

AGENDA

**November 20, 2008, NaviStar ThermoCool Irrigated RF Ablation Catheter
P030031**

**Circulatory System Devices Panel
Gaithersburg Holiday Inn
Gaithersburg, MD**

Panel Chairperson
Jeffery Borer, M.D.

Executive Secretary
James Swink

**8:00 am Call to Order
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions**

8:15 am 1st Open Public Hearing*

8:45 am Sponsor Presentation

10:15 am Sponsor Q&A

10:30 am Break

10:45 am FDA Presentation

12:15 am FDA Q & A

12:30 pm Lunch

1:30 pm Panel Deliberations and FDA Questions

3:30 pm 2nd Open Public Hearing*

4:00 pm Break

4:15 pm FDA and Sponsor Summations

4:45 pm Panel Vote

5:30 pm Adjournment

*** Open Public Hearings** – 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.