



**OBSTETRICS AND GYNECOLOGY DEVICES PANEL  
of the  
MEDICAL DEVICES ADVISORY COMMITTEE**

**Surgical Mesh for Transvaginal Repair of Pelvic Organ Prolapse  
in the Anterior Vaginal Compartment**

Hilton Washington, DC/North 620 Perry Pkwy., Gaithersburg, MD 20877  
Salons A, B, C and D

February 12, 2019

8:00 AM	Call to Order Panel Introductions	<b>Keith Isaacson, MD</b> <b>Chairperson</b>
	Conflict of Interest Statement	<b>Evela Washington</b> <b>Designated Federal Officer</b>
8:15 AM	Center for Devices and Radiological Health FDA Introduction <b>Sharon Andrews</b>	
8:30 AM	<i>Open Public Hearing*</i>	
10:00 AM	Break	
10:15 AM	<b>FDA Presentation</b>	
	Background <b>Kelly Colden, MD, MPH, FACOG</b>	
	Medical Device Reports (MDRs) & Published Literature <b>Jacqueline Cunkelman, MD, MPH</b>	
	Benefit/Risk Assessment <b>Angie Lee, MD</b>	
11:15 AM	Clarifying Questions from the Panel	
11:30 AM	Lunch	

- 12:30 PM      **Manufacturer Presentations**
- Boston Scientific*  
Uphold LITE and Xenform Presentation
- Introduction and Boston Scientific's Devices  
**Ronald Morton, Jr., MD, FACS**
- Therapies for Repair of POP and History of Mesh  
**Suzette E. Sutherland, MD, MS, FPMRS**
- Data Supporting Boston Scientific's Devices  
**Ronald Morton, Jr., MD, FACS**
- Training, Patient Selection, and Benefit/Risk of TVM  
**Miles Murphy, MD**
- BSC Conclusions  
**Ronald Morton, Jr., MD, FACS**
- 1:10 PM      *Coloplast*  
Restorelle DirectFix Anterior Presentation
- Dale Klous**  
Director of Clinical Science and Office of Medical Affairs
- 1:30 PM      Clarifying Questions from the Panel
- Professional Society Presentations**
- 1:50 PM      *American College of Obstetricians and Gynecologists (ACOG)*  
**Cheryl Iglesia, MD**
- 2:05 PM      *American Urogynecologic Society (AUGS)*  
**Geoffrey Cundiff, MD**
- 2:20 PM      *Society of Gynecologic Surgeons (SGS)*  
**Megan O. Shimpf, MD**
- 2:35 PM      Clarifying Questions from the Panel
- 2:50 PM      Break
- 3:00 PM      Panel Deliberations
- 4:00 PM      FDA Questions to the Panel  
**Ellen Olson, PhD**

6:00 PM Closing Remarks

6:15 PM 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.