April 30, 2021

Mr. Jeff Rose
Battelle Memorial Institute
505 King Avenue
Columbus, OH 43201

**Re: Revocation of EUA200210**

Dear Mr. Rose:

This letter is in response to Battelle Memorial Institute's (Battelle's) request dated April 2, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA200210) for the Battelle Critical Care Decontamination System (hereafter referred to as "Battelle Decontamination System") issued on March 28, 2020, and revised and reissued on March 29, 2020, June 6, 2020, and January 21, 2021. In its request, Battelle confirmed that it has ceased operation of all Battelle Decontamination System sites as well as associated marketing 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, pursuant to section 564(g)(2) of the Act, be revoked when 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 Battelle has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA200210 for the Battelle Decontamination System, pursuant to and section 564(g)(2)(C) of the Act. As of the date of this letter, the Battelle Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Battelle 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