

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL

July 29, 2004

Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

9:00 – 5:00		510(k) Discussion and Recommendations
9:00 a.m.	Call to Order	Warren Laskey, M.D. Acting Chairperson
9:05 – 9:30 a.m.	Office of Surveillance and Biometrics Presentation "Adverse Event Reports on Automatic External Defibrillators from 1996 - 2003" <i>Oscar H. Tovar, M.D., OSB/ODE</i>	
9:30 – 10:00 a.m.	*Open Public Session*	
10:00 – 11:15 a.m.	Sponsor Presentation: Philips Medical K040904: HeartStart Home	
11:15 – 11:30 a.m.	Questions and Answers	
11:30 – 11:45 a.m.	Break	
11:45 – 12:45 p.m.	FDA Presentation	
12:45 – 1:00 p.m.	Questions and Answers	
1:00 p.m.	Adjourn – Break for Lunch	
2:00 p.m.	Call to Order	
2:00 – 3:45 p.m.	Open Committee Discussion	Warren Laskey, M.D.
3:45 – 4:00 p.m.	Break	
4:00 – 5:00 p.m.	*Open Public Session* FDA Comments Sponsor Comments Recommendations & Vote	Warren Laskey, M.D.
5:00 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. 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.