May 5, 2023

Bala Raja Ph.D.
President and CEO
Luminostics, Inc.
48389 Fremont Blvd, Suite 112,
Fremont, CA, 94538

Re: Revocation of EUA202907

Dear Dr. Raja:

This letter is in response to the request from Luminostics, Inc., in a letter received May 2, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Clip COVID Rapid Antigen Test issued on December 7, 2020, reissued March 4, 2022, and revised on September 23, 2021, and November 1, 2022. FDA understands that as of the date of this letter there are no viable Clip COVID Rapid Antigen Test 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 Luminostics, Inc. has requested FDA withdraw the EUA for the Clip COVID Rapid Antigen Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202907 for the Clip COVID Rapid Antigen Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Clip COVID Rapid Antigen Test 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