August 15, 2024

Amanda Doe
Associate Director, Regulatory Affairs
Grifols Diagnostic Solutions Inc.
10804 Willow Court
San Diego, CA 92127

Re: Revocation of EUA201734

Dear Amanda Doe:
This letter is in response to the request from Grifols Diagnostic Solutions Inc., in an email dated April 4, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Procleix SARS-CoV-2 Assay issued on February 10, 2021, and amended on September 23, 2021. Grifols Diagnostic Solutions Inc. indicated that no further manufacturing of the Procleix SARS-CoV-2 Assay is planned and that any product distributed under the EUA has expired, and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Procleix SARS-CoV-2 Assay 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 Grifols Diagnostic Solutions Inc. has requested that FDA revoke the EUA for the Procleix SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201734 for the Procleix SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Procleix SARS-CoV-2 Assay 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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration