



Paper Ballot

Neurological Devices Panel of the Medical Devices Advisory Committee

Sequent Medical, Inc. Woven EndoBridge (WEB) Aneurysm Embolization System

September 27, 2018

The sponsor has proposed the following Indications for Use:

“The WEB Aneurysm Embolization System is indicated for the embolization of intracranial wide neck bifurcation aneurysms. The WEB Aneurysm Embolization System is further indicated to embolize saccular intracranial wide neck bifurcation aneurysms located in the anterior (middle cerebral artery (MCA) bifurcation, internal carotid artery (ICA) terminus, anterior communicating artery (AComm) complex) and posterior (basilar apex) circulations, ranging in size from 3 mm to 10 mm in dome diameter, where the neck size is 4 mm or greater or the dome-to-neck ratio is less than 2.”

The following questions relate to the approvability of the *Woven EndoBridge (WEB) Aneurysm Embolization System*. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented at the panel meeting.

Panelist Name: _____ **Total Votes** _____

Please place an “X” next to your vote for each question.

Voting Question 1:

Is there reasonable assurance that the WEB Aneurysm Embolization System is safe for use in patients who meet the criteria specified in the proposed indications for use?

YES _ **15**

NO _ **0**

ABSTAIN_ **0**

Voting Question 2:

Is there reasonable assurance that the WEB Aneurysm Embolization System is effective for use in patients who meet the criteria specified in the proposed indications for use?

YES **12**

NO **2**

ABSTAIN_1

Voting Question 3:

Do the benefits of the WEB Aneurysm Embolization System outweigh the risks for use in patients who meet the criteria specified in the proposed indications for use?

YES **12**

NO **1**

ABSTAIN_2