



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