August 18, 2020

Alan Maderazo Ph.D., RAC
VP of Quality, Regulatory & Clinical Affairs
GenMark Diagnostics, Inc.
5964 La Place Court,
Carlsbad, CA 92008

Re: EUA200021/S001
Trade/Device Name: ePlex SARS-CoV-2 Test
Dated: July 8, 2020
Received: July 9, 2020

Dear Dr. Alan Maderazo, RAC:

This is to notify you that your request to update the Instructions for Use (IFU) of the ePlex SARS-CoV-2 Test to; (1) add an alternative workflow option which does not require use of the Sample Delivery Device (SDD) or it's associated steps, (2) updates to the performance tables to describe new clinical and analytical studies performed to support the original and new workflows, and (3) add some minor updates to the intended use and the general warnings and precautions section request by FDA, is granted. Upon review, we concur that the data and information submitted in EUA200021/S001 supports the requested updates for use with the ePlex SARS-CoV-2 Test. We have also updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the ePlex SARS-CoV-2 Test issued on March 19, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health