

Circulatory Devices Panel for the Medical Devices Advisory Committee February 17, 2021

Discuss and make recommendations and vote on information regarding the premarket approval application (PMA) for the Lutonix 014 Drug Coated Balloon PTA catheter

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

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)
9:30	a.m.	Lutonix Presentations (75 min) Questions to Lutonix (15 min)
11:00	a.m.	Break (15 min)
11:15	a.m.	FDA Presentation (75 min) Questions to FDA (15 min)
12:45	a.m.	Lunch (45 min)
01:30	p.m.	*Open Public Hearing
02:30	p.m.	FDA Questions/Panel Deliberations
03:30	p.m.	Break (15 min)
03:45	p.m.	FDA Questions/Panel Deliberations Cont.
05:30	p.m.	Vote
06:00	p.m.	Summary of panel recommendations
06:15	p.m.	Adjorn

*** 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.