January 16, 2025

Fresenius Medical Care North America
Attention: Renee Howard, M.S.
Vice President Global Drug – Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: Revocation of EUA 048

Dear Ms. Howard:

This letter is in response to the request from Fresenius Medical Care North America (Fresenius) that the U.S. Food and Drug Administration (FDA) revoke the EUA for the multiFiltrate PRO System and multiBic/multiPlus solutions. This EUA was issued initially on April 30, 2020.

Fresenius has informed the FDA that it does not intend to offer the multiFiltrate PRO System and multiBic/multiPlus solutions under the EUA in the United States anymore. The multiFiltrate PRO System and the multiBic solution have obtained marketing clearance for certain uses under section 510(k) of the Federal Food, Drug and Cosmetic Act (the Act).[1] FDA understands that Fresenius will issue a communication to notify healthcare facilities and providers that have received the multiFiltrate PRO System and multiBic/multiPlus solutions under the EUA of this revocation and to stop using the multiBic solution as a replacement solution in continuous renal replacement therapy. The use of the multiBic solution as a replacement solution in continuous renal replacement therapy is no longer authorized under the EUA and such use has not obtained FDA-approval. However, and consistent with FDA policy[2], FDA does not intend to object to the use of the multiBic solution remaining in distribution when used consistent with the labeling conditions detailed under K233159 until such product has expired.

The authorization of a drug or device for emergency use under section 564 of 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). For the reasons stated in Fresenius' request, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 048 for the multiFiltrate PRO System and multiBic/multiPlus solutions pursuant to section 564(g)(2)(C) of the Act. As of the date of this

[1] The multiFiltrate PRO System obtained 510(k) clearance under K220281. The multiBic solution, marketed as pureFlow Dialysate Solutions, obtained 510(k) clearance under K233159. The multiBic solution has not obtained FDA-approval under section 505 of the Act for use as a replacement solution in continuous renal replacement therapy.

[2] See FDA's guidance titled *Transition Plan for Medical Devices Issued Emergency Use Authorizations Related to COVID-19* (March 2023).

letter, the multiFiltrate PRO System and multiBic/multiPlus solutions are 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,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2025.01.16 11:09:51 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration