

De Novo Request DEN160053 for the Neuronix Ltd.'s neuroAD Therapy System

Neurological Devices Advisory Panel Meeting
March 21st, 2019

Questions for Panel Deliberation

Does the U.S. pivotal study demonstrates a clinically meaningful benefit for the neuroAD as an adjunctive therapy?

When the neuroAD is used as an adjunctive therapy, what minimum amount of improvement in ADAS-Cog alone is clinically meaningful, as well as what is the minimum amount of clinically meaningful improvement in the CGIC?

Is the ADAS-Cog \leq 30 population is a clinically plausible subset and can patients be screened using the ADAS-Cog for the neuroAD?

Is the post-hoc identification of the ADAS-Cog \leq 30 population at a later time point when no treatment is given an adequate analysis of the pivotal study data, in concert with the supplemental data provided, to demonstrate probable benefit?

Are the risks for the neuroAD adequately reported and characterized?

Do the probable benefits to health outweigh
the probable risks?

THANK YOU