October 1, 2024

Venkata Vempati
B. Braun Medical, Inc.
3773 Corporate Pkwy
Center Valley, PA 18034

Re: Revocation of EUA200227

Dear Venkata Vempati:

This letter serves to correct an error in our October 1, 2024, revocation letter. We inadvertently stated that this EUA had been issued on April 1, 2020. We have corrected that date below to reflect the April 11, 2020, issuance. The signature on this letter will reflect the date of the correction but the October 1, 2024 date of the letter reflects the effective date of the revocation.

This letter is in response to your request dated August 6, 2024, that the Food and Drug Administration (FDA) provide advice about the process for withdrawing the Emergency Use Authorization (EUA200227) issued on April 11, 2020, for B. Braun Medical's Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES. We are considering this as a request to revoke this EUA. Your request is in response to the lack of customer interest and lack of need for use of the device for the indications granted under this EUA considering the improved COVID-19 situation. The B. Braun Medical's Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES were authorized for emergency use by FDA for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or suspected of having COVID-19 and for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System.

FDA understands that B. Braun Medical does not plan to continue to distribute the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES for the indications authorized in EUA200227. If you decide later that you want to do so, those indications would require emergency use authorization or marketing authorization (premarket approval under section 515 of the Federal Food Drug and Cosmetic Act (the Act), 510(k) clearance (premarket notification under section 510(k) of the Act), or De Novo classification (under section 513 of the Act)).

You indicated in your email dated September 16, 2024, that the EUA included additional indications beyond the 510(k)-cleared device indications and that the only changes that you made to the 510(k)-cleared device were to include an addendum to the instructions for use and to add fact sheets to the existing labeling. In that email, you committed to, upon EUA revocation, do the following:

1) Post a customer letter on your website and send the letter to customers to direct them to dispose of the EUA-related labeling;

2) Remove from the website the current EUA Customer Letter, the Fact Sheets for Healthcare Providers, and the corresponding Instructions for Use addendum for the B. Braun Space and Outlook Pumps; and
3) Notify customers, via the B. Braun website, that the EUA for the B. Braun infusion pumps has been revoked, and that customers should dispose of the Customer Letter, the Fact Sheets for Healthcare Providers, and the Instructions for Use addendum for the B. Braun Space and Outlook Pumps.

In an additional email, dated September 25, 2024, you indicated that you also intend to:

1) Instruct customers to dispose of the EUA-specific IFU addendum and to use the device with the 510(k) cleared labeling; and

2) Offer customers the ability to either download the electronic copy of the 510(k)-cleared device labeling from B. Braun's website or contact the customer representative to request a paper copy of the same, as needed.

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 B. Braun Medical Inc. has requested that FDA revoke the EUA for the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes, pursuant to 564(g)(2)(C), EUA200227 for the B. Braun Perfusor Syringe Infusion Pump System, Outlook ES and the Infusomat Space Volumetric Infusion Pump. As of the date of this letter, the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES are no longer authorized for emergency use by FDA[1].

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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

[1] As outlined in our April 1, 2020, EUA letter, the B. Braun Space and Outlook Pumps have each respectively received marketing authorization from FDA under section 510(k) of the Act. This EUA revocation does not impact the 510(k)-cleared devices or their indications for use.