



April 27, 2020

James A. Boiani, Esq.
Epstein Becker & Green, P.C.
1227 25th Street, N.W.
Suite 700
Washington, DC 20037

Re: Citizen Petition – Docket Number FDA-2019-P-5048

Sent via email to: jboiani@ebglaw.com

Dear Mr. Boiani:

This is an interim response to the petition dated and received by the Food and Drug Administration (FDA) on October 29, 2019. In the petition, you requested FDA to refrain from making a determination that a device is substantially equivalent to the IB-Stim (21 CFR 876.5340) without preclinical studies in an animal model and at least one head-to-head clinical trial establishing non-inferiority of such device to the IB-Stim.

Because your petition raises issues requiring further review and analysis by agency officials, FDA is unable to reach a decision on your petition at this time. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact John Maiers of our Regulations Staff at (301) 796-0343.

Sincerely yours,

Ellen J. Flannery, JD
Deputy Center Director for Policy
Center for Devices and
Radiological Health