Acknowledgment Letter

3/6/2020

Roland Strickland, Regulatory Affairs and Clinical Trial Manager
Biomerica, Inc.
17571 Von Karman Avenue
Irvine, CA 92614
UNITED STATES

Dear Roland Strickland:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA200037
Received: 3/6/2020
Applicant: Biomerica, Inc.
Device: Biomerica COVID-19 IgG/IgM Rapid Test

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health