U.S. FOOD & DRUG ADMINISTRATION

April 30, 2021

Christopher Bentsen, MS, RAC, FRAPS
Bentsen Regulatory and Clinicals Consulting LLC
Representing – SML GENETREE Co., Ltd.
11710 41st Avenue NW
Gig Harbor, WA 98332

Re: EUA201814/S003
Trade/Device Name: Ezplex SARS-CoV-2 G Kit
Dated: March 25, 2021
Received: March 26, 2021

Dear Mr. Bentsen:

This is to notify you that your request to update the Instructions for Use (IFU) of the Ezplex SARS-CoV-2 G Kit to include an Emergency Use Only label to be affixed to the Research Use Only instrument authorized for use with the Ezplex SARS-CoV-2 G, is granted. Upon review, we concur that the information submitted in EUA201814/S003 supports the requested updates. In addition, FDA has updated the Limitations section in the IFU, as well as the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients 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 Ezplex SARS-CoV-2 G Kit issued on January 13, 2021.

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