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

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
3:15 p.m.     Break

3:30 p.m.     FDA Questions to the Panel
               CDR Sadaf Toor, MS

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.