AGENDA

NEUROLOGICAL DEVICES PANEL Of the MEDICAL DEVICES ADVISORY COMMITTEE

Gaithersburg Holiday Inn 2 Montgomery Village Avenue, Gaithersburg, MD Ballroom

May 14, 2009

Panel Henry		er, M.D.	Executive Secretary Peter L. Hudson, Ph.D.
8:00	a.m.	Call to Order Conflict of Interest and Deputization to Voting Member Status Statements Panel Introductions	
Confluent Surgical, Inc. DuraSeal Xact TM Sealant System, P080013			t System, P080013
8:30	a.m.	1st Open Public Hearing*	
9:00	a.m.	Sponsor Presentation	
10:30	a.m.	Break	
10:40	a.m.	FDA Presentation	
11:40	a.m.	Panel Deliberations	
12:15	p.m.	Lunch	
1:00	p.m.	Panel Deliberations and FDA Questions	
3:00	p.m.	2 nd Open Public Hearing*	
3:30	p.m.	Break	
3:45	p.m.	FDA and Sponsor Summations	
4:15	p.m.	Panel Vote	
5:00	p.m.	Adjournment	

* Open Public Hearings – 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.