



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

Medical Devices Classification/Reclassification

February 26, 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.	OPEN Public Hearing
09:15 a.m.	Break
09:30 a.m.	FDA Presentation: Reclassification of Urogynecologic Surgical Mesh Instrumentation
10:00 a.m.	Panel Deliberation
10:15 a.m.	FDA Questions
10:45 a.m.	FDA Presentation: Classification of Device Thermal, Hemorrhoids (LXX)
11:15 a.m.	Panel Deliberation
11:30 p.m.	FDA Questions
12:00 p.m.	FDA Presentation: Classification of Cushion, Hemorrhoid (LRL)
12:30 a.m.	Panel Deliberations
12:45 p.m.	FDA Questions
1:00 p.m.	FDA Presentation: Classification of Separator, automated, blood cell and plasma, therapeutic (LKN)
1:30 p.m.	Panel Deliberations
1:45 p.m.	FDA Questions
2:00 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.