



August 22, 2023

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

Re: EUA210401/S010
Trade/Device Name: IntelliSwab COVID-19 Rapid Test Pro
Dated: May 26, 2023
Received: May 26, 2023

Dear Tamasha Parsons:

This is to notify you that your request to update the IntelliSwab COVID-19 Rapid Test Pro to (1) extend the shelf-life to 11 months for the IntelliSwab COVID-19 Rapid Test Pro Kit Controls when stored at 2°C – 8°C, based on the results of your stability studies, (2) extend the open vial/in use stability for the IntelliSwab COVID-19 Rapid Test Pro Kit Controls to up to 8 weeks when recapped and stored at 2°C – 8°C, and (3) update the Instructions for Use (IFU) of the IntelliSwab COVID-19 Rapid Test Pro Kit Controls to reflect the updated open vial/in use stability, is granted. Upon review, we concur that the data and information submitted in EUA210401/S010 support the requested updates for the IntelliSwab 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 IntelliSwab COVID-19 Rapid Test Pro reissued on January 27, 2022.

Sincerely yours,

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