

Circulatory Devices Panel for the Medical Devices Advisory Committee

November 2, 2021 Meeting Agenda

Panel Chairperson: Dr. Richard Lange, M.D.

Designated Federal Officer: Akinola Awojope, Dr.PH.

9:00 am	Call to Order Panel Introductions	10 minutes	Panel Chair
9:10 am	Conflict of Interest	5 minutes	DFO
9:15 am	FDA Presentation Part 1	45 minutes	OHT2
10:00 am	Clarifying Questions from the panel	15 minutes	Panel
10:15 am	Endologix Presentation Part 1	45 minutes	Endologix
11:00 am	Clarifying Questions from the panel	15 minutes	Panel
11:15 am	Break	10 minutes	
11:25 am	Open Public Hearing*	1 hour	Public
12:25 am	Break (Lunch)	35 minutes	
1:00 pm	Clinical Research Groups - Kaiser Permanente - VISION/VQI - Harvard CMS	45 minutes (15 minutes per)	Representatives from each group
1:45 pm	FDA Presentation Part 2	15 minutes	OHT2
2:00 pm	Endologix Presentation Part 2	15 minutes	Endologix
2:15 pm	Clarifying Questions from the panel	20 minutes	Panel
2:35 pm	Break	10 minutes	
2:45 pm	Guest Speaker Presentations - Dr. Gustavo Oderich - Dr. Rodney White	10 minutes (5 minutes per)	
2:55 pm	Clarifying Questions from the panel	5 minutes	Panel
3:00 pm	Panel Deliberations	1 hour	OHT2
4:00 pm	Break	10 min	
4:10 pm	Questions and Summary of Panel Recommendations	1 hour	OHT2
5:10 pm	Adjourn		

^{*} 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. Then the Chair will recognize unscheduled speakers as time allows.