March 1, 2023

Sharmini Muralitharan, PhD., RAC,
Director Regulatory Affairs
Qorvo Biotechnologies, LLC.
14505 21st Ave N., Suite 212
Plymouth, MN 55447

Re: EUA203121/S003
Trade/Device Name: Omnia SARS-CoV-2 Antigen Test
Dated: November 15, 2022
Received: November 15, 2022

Dear Dr. Muralitharan:

This is to notify you that your request to update the authorized labeling of the Omnia SARS-CoV-2 Antigen 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 EUA203121/S003 supports the requested updates for use with the Omnia SARS-CoV-2 Antigen Test. 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.

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