FDA U.S. FOOD & DRUG ADMINISTRATION

April 16, 2019

Parag Bhurhandi
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Sent via email to: parag@boditech.co.kr

Re: Docket Number FDA- 2019-P-1800

Dear Dr. Bhurhandi:

This is a response to the petition you provided dated April 14, 2019. In your petition, you requested that FDA take all administrative actions required for reclassification of medical devices associated with Product Code NCD (Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis) from class III to class II.

FDA is unable to process your request because your petition was improperly submitted as a Citizen Petition rather than a Petition for Reclassification. FDA considers your Citizen Petition on the matter to be denied but you may re-submit your request in the form of a Petition for Reclassification. Please refer to 21 CFR 860.123 for details on how to submit a Petition for Reclassification. If you choose to submit a Petition for Reclassification, please reference the docket number above.

If you have any questions about this response, please contact Jean Olson of our Regulations Staff at Jean.Olson@FDA.HHS.GOV.

Sincerely,

Ellen Flannery

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