April 4, 2023

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

Re: EUA210401/S007
Trade/Device Name: InteliSwab COVID-19 Rapid Test Pro
Dated: November 18, 2022
Received: November 18, 2022

Dear Tamasha Parsons:

This is to notify you that your request to update the InteliSwab COVID-19 Rapid Test Pro to (1) incorporate a change of raw material used in production of the COVID-19 Positive Control included in the InteliSwab COVID-19 Rapid Test Pro Kit Controls (required for use with the InteliSwab COVID-19 Rapid Test Pro and available separately), (2) update the Instructions for Use (IFU) of the InteliSwab COVID-19 Rapid Test Pro Kit Controls to reflect the raw material change, and (3) authorize a shelf-life of 7 months for the InteliSwab COVID-19 Rapid Test Pro Kit Controls manufactured with the new raw material, when stored at 2°C – 8°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210401/S007 support the requested updates for the InteliSwab COVID-19 Rapid Test Pro. 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 InteliSwab COVID-19 Rapid Test Pro reissued on January 27, 2022.

Sincerely yours,

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