U.S. FOOD & DRUG ADMINISTRATION

May 30, 2019

Dr. Parag Bhurhandi,
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24398
Republic of Korea (South Korea)

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

Re: Reclassification Petition – Docket Number FDA-2019-P-1800

Dear Dr. Bhurhandi:

Your petition, dated, May 20, 2019, to the Food and Drug Administration (FDA) requesting reclassification of medical devices associated with FDA Medical Device Product Code NCD (Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis) from class III to class II was received on May 22, 2019.

It was assigned docket number FDA-2019-P-1800. 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 and in no way reflects an agency decision on the substantive merits of the petition. If you have any questions about this response, please contact Jean Olson at Jean.Olson@FDA.HHS.GOV.

Sincerely,

Jean Olson
Regulatory Documents and
Special Projects Team
Center for Devices and
Radiological Health

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