CIRCULATORY SYSTEM DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY
The OPTIMIZER 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.