June 24, 2021

Daniel Kim
OSANG Healthcare Co., Ltd.
132 Anyangcheondong-ro,
Dongan-gu, Anyang-si,
Gyeonggi-do,
14040, Korea

Re: EUA200142/S001
Trade/Device Name: GeneFinder COVID-19 Plus Real*Amp* Kit
Dated: October 13, 2020
Received: October 13, 2020

Dear Daniel Kim:

This is to notify you that your request to update the Instructions for Use for the GeneFinder COVID-19 Plus Real*Amp* Kit to; (1) update the performance section to include the results of testing the FDA SARS-CoV-2 Reference Panel, (2) include edits to the Warnings and Precautions Section and Limitations Section that reflect more recent authorizations, and (3) make a number of minor clarifications and corrections, is granted. Upon review, we concur that the data and information submitted in EUA200142/S001 supports the requested updates for use with the GeneFinder COVID-19 Plus Real*Amp* Kit. In addition, FDA have updated the Fact Sheet for Healthcare Providers and 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 the GeneFinder COVID-19 Plus Real*Amp* Kit issued on April 18, 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

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