



May 15, 2019

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Dear Drs. Aladdin and Carome:

Thank you for your April 9, 2019 letter urging the Food and Drug Administration (FDA) to deny the request from Neuronix Ltd., of Yoqneam, Israel, for a De Novo classification of its NeuroAD device. We appreciate your review of the pivotal study as presented by the FDA and Neuronix Ltd. at the March 21, 2019 public meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee (the Panel), which is available on our website at <https://www.fda.gov/advisory-committees/advisory-committee-calendar/march-21-2019-neurological-devices-panel-medical-devices-advisory-committee-meeting-announcement#event-materials>.

As you know, the FDA may seek the independent expert advice of our Advisory Committees on any scientific, clinical, or policy matter. And although not required to seek the Panel's advice in this matter, and not bound by the Panel's advice in any matter, we give serious consideration to the advice we receive. The advice on this matter will inform our decision, as it does any matter we bring before an Advisory Committee.

If general controls or general and special controls are insufficient to provide reasonable assurance of safety and effectiveness, or the information or the data provided in a De Novo request are insufficient to determine whether general controls or general and special controls can provide a

reasonable assurance of safety and effectiveness, we will decline the De Novo request.

If FDA grants a request for De Novo classification, FDA can disclose a summary of its decision. The public may request information through the Freedom of Information Act (FOIA) once the matter is closed. The instructions for submitting a FOIA request are provided at <https://www.fda.gov/about-fda/about-center-devices-and-radiological-health/cdrh-foia-how-get-records-cdrh#s6>.

We value input from our stakeholders and appreciate the time you have taken to share your views with us.

Sincerely,

Carlos Peña, Ph.D.  
Director  
Office of Health Technology 5: Neurological and  
Physical Medicine Devices  
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Center for Devices and Radiological Health