



**CIRCULATORY SYSTEM DEVICES PANEL
AGENDA*****Amplatzer™ PFO Occluder*****Hilton Washington DC North/Gaithersburg
620 Perry Pkwy., Gaithersburg, MD 20877
Salons A, B, C and D*****May 24, 2016***

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|------------|--------------------------------------------|--------------------------------------------------------|
| 8:00 a.m. | Call to Order Introduction of Committee | Richard Page, MD Chairperson |
| | Conflict of Interest Statement | Evella Washington Designated Federal Officer |
| 8:15 a.m. | Sponsor Presentation | |
| 9:45 a.m. | Sponsor Q&A | |
| 10:00 a.m. | Break | |
| 10:15 a.m. | FDA Presentation | |
| 11:45 a.m. | FDA Q&A | |
| 12:00 p.m. | Lunch | |
| 1:00 p.m. | Open Public Hearing | |
| 2:00 p.m. | Panel Deliberations | |
| 3:15 p.m. | Break | |
| 3:30 p.m. | FDA Questions to the Panel | |
| 5:00 p.m. | FDA and Sponsor Summations | |
| 5:30 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.