March 29, 2021

Sridhar Kota, PhD
Inspire Rx, LLC
2205 Commonwealth Drive, Suite D
Ann Arbor, MI 48105
(734) 975-9245
kota@umich.edu

Dear Dr. Kota:

This letter is in response to your request on behalf of Inspire Rx, LLC that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the Inspire Rx, LLC Portable Negative Pressure Isolation & Procedural Tent System, (hereafter referred to as the "AerosolVE Device"[1]) by healthcare providers (HCP)[2] as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed diagnosis of coronavirus disease 2019 (COVID-19), at the time of definitive airway management, or when performing airway-related

[1] The AerosolVE Device is a non-sterile, single-patient use, portable, negative pressure, clear vinyl isolation and procedural tent enclosure which is placed over a patient's upper body, and can be attached to hospital beds, surgical beds, and stretchers. The device is comprised of a disposable tent unit that includes the foldable, fire retardant clear vinyl tent enclosure, an integral HEPA filter, exhaust tubing, and a reusable fan. The negative pressure environment is generated via the exhaust tubing connected to the reusable AerosolVE Device fan, which is plugged into a standard 120VAC wall outlet. The HCP can cut up to 8 slits into the vinyl surface of the tent, where needed, to provide full and direct access to the patient. The AerosolVE Device is not intended to replace the need for PPE or room sanitation and disinfection procedures. The maximum duration of use is 30 minutes if end-tidal CO_2 monitoring is not available, with air flow fan on and under direct observation. When needed for intermittent use, total duration of use is limited to up to fourteen (14) days.

[2] For this EUA, HCP refers to practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or health professionals that have a role in using such a device.

medical procedures,[3] or during certain transport[4] of such patients, during the COVID-19 pandemic.[5]

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.[6] 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 during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[7]

There are no FDA-approved or -cleared devices for use as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates from patients during the COVID-19 pandemic. The use of the AerosolVE Device may provide a greater level of protection for HCP during aerosol-generating airway management procedures (such as intubation and extubation), and in non-invasive respiratory care (such as high-flow nasal cannula oxygen, nebulizers and CPAP/ BiPAP), and during certain patient transport. Based on FDA's review of literature data, bench testing of particulate clearance, HCP to patient communication, internal environment, and HEPA filter performance, and when evaluating the safety and usability of the AerosolVE Device when used over a patient's upper body, and a usability study of the AerosolVE Device, FDA has concluded that the AerosolVE Device may be effective, and that the known and potential benefits outweigh the known and potential risks, when the AerosolVE Device is used as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed cases of COVID-19, as described in the Scope of Authorization (Section II) of this letter.

---

[3] Non-transport use of the AerosolVE Device is only authorized for emergency use during definitive airway management (e.g., intubation, extubation and suctioning airways), or when performing any airway-related medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or continuous positive airway pressure/bi-level positive airway pressure [CPAP/BiPAP] mask use, airway suctioning, percussion and postural drainage).

[4] Use of the AerosolVE Device during patient transport is only authorized for emergency use within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), SpO_2% (oxygen saturation), end tidal carbon dioxide ($EtCO_2$), if available, throughout transport. If end-tidal CO_2 monitoring is not available, then the use of the AerosolVE Device should be limited to no more than 30 minutes with air flow fan on and under direct observation. The patient should always have supplemental oxygen during all authorized uses of the AerosolVE Device.

[5] During the public health emergency, it would not be feasible to require HCP to limit use of the AerosolVE Device to patients with suspected or confirmed COVID-19; therefore, the authorization does not restrict use to such patients.

[6] 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 7, 2020).

[7] 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 AerosolVE Device, as 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 AerosolVE Device, as described in the Scope of Authorization (Section II) of this letter, meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2 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 AerosolVE Device may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport (when end-tidal CO_2 monitoring is not available) for a maximum duration of use of 30 minutes, of patients with suspected or confirmed diagnosis of COVID-19[8] and that the known and potential benefits of the AerosolVE Device for such use outweigh its known and potential risks; and,

3. There is no adequate, approved, and available alternative to the emergency use of the AerosolVE Device.[9]

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 AerosolVE Device by HCPs as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by temporarily isolating patients with known or suspected COVID-19,[10] at the time of definitive airway management (e.g., intubation, extubation and suctioning airways), or when performing any airway-related medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or CPAP/BiPAP mask use, airway suctioning, percussion and postural drainage), or during certain patient transport. When being used for transport of such patients, the AerosolVE Device is limited to use within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. Maintenance of negative pressure with adequate air flow must be

[8] Refer to footnote 5.
[9] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[10] See footnote 5 stating that it would not be feasible to require HCP to limit the AerosolVE Device use for patients with suspected or confirmed COVID-19 during this public health emergency; therefore, the authorization does not restrict use to such patients.

ensured. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), SpO_2%, and $EtCO_2$, if available, throughout transport. If end-tidal CO_2 monitoring is not available, then the use of the AerosolVE Device must be limited to no longer than 30 minutes with air flow fan on and under direct observation. For all authorized uses, the patient should always have supplemental oxygen during use of the AerosolVE Device. If intermittent use is needed, total duration of use is limited to up to fourteen (14) days. The AerosolVE Device is for use in addition to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

This product should be removed from the patient if it impedes the ability to perform the standard of care, or if there is difficulty visualizing or identifying anatomic landmarks, or if it impedes the ability to intubate the patient after the first try.

The AerosolVE Device is not authorized for the following uses:

- On patients needing emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On patients with anticipated or known history of claustrophobia
- On patients with communication disorders that might interfere with clinical care
- On patients under the age of 18
- On bariatric patients
- On patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure
- On patients requiring procedures that involve exceeding the maximum direct access slits or holes as stated in this IFU
- On patients in elderly care centers (non-hospital environment)
- On patients in ambulance transport

Authorized Product

The AerosolVE Device is a non-sterile, single-patient use, portable, negative pressure isolation and procedural tent system made of clear vinyl, which is placed over a patient's upper body and can be attached to hospital beds, surgical beds, and hospital stretchers. The isolation system is comprised of a disposable tent unit that includes the foldable, fire retardant clear vinyl tent enclosure, an integral HEPA filter, exhaust tubing, and a reusable fan. To utilize the AerosolVE Device, the tent unit is removed from the packaging, unfolded, and placed over the patient. The bottom of the tent is open to allow health care providers to place it without disturbing the patient. The fan is placed on the floor and the exhaust tubing is connected between it and the HEPA filter, located within the tent. The fan is then plugged into a standard 120VAC wall outlet and the flow indicators on the fan outlet indicate when the airflow is sufficient for use with the patient. The HCP may cut slits (no more than eight (8) 406 mm/16 inch long or four (4) 100 mm/4 inch holes, per tent) into the vinyl surface of the tent, where needed, to access to the patient.

The negative pressure environment is generated via the AerosolVE Device fan. After use, the disposable tent unit is disposed of and the fan can be disinfected for reuse. The disposable AerosolVE Device may be used intermittently, as needed, for up to fourteen (14) days.

Use of the AerosolVE Device requires the following key components:

- AerosolVE Device Disposable Kit which includes the tent, tent base, HEPA filter, exhaust tubing, 2 tape strips, and 1 airflow indicator strip; and
- AerosolVE Device Fan Unit Kit which includes the fan with integral base and 2 airflow indicator strips; and
- AerosolVE Device Instructions for Use.
- For transport within the Hospital: hospital grade uninterrupted power supply (UPS, not provided in the device kit, provided by the healthcare facility).

The above described AerosolVE Device is authorized to be accompanied with the "Instructions for Use: AerosolVE Device," (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#barrier), together with the following product-specific information pertaining to the emergency use, which is required to be made available to HCPs and patients, respectively:

- Fact Sheet for Healthcare Providers: Emergency Use of the AerosolVE Device
- Fact Sheet for Patients: Emergency Use of the AerosolVE Device

The above described product, when accompanied with the "Instructions for Use: AerosolVE Device" and the two Fact Sheets (identified above, and collectively referred to as "authorized labeling") is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

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 AerosolVE Device when used and labeled consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of this product.

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 AerosolVE Device may be effective as described within, when used consistent 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, including the information supporting the conclusions described in Section I above, and concludes that the AerosolVE Device, as described in the Scope of Authorization of this letter (Section II), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the AerosolVE Device under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and

under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under section 564(b)(1) of the Act, the AerosolVE Device is authorized to be used and distributed as set forth in this EUA.

III. Waiver of Certain FDA Requirements

Under section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under section 520(f)(1) of the Act. FDA waives all such requirements, including the quality system requirements under 21 CFR Part 820.

IV. Conditions of Authorization

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

Inspire Rx, LLC, as Sponsor of the Authorized Product

A. Inspire Rx, LLC may request changes to this EUA for AerosolVE,[11] including changes to the authorized labeling. Any requests for changes to this EUA should be submitted to the Office of Health Technology 4 (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Such changes require appropriate authorization from FDA prior to implementation.

B. Inspire Rx, LLC must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices), as well as those described in Section II of this letter, Scope of Authorization. Compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

C. Inspire Rx, LLC must have a process in place for reporting adverse events in accordance with 21 CFR Part 803. Inspire Rx, LLC must report any adverse events of which it becomes aware to FDA in accordance with 21 CFR Part 803. Inspire Rx, LLC must establish a process to collect adverse event information from healthcare facility customers.

[11] The following types of revisions may be authorized without reissuing this letter: (1) non-substantive editorial corrections to this letter; (2) new types of authorized labeling, including new fact sheets; (3) new carton/container labels; (4) expiration dating extensions; (5) changes to manufacturing processes, including tests or other authorized components of manufacturing; (6) new conditions of authorization to require data collection or study; (7) new instruments, associated software, components or materials in the authorized product or modifications in the way that the device is used. For changes of the type listed in (6) or (7), review and concurrence is required from the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

D. Inspire Rx, LLC must notify FDA of any authorized distributor(s)[12] of the AerosolVE Device, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA and any updates.

Inspire Rx, LLC and any Authorized Distributor(s)

E. Inspire Rx, LLC and authorized distributors must distribute the AerosolVE Device with the authorized labeling only to healthcare facilities with HCPs who are adequately equipped, trained, and capable of using the AerosolVE Device.

F. Inspire Rx, LLC and authorized distributors must make the authorized labeling available on their websites.

G. Authorized distributors must make Inspire Rx, LLC aware of any adverse events of which they become aware.

H. Through a process of inventory control, Inspire Rx, LLC and authorized distributors must maintain records of the healthcare facilities to which they distribute the AerosolVE Device and the number of products they distribute.

I. Inspire Rx, LLC and authorized distributor(s) are 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.

Inspire Rx, LLC, any Authorized Distributor(s), and Healthcare Facilities

J. Inspire Rx, LLC, any authorized distributor(s), and healthcare facilities must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Healthcare Facilities

K. Healthcare facilities using the AerosolVE Device must make available to patients the accompanying Patient Fact Sheet and make available to HCPs the accompanying Healthcare Provider Fact Sheet.

L. Healthcare facilities using the AerosolVE Device must make Inspire Rx, LLC and FDA aware of any adverse events pursuant to 21 CFR Part 803.

M. Healthcare facilities must ensure HCPs are adequately equipped, trained, and capable of using the AerosolVE Device.

N. Healthcare facilities must maintain records of the AerosolVE Device usage.

[12] Inspire Rx, LLC is currently the sole distributor of the AerosolVE Device. “Authorized Distributor(s)” are identified by the sponsor in an EUA submission as an entity allowed to distribute the device.

Conditions Related to Printed Materials, Advertising and Promotion

O. All descriptive printed matter, advertising, and promotional materials relating to the use of the AerosolVE Device shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (q)(1) and (r) of the Act and FDA implementing regulations.

P. No descriptive printed matter, advertising, or promotional materials relating to the use of the AerosolVE Device may represent or suggest that such products are safe or effective for the prevention or treatment of COVID-19.

Q. All descriptive printed matter, advertising, and promotional materials relating to the use of the AerosolVE Device shall state that:

- The AerosolVE Device has neither been cleared or approved by FDA, but has been authorized for emergency use by FDA under an EUA for use by HCP as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing any airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic; and,

- The emergency use of the AerosolVE Device has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization 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