

AGENDA
MEDICAL DEVICES DISPUTE RESOLUTION PANEL

April 19, 2007

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

8:30 a.m. – 5:30 p.m.: Medical Devices Dispute Presentations, Discussion, Recommendation and Vote -- Convened to hear a scientific dispute between FDA's Office of Device Evaluation (ODE) and Cardima, Inc. related to the approvability of a premarket approval application (PMA) for the REVELATION Tx Microcatheter Ablation System.

8:30-8:45	Call to Order	Scott Ramsey, M.D., Ph.D., Panel Chair
8:45-9:15	Open Public Hearing *	
9:15-10:45	Cardima Presentation	
10:45-11:00	BREAK	
11:00-12:30	ODE Presentation	
12:30-1:15	LUNCH	
1:15-1:30	Cardima Follow-up/Rebuttal	
1:30-1:45	ODE Follow-up/Rebuttal	
1:45-2:15	Open Public Hearing*	
2:15-4:00	Open Committee Discussion (including any panel questions of, and requests for clarification from, Cardima and ODE).	
4:00-4:10	BREAK	
4:10-4:20	ODE Summation	
4:20-4:30	Cardima Summation	
4:30-5:30	Panel Deliberation and Vote	
5:30	Adjourn	

* **OPEN PUBLIC HEARINGS:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the Panel. The Executive Secretary will present the speakers who have requested time for a presentation. After the scheduled speakers have spoken, the Chair may ask them to remain if the Panel wishes to question them further. The Chair will recognize unscheduled speakers as time allows. Note: Only the Chair and members of the Panel may question speakers during the open public hearings.