



**CIRCULATORY SYSTEM DEVICES PANEL  
of the  
MEDICAL DEVICES ADVISORY  
The OPTIMZER SMART Impulse Dynamics (USA), Inc.  
December 4, 2018**

**Panel Chairperson**  
Richard A. Lange, MD

**Designated Federal Officer**  
Patricio Garcia, MPH

08:00 a.m.	Call to Order Panel Introductions Conflict of Interest Statements
08:15 a.m.	Breakthrough Devices Program
08:30 a.m.	Sponsor Presentation
10:00 a.m.	Q&A Sponsor
10:15 a.m.	Break
10:30 a.m.	FDA Presentation
12:00 p.m.	Q&A FDA
12:15 p.m.	Lunch
1:00 p.m.	Open Public Hearing*
2:00 p.m.	Panel Deliberations
2:45 p.m.	Break
3:00 p.m.	FDA Questions
5:30 p.m.	Sponsor and FDA Summations
5:40 p.m.	Panel Vote
6:00 p.m.	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.