



**GASTROENTEROLOGY AND UROLOGY DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE**

**TOPAS™ Treatment for Fecal Incontinence
Astora Women's Health, LLC**

February 25, 2016

Panel Chairperson
Mark Talamini, M.D.

Designated Federal Officer
Patricio G. Garcia, M.P.H.

08:00 a.m.	Call to Order Panel Introductions Conflict of Interest Statements
08:15 a.m.	Sponsor Presentation
09:30 a.m.	Q&A Sponsor
10:00 a.m.	Break
10:15 a.m.	FDA Presentation
11:30 a.m.	Q&A FDA
12:00 pm	Lunch
1:00 p.m.	Open Public Hearing*
2:00 p.m.	Panel Deliberations (Continued)
2:45 p.m.	Break
3:00 p.m.	FDA Questions
5:30 p.m.	FDA and Sponsor Summations
5:40 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.