



**WRP Asia Pacific Sdn Bhd**

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April 19, 2021

To Whom It May Concern

**Re: Powder Free Blue Nitrile Examination Glove 510(k) Number**

We, WRP ASIA PACIFIC SDN. BHD., being the manufacturer for the medical devices as described hereafter:

**Powder Free Blue Nitrile Examination Glove (Online Powder Free)**

declare that the 510(k) numbers K133168 and K141982 are superseded by K161422.

We have several 510k numbers for the mentioned product above with different claim on the products. For your information, a new 510k approval would be required by FDA each time the manufacturer wants to modify the claims made.

In October 2016, we had received approval for 510(k)# K161422 after we had this product tested against fourteen (14) chemotherapy drugs (refer to the test report attached). Prior to that testing, the product was approved under 510(k)# K133168 which was issued in August 2014. There is no significant difference between the two products, these are identical in terms of formulation and process, except for the claims made.

The non-chemo 510(k)# K133168 had been provided earlier for; Flexxy Touch Powder Free Nitrile Examination Gloves, Non-Sterile (Blue). As the requested package information did not indicate the need for chemotherapy claim, the factory had supplied you the gloves with the 510(k) number to its relevance. The gloves will be shipped using the 510(k)# K161422 once the packaging is revised to include the chemotherapy drugs permeation claim.

Yours truly,

**On behalf of WRP ASIA PACIFIC SDN. BHD.**

Saravanan Ramasamy  
Head of QA/RA