

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL

October 23, 2002

Holiday Inn, Walker/Whetstone Rooms, 2 Montgomery Avenue, Gaithersburg, MD

8:30 –4:30		510(k) Discussion and Recommendations
8:30 a.m.	Call to Order	Cynthia M. Tracy, M.D., Chairperson
8:35 – 9:05 a.m	Office of Surveillance and Biometrics Presentation "Adverse events and deaths associated with hemostasis following cardiac catheterization: Comparison of manual compression vs. collagen plug and suture hemostasis devices." <i>Dale R. Tavris, M.D., M.P.H.; Chief, Epidemiology Branch; CDRH/OSB/DPS</i>	
9:05 – 9:30 a.m. *	Open Public Session*	
9:30 – 10:30 a.m.	Sponsor Presentation: EMBOL-X, Inc. K022071, EMBOL-X Aortic Filter	
10:30 – 10:45 a.m.	Questions and Answers	
10:45 – 11:00 a.m.	Break	
11:00 – 11:30 a.m.	FDA Presentation	
11:30 – 11:45 p.m.	Questions and Answers	
11:45 – 12:00 p.m.	Open Committee Discussion	Cynthia M. Tracy, M.D.
12:00 p.m.	Adjourn – Break for Lunch	
1:00 – 2:00 p.m.	Call to Order	
2:00 – 2:15 p.m.	Break	
2:15 –4:00 p.m.	*Open Public Session* FDA Comments Sponsor Comments Open Committee Discussion and Recommendations	Cynthia M. Tracy, M.D.
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. Tracy will recognize unscheduled speakers as time allows.

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