January 17, 2023

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

Re: EUA210401/S006
Trade/Device Name: InteliSwab COVID-19 Rapid Test Pro
Dated: August 9, 2022
Received: August 9, 2022

Dear Tiffany Miller:

This is to notify you that your request to update authorized labeling of the InteliSwab COVID-19 Rapid Test Pro; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A of the letter, and make various updates to the authorized labeling as required and described in Appendix B of the letter, (2) include results of additional reactivity studies, (3) updates to the layout of the Quick Reference Guide InteliSwab COVID-19 Rapid Test Pro to improve usability, and (4) other minor general labeling updates, is granted. Upon review, we concur that the data and information submitted in EUA210401/S006 supports the requested updates for use with the InteliSwab COVID-19 Rapid Test Pro and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and 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