May 20, 2019

To
Food and Drug Administration,
Center for Devices and Radiological Health,
Regulations Staff,
Document Mail Center-WO66-G609,
10903 New Hampshire Ave., Silver Spring,
MD 20993-0002.

Subject: Submission of a '**Reclassification Petition**' **(Docket Number FDA-2019-P-1800) under Section 513(f)(3)** of the FD&C Act to request the FDA Commissioner **for reclassification of medical devices associated with FDA Device Product Code NCD from Class III to Class II**

To whom it may concern,

The undersigned submits this petition for requesting reclassification of the medical devices associated with **FDA Medical Device Product Code NCD (Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis).**

These devices are **currently classified into Class III** subject to pre-market approval under Section 513(f)(1) of the FD&C Act.

This **petition** is being submitted in accordance with the provisions of Section 513(f)(3) of the FD&C Act **for reclassification** of these devices **to Class II** subject to 510k (Special Controls).

This petition was previously submitted online on April 14, 2019 as a Citizen Petition as per 21 CFR 10.30 and FDA had assigned it Docket Number FDA-2019-P-1800.

FDA had suggested the undersigned to resubmit the petition as a reclassification petition as per 21 CFR 860.123.

We believe that this reclassification petition now contains all the required information in the format prescribed by 21CFR 860.123.

However, should you have any questions or require additional information, please contact the undersigned by e-mail.

We request for your earliest attention to and favorable decision on this reclassification petition.

Thank you for your time and consideration.

Enclosed:

1. Three paper copies including one original copy of the reclassification petition
2. One 'eCopy' CD of the reclassification petition

"The eCopy is an exact duplicate of the paper copy"

Sincerely yours,

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