



June 30, 2021

Monte Brown, MD
Vice President of Administration and Secretary
Duke University Health System
107B Davison Building
Durham, NC 27710

Re: Revocation of EUA

Dear Dr. Brown:

This letter is in response to Duke University Health System's (Duke's) request dated April 9, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Duke Decontamination System for Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor (hereafter referred to as "Duke Decontamination System") issued on May 7, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. Duke will no longer make the Duke Decontamination System available for the authorized emergency use. In its request, Duke confirmed that it has ceased operation of all Duke Decontamination System sites as well as associated activities.

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 be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Duke has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Duke's EUA for the Duke Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Duke Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Duke to inform its customers of this revocation.

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

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration