

Voting Questions
Neurological Devices Panel of the
Medical Devices Advisory Committee
February 22, 2013

Premarket Approval: P100026, NeuroPace® RNS® System
NeuroPace, Inc.

The sponsor has proposed the following indications for use:

“The RNS System is an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures from no more than two foci that are refractory to two or more antiepileptic medications.”

The following questions relate to the approvability of the NeuroPace® RNS® System. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today.

Voting Question 1:

Is there reasonable assurance that the NeuroPace® RNS® System is safe for use in patients who meet the criteria specified in the proposed indication?

Voting Question 2:

Is there reasonable assurance that the NeuroPace® RNS® System is effective for patients who meet the criteria specified in the proposed indication?

Voting Question 3:

Do the benefits of the NeuroPace® RNS® System for use in patients who meet the criteria specified in the proposed indication outweigh the risks for use in patients who meet the criteria specified in the proposed indication?