

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL

March 17, 2005

Hilton Washington DC North/Gaithersburg, Crystals Ballroom, 620 Perry Parkway, Gaithersburg, MD.

8:00 – 4:00

510(k) Discussion and Recommendations

8:00 a.m.	Call to Order	William H. Maisel, M.D., M.P.H. Chairperson
8:05 – 8:35 a.m.	*Open Public Session*	
8:35 – 9:35 a.m.	Sponsor Presentation: Alsius Corporation K040429: CoolGard 3000/Icy Heat Exchange Catheter Thermal Regulating System	
9:35 – 9:50 a.m.	Questions and Answers	
9:50 – 10:50 a.m.	FDA Presentation	
10:50 – 11:05 a.m.	Questions and Answers	
11:05 – 11:20 a.m.	Break	
11:20 – 12:30 p.m.	Open Committee Discussion	
12:30 p.m.	Adjourn – Break for Lunch	
1:30 p.m.	Call to Order	
1:30 – 3:00 p.m.	Open Committee Discussion	William H. Maisel, M.D., M.P.H.
3:00 – 4:00 p.m.	*Open Public Session* FDA Comments Sponsor Comments Recommendations & Vote	William H. Maisel, M.D., M.P.H.
4:00 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. Wood 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. Maisel will recognize unscheduled speakers as time allows.

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