U.S. FOOD & DRUG ADMINISTRATION

February 22, 2023

Lisa Baumhardt, MS, MJ, MT (ASCP), RAC, FRAPS
Senior Medical Device Regulatory Expert
Hyman, Phelps & McNamara, P.C.
Representing: OSANG LLC
215 N. Marengo Ave. 3rd Floor
Pasadena, CA 91101

Re: EUA220037/S006
Trade/Device Name: OHC COVID-19 Antigen Self Test
Dated: November 10, 2022
Received: November 10, 2022

Dear Lisa Baumhardt:

This is to notify you that your request to update the authorized labeling of the OHC COVID-19 Antigen Self Test and the brand name/trade QuickFinder COVID-19 Antigen Self Test in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to; (1) revise the authorized use(s) as required and described in Appendix A, and (2) make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the information submitted in EUA220037/S006 supports the requested updates for use with the OHC COVID-19 Antigen Self Test and the authorized brand name/trade QuickFinder COVID-19 Antigen Self Test. The Fact Sheet for Healthcare Providers (HCPs) 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.

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