



Circulatory System Devices Panel for the Medical Devices Advisory Committee

**Discuss and make recommendations on information regarding the 510 (K) application for the
TriGUARD 3 Cerebral Embolic Protection Device**

Panel Chairperson:

Dr. Richard Lange, M.D., M.B.A.

Designated Federal Officer

Aden S. Asefa, M.P.H.

9:00	a.m.	Call to Order Conflict of Interest Panel Introductions
9:15	a.m.	Welcome & Introduction (FDA) 510K Review
9:30	a.m.	Keystone Heart, Ltd. Presentations (90 min) Questions to Keystone Heart, Ltd. (15 min)
11:15	a.m.	Break (15 min)
11:30	a.m.	FDA Presentation (90 min) Questions to FDA (15 min)
01:15	p.m.	Lunch (45 min)
02:00	p.m.	*Open Public Hearing
03:00	p.m.	FDA Questions/Panel Deliberations
04:30	p.m.	Break
04:45	p.m.	FDA Questions/Panel Deliberations Cont.
05:30	p.m.	Summary of Panel Recommendations
06:00	p.m.	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.