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 (LKKX)
- **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.