



FDA Gastroenterology and Urology Devices Panel Advisory Committee Meeting

July 14, 2021

The committee will discuss and make recommendations on information regarding the premarket approval application (PMA) for the TransMedics® Organ Care System™ (OCS) Liver System

9:00 a.m.	Call to Order and Opening Remarks Introduction of the Committee	Steven D. Schwaitzberg, MD Panel Chair
9:05 a.m.	Conflict of Interest Statement	James Swink Designated Federal Officer
9:15 a.m.	TransMedics® Presentation	
10:45 a.m.	Clarifying questions from the Panel	
11:00 a.m.	Break	
11:15 a.m.	FDA Presentation	
12:45 p.m.	Clarifying Questions from the Panel	
1:00 p.m.	<i>Lunch</i>	
2:00 p.m.	*Open Public Hearing Session	
3:00 p.m.	Panel Deliberations	
4:00 p.m.	Break	
4:15 p.m.	Panel Deliberations Continued/FDA Questions	
5:30 p.m.	Vote	
6:00 p.m.	Summary of Panel Recommendations	
6:15 p.m.	Adjourn	Panel Chair

* **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.