



Month 23, 2023

Tamasha Parsons
Sr. Regulatory Affairs Specialist
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Re: EUA210378/S010
Trade/Device Name: IntelliSwab COVID-19 Rapid Test
Dated: February 13, 2023
Received: February 13, 2023

Dear Tamasha Parsons:

This is to notify you that your request to update the IntelliSwab COVID-19 Rapid Test to extend the shelf-life expiration date to 18 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/S010 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 reissued on January 12, 2023.

Sincerely yours,

Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health