U.S. FOOD & DRUG ADMINISTRATION

February 2, 2024

Marlene A. Hanna, RAC
Senior Director, Regulatory Affairs
Ortho Clinical Diagnostics, Inc. (QuidelOrtho)
100 Indigo Creek Drive
Rochester, NY 14626

Re: Revocation of EUA200233

Dear Ms. Hanna:

This letter is in response to the request from Ortho Clinical Diagnostics, Inc. (QuidelOrtho), in an email dated January 12, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator issued on April 14, 2020, revised on May 9, 2020, October 30, 2020, and January 29, 2021, reissued on March 29, 2021, and revised September 23, 2021. Ortho Clinical Diagnostics (QuidelOrtho) indicated that they have ceased manufacturing of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator reagents for the EUA labeled product and requested that the EUA be revoked. As of the date of this letter, Ortho Clinical Diagnostics, Inc. (QuidelOrtho) has fully transitioned to the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack, VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator product that was granted a De Novo classification under DEN210040.

Consistent with the transition, FDA understands that as of the date of this letter there will no longer be any viable VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator reagents for the EUA labeled product remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Ortho Clinical Diagnostics, Inc. (QuidelOrtho) has requested that FDA revoke the EUA for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200233 for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2

Total Calibrator, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration