warren Laskey, M.D.

3:45 – 4:00 p.m. **Open Public Hearing***

4:00 **Adjourn**

4:15 – 5:00 p.m. **Closed session*****

OPEN PUBLIC HEARINGS*

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

Dr. Ewing 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.

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

hearing.

CLOSED SESSION***

The session will be closed to the public from 4:15-5:00p.m., in order to allow the Panel to hear trade secret and/or confidential information.