



August 3, 2022

Tiffany Miller
VP Regulatory Affairs
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Re: EUA210378/S007
Trade/Device Name: IntelliSwab COVID-19 Rapid Test
Dated: June 1, 2022
Received: June 2, 2022

Dear Tiffany Miller:

This is to notify you that your request to update the IntelliSwab COVID-19 Rapid Test to extend the shelf-life expiration date to 12 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210378/S007 support the requested update for the IntelliSwab COVID-19 Rapid Test. 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 IntelliSwab COVID-19 Rapid Test re-issued on January 27, 2022.

Sincerely yours,

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