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**CIRCULATORY SYSTEM DEVICES PANEL  
AGENDA****July 21, 2011****Circulatory System Devices Panel****Gaithersburg Hilton****Berlin Heart EXCOR Pediatric Ventricular Assist Device****H100004****Panel Chairperson**

Clyde Yancy, M.D.

**Designated Federal Officer**

James Swink

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|--------------|-----------|--|
| <b>8:00</b>  | <b>am</b> | <b>Call to Order<br/>Conflict of Interest and Deputization of the Voting Members<br/>Panel Introductions</b> |
| <b>8:15</b>  | <b>am</b> | <b>Sponsor Presentation</b>  |
| <b>9:15</b>  | <b>am</b> | <b>Sponsor Q&amp;A</b>   |
| <b>9:45</b>  | <b>am</b> | <b>Break</b>   |
| <b>10:00</b> | <b>am</b> | <b>FDA Presentation</b>  |
| <b>11:00</b> | <b>am</b> | <b>FDA Q &amp; A</b>   |
| <b>11:30</b> | <b>pm</b> | <b>Lunch</b>   |
| <b>1:00</b>  | <b>pm</b> | <b>Open Public Hearing*</b>  |
| <b>2:00</b>  | <b>pm</b> | <b>Panel Deliberations and FDA Questions</b>   |
| <b>3:30</b>  | <b>pm</b> | <b>Break</b>   |
| <b>3:45</b>  | <b>pm</b> | <b>Panel Deliberations and FDA Questions</b>   |
| <b>5:00</b>  | <b>pm</b> | <b>FDA and Sponsor Summations</b>  |
| <b>5:30</b>  | <b>pm</b> | <b>Panel Vote</b>  |
| <b>6:00</b>  | <b>pm</b> | <b>Adjournment</b>   |

\* **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.