

April 11, 2020

Tracy Maddock
B. Braun Medical, Inc.
901 Marcon Boulevard
Allentown, PA 18109

Dear Tracy Maddock:

This letter is in response to your request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES (“B. Braun Space and Outlook Pumps¹”) for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or suspected of having the Coronavirus Disease 2019 (COVID-19) and to decrease the exposure of healthcare providers (HCP) to such patients during the COVID-19 pandemic. Also in response to your request, FDA is issuing this EUA for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System.

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.² Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.³

Based on review of available evidence, FDA has concluded that using an infusion pump connected to a nebulizer for tracheal delivery of nebulized medications allows for prolonged treatment with these medications, while risks to patients are the same as for other routes of administration.

¹ The B. Braun Space and Outlook Pumps have each respectively received marketing clearance from FDA under section 510(k) of the Act. This emergency use authorization authorizes uses that are not under the cleared indications for use of the products and are an “unapproved use of an approved product” under section 564(a)(2)(B) of the FD&C Act. This letter only applies to the emergency use of the B. Braun Space and Outlook Pumps.

² U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 7316 (February 4, 2020) (accessible at <https://www.fda.gov/media/135010/download>).

³ U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 17335 (March 27, 2020).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of the B. Braun Space and Outlook Pumps, described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the B. Braun Space and Outlook Pumps 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, decreasing the exposure of HCPs to such patients during the COVID-19 pandemic, and for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System, meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the B. Braun Space and Outlook Pumps may be effective for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat COVID-19 patients of all ages and for the ground medical transport use of the Infusomat Space Volumetric Infusion Pump System, and that the known and potential benefits of the B. Braun Space and Outlook Pumps for these uses, outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of the B. Braun Space and Outlook Pumps for treating patients during the COVID-19 pandemic.⁴

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the B. Braun Space and Outlook Pumps by HCPs 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, while decreasing the exposure of HCPs to such patients during the COVID-19 pandemic, and for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System.

The Authorized Product Details

The B. Braun Space and Outlook Pumps are comprised of three FDA-cleared devices:

- The Perfusor Space Syringe Infusion Pump System

⁴ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

The Perfusor® Space Syringe Infusion Pump System includes an external, transportable, electronic infusion pump and pump accessories. The Perfusor® Space Syringe Infusion Pump is capable of wireless communication both inbound and outbound. Autoprogramming of the pump is possible where the pump receives infusion parameters wirelessly from the electronic health record over the hospital Wireless Local Access Network. The B. Braun Space Station is a flexible docking and communication system designed to accommodate multiple Perfusor® Space Syringe Infusion Pumps for use in a medical facility.

- Infusomat Space Volumetric Infusion Pump System,

The Infusomat® Space Volumetric Infusion Pump System includes an external, electronic infusion pump and pump accessories. The pump is transportable within a facility. The Infusomat® Space pump utilizes a linear peristaltic pumping mechanism and is intended to provide infusions of parenteral fluids. The Infusomat® Space Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities. Infusomat® Space is capable of wireless communication both inbound and outbound.

- Outlook ES

The Outlook ES is an electrical, external volumetric infusion pump intended to provide infusion of parenteral fluids. The system is created by using dedicated cassettes and is intended to provide accurate and continuous flow of these fluids to the patient. The pump is software controlled and operates using volumetric displacement with a stepper-motor mechanism. The Outlook ES is intended to provide a way to automate the programming of infusion parameters.

The following information and fact sheets pertaining to the emergency use of the B. Braun Space and Outlook Pumps are authorized to be made available to HCP and patients, as applicable:

- Manufacturer's Instructions for Use
- Fact Sheet for Healthcare Providers: Emergency Use of the B. Braun Space and Outlook Pumps;
- Fact Sheet for Patients: Emergency Use of the B. Braun Space and Outlook Pumps

The device should be used according to the Manufacturer's Instructions for Use for these devices, with consideration for the recommendations in the Fact Sheet for Healthcare Providers and Fact Sheet for Patients (hereafter referred to as "Fact Sheets"). HCPs should follow their hospital's protocol for integrating the pumps with a nebulizer.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the B. Braun Space and Outlook Pumps, when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the B. Braun Space and Outlook Pumps may be effective for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat COVID-19 patients of all ages and for the ground medical transport use of the

Infusomat Space Volumetric Infusion Pump System, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA and concludes that the B. Braun Space and Outlook Pumps, for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat COVID-19 patients of all ages and for the ground medical transport use of the Infusomat Space Volumetric Infusion Pump System (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

III. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions on this authorization:

B. Braun Medical, Inc (B. Braun)

- A. B. Braun will provide all customers the Fact Sheets and ensure that the manufacturer's Instructions for Use are available for the B. Braun Space and Outlook Pumps before the device may be used (i.e., before a healthcare facility begins preparing medications for delivery from the B. Braun Space and Outlook Pumps into a nebulizer for which the healthcare facility already owns or for which the healthcare facility has notified B. Braun of its intent to purchase consistent with the use outlined in the Scope of Authorization of this letter (Section II)), as follows:
 - a) B. Braun will notify and make available to all existing customers the Fact Sheets for the B. Braun Space and Outlook Pumps through posting on the B. Braun website. In this notification, B. Braun will instruct healthcare facilities to notify B. Braun if the healthcare facility intends to use the B. Braun Space and Outlook Pumps for the emergency use. B. Braun will send the appropriate Fact Sheets to each customer who notifies B. Braun that they intend to use the B. Braun Space and Outlook Pumps for the emergency use, consistent with Section II of this letter.
 - b) B. Braun will make available to all new customers the manufacturer's Instructions for Use and Fact Sheets for the B. Braun Space and Outlook Pumps, consistent with Section II of this letter. B. Braun will instruct new customers to notify B. Braun if the healthcare facility intends to use the B. Braun Space and Outlook Pumps for the emergency use.
- B. B. Braun must comply with all applicable labeling requirements under the FD&C Act and FDA regulations, except for unique device identifier requirements (see Subpart B of 21 CFR part 801).
- C. B. Braun will have a process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803. Adverse events of which B. Braun becomes aware will be reported to FDA. Adverse events related to use with a nebulizer will be identified within the medical device report(s) to distinguish them from events related to FDA-cleared products.

- D. B. Braun will ensure that any records associated with this EUA, including, but not limited to, records of healthcare facilities that have notified B. Braun that the facility is using the B. Braun Space and Outlook Pumps consistent with Section II of this letter, are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- E. Through a process of inventory control, B. Braun will maintain records of the customers to which they distribute the Fact Sheets.
- F. B. Braun is authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.
- G. B. Braun will notify FDA of any authorized distributor(s) of the product, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA.

Authorized Distributor(s)

- H. Authorized distributor(s) will make B. Braun Space and Outlook Pumps available with the Fact Sheets.
- I. Through a process of inventory control, authorized distributor(s) will maintain records of the customers to which they distribute the B. Braun Space and Outlook Pumps and number of infusion pumps they distribute.
- J. Authorized distributor(s) are authorized to make available additional information relating to the emergency use of the B. Braun Space and Outlook Pumps that is consistent with, and does not exceed, the terms of this letter of authorization.

Conditions Related to Advertising and Promotion

- K. All printed matter, including advertising and promotional materials, relating to the use of the B. Braun Space and Outlook Pumps shall be consistent with the Fact Sheets, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- L. No printed matter, including advertising and promotional materials, advertising or promotional descriptive printed matter relating to the use of B. Braun Space and Outlook Pumps' emergency use (i.e., for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat affected patients or those suspected of having the COVID-19 may represent or suggest that such products are safe or effective for the prevention or treatment of patients during the COVID pandemic.
- M. All printed matter, including advertising and promotional materials relating to the use of B. Braun Space and Outlook Pumps clearly and conspicuously shall state that:

- The B. Braun Space and Outlook Pumps have not been FDA cleared or approved for this emergency use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients with or suspected of having COVID-19 and for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System;
- The B. Braun Space and Outlook Pumps have been 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;
- The B. Braun Space and Outlook Pumps 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 are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the B. Braun Space and Outlook Pumps under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of the B. Braun Space and Outlook Pumps during the COVID-19 pandemic is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures