May 21, 2024

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: EUA240007/S001
Trade/Device Name: QuickFinder COVID-19/Flu Antigen Self Test
Dated: April 18, 2024
Received: April 18, 2024

Dear Lisa Baumhardt:

This is to notify you that your request to update the QuickFinder COVID-19/Flu Antigen Self Test with data evaluating additional inclusivity of the product to fulfill Condition of Authorization U of the April 3, 2024, Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA240007/S001 supports the requested update for the QuickFinder COVID-19/Flu Antigen Self Test and fulfills Condition of Authorization U of the April 3, 2024, Letter. 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 QuickFinder COVID-19/Flu Antigen Self Test issued on April 3, 2024.

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