

December 17, 2021

Ayu Sucipto  
Regulatory Affairs Specialist  
Siemens Healthcare Diagnostics Inc.  
511 Benedict Ave.  
Tarrytown, NY 10591  
**Re: Revocation of EUA201697**

Dear Ayu Sucipto:

This letter is in response to a request from Siemens Healthcare Diagnostics Inc. (Siemens), received December 9, 2021, that the U.S. Food and Drug Administration (FDA) voluntarily remove the ADVIA Centaur SARS-CoV-2 IgG (COV2G) – EUA201697 issued on July 31, 2020 and amended on September 23, 2021, from FDA’s list of authorized EUA devices. FDA understands that the authorized product is no longer being marketed.

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 Siemens has notified FDA that Siemens has decided to no longer market the authorized product and requested FDA voluntarily remove the ADVIA Centaur SARS-CoV-2 IgG (COV2G) – EUA 201697 from FDA’s list of authorized EUA devices, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201697 for the ADVIA Centaur SARS-CoV-2 IgG (COV2G), pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the ADVIA Centaur SARS-CoV-2 IgG (COV2G) 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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Jacqueline A. O’Shaughnessy, Ph.D.  
Acting Chief Scientist  
Food and Drug Administration