December 5, 2025

Ashley Vu
Regulatory Affairs Manager
Thermo Fisher Scientific, Inc.
5781 Van Allen Way,
Carlsbad, CA, 92008
Re: Revocation of EUA210257

Dear Ashley Vu:
This letter is in response to the request from Life Technologies Corporation (a legal entity of Thermo Fisher Scientific, Inc.), in a letter dated November 17, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit issued on April 9, 2021, revised and reissued on September 7, 2021, and October 12, 2021, and amended on March 3, 2022, and November 4, 2022. FDA understands that as of the date of this letter there is no viable Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit reagents 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 Life Technologies Corporation (a legal entity of Thermo Fisher Scientific, Inc.) has requested that FDA revoke the EUA for the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210257 for the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kitis 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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration