



## **Neurological Devices Panel for the Medical Devices Advisory Committee**

**Hilton Washington, DC/North. Salons A-D of Ballroom  
September 27, 2018**

**On September 27, 2018, the Committee will discuss, make recommendations, and vote on the premarket approval (PMA) P170032 application sponsored by Sequent Medical, Inc. for the Woven EndoBridge (WEB) Aneurysm Embolization System, which is indicated for the embolization of intracranial wide neck bifurcation aneurysms.**

**Panel Chairperson:**  
Mary E. Jensen, M.D.

**Designated Federal Officer**  
Aden S. Asefa, M.P.H.

<b>8:00</b>	<b>a.m.</b>	<b>Call to Order Conflict of Interest Panel Introductions</b>
<b>8:15</b>	<b>a.m.</b>	<b>Welcome &amp; Introduction (FDA)</b>
<b>8:30</b>	<b>a.m.</b>	<b>Sequent Medical, Inc. Presentation (75 min)  Questions to Sequent Medical, Inc. (15 min)</b>
<b>10:00</b>	<b>a.m.</b>	<b>Break</b>
<b>10:15</b>	<b>a.m.</b>	<b>FDA Presentation (60 min)  Questions to FDA (15 min)</b>
<b>11:30</b>	<b>a.m.</b>	<b>Open Public Hearing*</b>
<b>12:30</b>	<b>p.m.</b>	<b>Lunch</b>
<b>01:30</b>	<b>p.m.</b>	<b>Panel Deliberations</b>
<b>02:30</b>	<b>p.m.</b>	<b>FDA Questions</b>
<b>03:30</b>	<b>p.m.</b>	<b>Break</b>
<b>03:45</b>	<b>p.m.</b>	<b>FDA Questions Cont.</b>
<b>04:30</b>	<b>p.m.</b>	<b>Panel Vote</b>
<b>05:00</b>	<b>p.m.</b>	<b>Adjourn</b>

**\*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.