## **AGENDA**

## March 18, 2009, TherOx Aqueous Oxygen System (AO System) P080005

## Circulatory System Devices Panel Gaithersburg Hilton Gaithersburg, MD

**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	FDA Bayesian Overview
8:30	am	1st Open Public Hearing*
9:00	am	Sponsor Presentation
10:30	am	Sponsor Q&A
10:45	am	Break
11:00	am	FDA Presentation
12:30	am	FDA Q & A
12:45	pm	Lunch
1:30	pm	Panel Deliberations and FDA Questions

2<sup>nd</sup> Open Public Hearing\*

**FDA** and Sponsor Summations

**Panel Chairperson** 

Jeffery Borer, M.D.

3:30

4:00

4:15

4:45

5:30

pm

pm

pm

pm

**Break** 

**Panel Vote** 

Adjournment

<sup>\*</sup> 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.