



**CIRCULATORY SYSTEM DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE**

Claret Medical, Inc.- Sentinel[®] Cerebral Protection System

February 23, 2017

- 08:00 a.m. Call to Order
Panel Introductions
Richard Page, MD
Chairperson
- Conflict of Interest Statement
Evella Washington
Designated Federal Officer
- 08:15 a.m. Sponsor Presentation
- 09:45 a.m. Sponsor Q&A
- 10:00 a.m. Break
- 10:15 a.m. Introduction and Summary of SENTINEL Study Design
CDR Sadaf A. Toor, MS
Office of Device Evaluation
- SENTINEL Study Clinical Results and Considerations
Donna Buckley, MD, MS
Office of Device Evaluation
- SENTINEL Study Statistical Conclusions and Considerations
Li Ming Dong, PhD
Office of Surveillance and Biometrics
- Conclusions
CDR Sadaf Toor, MS
- 11:45 a.m. FDA Q&A
- 12:00 pm Lunch
- 1:00 p.m. Open Public Hearing*
- 2:00 p.m. Panel Deliberations

AGENDA, continued

- 3:15 p.m. Break
- 3:30 p.m. FDA Questions to the Panel
CDR Sadaf Toor, MS
- 6:00 p.m. Adjournment

DRAFT

* **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.