

AGENDA
NEUROLOGICAL DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE

ISS500 Ischemic Stroke System sponsored by BrainsGate Ltd.
December 10, 2021

Panel Chairperson
Mary Jensen, M.D.

Designated Federal Officer
Jarrod Collier, M.S.

09:00 a.m.	Call to Order Panel Introductions Conflict of Interest Statements
09:10 a.m.	Sponsor Presentation
10:40 a.m.	Q&A Sponsor
10:55 a.m.	Break
11:10 a.m.	FDA Presentation
12:40 p.m.	Q&A FDA
12:55 p.m.	Lunch
01:55 p.m.	Open Public Hearing*
02:55 p.m.	Follow up Questions from morning sessions
03:25 p.m.	Panel Deliberations
04:10 p.m.	Break
04:25 p.m.	FDA Questions
05:30 p.m.	FDA and Sponsor Summations
05:40 p.m.	Panel Vote
06:00 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.