



**U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Circulatory System Devices Panel Meeting Topic: V-Wave Ventura Interatrial Shunt System**

AGENDA

December 3, 2025

9:00 AM	Circulatory System Devices Panel Call to Order/ Introduction of Panel/ Committee (15 min.) <i>Dr. Richard Lange, Temporary Chairperson, Circulatory Systems Devices Panel</i>
9:15 AM	Conflict of Interest Statement (15 min.) <i>Kendra Brooks, Designated Federal Officer, CDRH, FDA</i>
9:30 AM	V-wave Presentation (90 min.)
11:00 AM	Questions to V-wave (15 min.)
11:15 AM	Break (15 min.)
11:30 AM	FDA Presentation (90 min.)
1:00 PM	Questions to FDA (15 min.)
1:15 PM	Lunch (45 min.)
2:00 PM	Open Public Hearing* (60 min.)
3:00 PM	Panel Deliberation (60 min.)
4:00 PM	Break (15 min.)
4:15 PM	FDA Questions (75 min.)
5:30 PM	Vote (15 min.)
5:45 PM	Summary of Panel Recommendations (15 min.)
6:00 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. 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.