

# AGENDA

## Gastroenterology-Urology Devices Panel of the MEDICAL DEVICES ADVISORY COMMITTEE

Holiday Inn  
2 Montgomery Village Ave  
Gaithersburg, MD

June 27, 2013

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### Session I: Sorbent Hemoperfusion Systems

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8:00 a.m.	Call to Order Introduction of Committee	<b>Mark A. Talamini, M.D.</b> Chairperson
	Conflict of Interest Statement	<b>Shanika Craig, M.H.A., M.B.A.</b> Designated Federal Officer
8:20 a.m.	Reclassification Presentation	<b>Marjorie Shulman, M.B.A.</b> Director, Premarket Notification (510(k)) Program
8:30 a.m.	Clarifying Questions from Committee	
8:45 a.m.	FDA Presentation	
9:30 a.m.	Clarifying Questions from Committee	
9:40 a.m.	Break	
9:50 a.m.	Open Public Hearing	
10:20 a.m.	Committee Questions to Open Public Hearing Speakers	
10:30 a.m.	Panel Deliberations	
11:30 p.m.	FDA Questions to the Panel	
12:40 p.m.	Summations	
12:45 p.m.	<b>LUNCH</b>	

# AGENDA

## Gastroenterology-Urology Devices Panel of the MEDICAL DEVICES ADVISORY COMMITTEE

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### Session II: Implanted Blood Access Devices

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1:30 p.m.	Call to Order Introduction of Committee	<b>Mark A. Talamini, M.D.</b> Chairperson
	Conflict of Interest Statement	<b>Shanika Craig, M.H.A., M.B.A.</b> Designated Federal Officer
1:45 p.m.	FDA Presentation	
2:30 p.m.	Clarifying Questions from Committee	
2:40 p.m.	Open Public Hearing	
3:10 p.m.	Committee Questions to Open Public Hearing Speakers	
3:20 p.m.	Break	
3:30 p.m.	Panel Deliberations	
5:00 p.m.	FDA Questions to the Panel	
6:20 p.m.	Summations	
6:30 p.m.	Adjournment	