DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 15, 2019

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

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner to take all administrative actions required for reclassification of medical devices associated with Product Code NCD from Class III to Class II was received by this office on 04/14/2019.

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 in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2019.04.15 16:20:51 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)