March 15, 2016
Circulatory System Devices Panel
Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System
Holiday Inn Gaithersburg MD

8:00 a.m. Call to Order
Introduction of Committee
Conflict of Interest Statement

Richard Page, MD
Chairperson

CDR Dimitrus Culbreath
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.