



**CIRCULATORY SYSTEM DEVICES PANEL
AGENDA****March 16, 2016****Circulatory System Devices Panel
AngelMed Guardian System (P150009)
Holiday Inn Gaithersburg MD**

8:00 a.m.	Call to Order Introduction of Committee	Richard Page, MD Chairperson
	Conflict of Interest Statement	CDR Dimitrus Culbreath Designated Federal Officer
8:15 a.m.	Sponsor Presentation	
9:45 a.m.	Sponsor Q&A	
10:00 a.m.	Break	
10:15 a.m.	FDA Presentation	
11:45 a.m.	FDA Q&A	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Panel Deliberations	
3:15 p.m.	Break	
3:30 p.m.	FDA Questions to the Panel	
5:00 p.m.	FDA and Sponsor Summations	
5:30 p.m.	Panel Vote	
6:00 p.m.	Adjournment	

* **Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.