



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

October 30, 2019

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Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to refrain from making a determination of certain subject devices' substantial equivalence to the IB-Stim (21 C.F.R. § 876.5340, Product Code QHH) without preclinical studies and at least one clinical trial establishing non-inferiority of the subject device to the IB-Stim in head-to-head evaluations was received by this office on 10/29/2019.

It was assigned docket number FDA-2019-P-5048. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)