



**FDA CDRH  
General and Plastic Surgery Devices Panel of the  
Medical Devices Advisory Committee**

**October 26-27, 2022  
\*\*\*Virtual\*\*\***

*The committee will discuss and make recommendations on the classification proposals for tissue expanders and accessories, mammary sizers, wound dressings with animal-derived materials, absorbable synthetic wound dressings, and hemostatic wound dressings with or without thrombin, nail prostheses, ultrasonic surgical instruments, single-use reprocessed ultrasonic surgical instruments, and neurosurgical ultrasonic instruments.*

**Day 1 – October 26, 2022**

9:00 a.m.	Call to Order, Opening Remarks and Introduction of the Committee	<b>Hobart Harris, MD, MPH</b> Panel Chair
9:05 a.m.	Conflict of Interest Statement	<b>Candace Nalls</b> Designated Federal Officer
9:30 a.m.	<b><i>*Open Public Hearing</i></b>	
10:00 a.m.	Classification Overview	FDA Regulatory Policy Group
10:30 a.m.	FDA Presentation – LCJ – Tissue expander and accessories	Tajanay Ki
10:55 a.m.	Clarifying Questions from Panel	Panel Chair
11:00 a.m.	Panel Questions and Deliberations	Panel Chair
12:00 p.m.	FDA Presentation – MRD – Mammary sizer	Tajanay Ki
12:25 p.m.	Clarifying Questions from Panel	Panel Chair
12:30 p.m.	Panel Questions and Deliberations	Panel Chair
1:00 p.m.	Lunch	
2:00 p.m.	<b><i>*Open Public Hearing</i></b>	

2:30 p.m.	FDA Presentation – KGN – Wound dressing with animal-derived material	Tek Lamichhane
2:55 p.m.	Clarifying Questions from Panel	Panel Chair
3:00 p.m.	Panel Questions and Deliberations	Panel Chair
3:30 p.m.	FDA Presentation – Absorbable synthetic wound dressing	Min Zhang
3:55 p.m.	Clarifying Questions from Panel	Panel Chair
4:00 p.m.	Panel Questions and Deliberations	Panel Chair
4:30 p.m.	FDA Presentation – Topical hemostatic wound dressing without thrombin and with licensed thrombin	Sambasiva Arepalli
4:55 p.m.	Clarifying Questions from Panel	Panel Chair
5:00 p.m.	Panel Questions and Deliberations	Panel Chair
6:00 p.m.	Panel Summation	Panel Chair
6:15 p.m.	Adjourn	<b>Panel Chair</b>

**Day 2 – October 27, 2022**

9:00 a.m.	Call to Order, Opening Remarks and Introduction of the Committee	<b>Hobart Harris, MD, MPH</b> Panel Chair
9:05 a.m.	Conflict of Interest Statement	<b>Candace Nalls</b> Designated Federal Officer
9:30 a.m.	<b><i>*Open Public Hearing</i></b>	
10:00 a.m.	Classification Overview	FDA Regulatory Policy Group
10:30 a.m.	FDA Presentation – MQZ – Prosthesis, nail	Meixia Bi
10:55 a.m.	Clarifying Questions from Panel	Panel Chair
11:00 a.m.	Panel Questions and Deliberations	Panel Chair
11:30 a.m.	FDA Presentation – LFL/NLQ/LBK – Ultrasonic surgical instruments/Single-use reprocessed ultrasonic surgical instruments/Neurosurgical ultrasonic instruments	Rachel Thomas

11:55 a.m.	Clarifying Questions from Panel	Panel Chair
12:00 p.m.	Panel Questions and Deliberations	Panel Chair
1:00 p.m.	Panel Summation	Panel Chair
1:15 p.m.	Adjourn	<b>Panel Chair</b>

\* **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.