February 27, 2023

Ronald Lollar
VP, Clinical and Regulatory Affairs – Infectious Disease
Quidel Corporation
9975 Summers Ridge Road
San Diego, CA 92121

Re: EUA200742/S005
Trade/Device Name: Sofia SARS Antigen FIA
Dated: November 17, 2022
Received: November 17, 2022

Dear Mr. Lollar:

This is to notify you that your request to update the authorized labeling of the Sofia SARS Antigen FIA; (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, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include with results of additional reactivity studies, is granted. Upon review, we concur that the information submitted in EUA200742/S005 supports the requested updates for use with the Sofia SARS Antigen FIA and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers (HCPs) 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 Sofia SARS Antigen FIA re-issued on June 11, 2021.

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