U.S. FOOD & DRUG ADMINISTRATION

September 24, 2020

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Director of Regulatory Affairs and Quality
Office of Regulatory Affairs and Quality (ORAQ)
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Dear Dr. Parrish:

This letter is in response to your request on behalf of Duke University that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of COVIAGE[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 isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, when performing airway-related 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

[1] COVIAGE is a negative pressure, clear tent enclosure which is attached to hospital beds and/or hospital stretchers. The tent contains four pairs of sleeves with attached gloves to allow for isolated patient access and a two-way access box through which medical supplies, food, water, etc. can be passed into and out of the tent. The negative pressure environment is generated via a HVAC System including two air filters connected in series. COVIAGE is not intended to replace the need for PPE or room sanitation and disinfection procedures. COVIAGE is not approved or cleared for marketing in the US.

[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.

[3] Authorized non-transport use of COVIAGE is only for 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] Authorized use of COVIAGE during patient transport is only within a hospital setting for temporary transfer (less than 40 minutes, at which time the battery may be depleted) 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. The patient should always have supplemental oxygen during all authorized uses of COVIAGE.

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

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 COVIAGE may provide a greater level of protection for HCP during high-risk procedures involving manipulation of the airway, such as endotracheal intubations 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 bench performance testing of filtration efficiency and structural stability, and usability testing evaluating various medical and practical tasks during the use of COVIAGE, FDA has concluded that COVIAGE may be effective 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 isolation of hospitalized patients with suspected or confirmed cases of COVID-19, as described below.

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 COVIAGE, 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 COVIAGE, 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 COVIAGE 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, when performing airway-related medical procedures, or during certain transport of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of COVIAGE for such use outweigh its known and potential risks[8]; and,

[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).
[8] Refer to footnote 5.

3. There is no adequate, approved, and available alternative to the emergency use of COVIAGE.[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 COVIAGE by HCP as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by isolating patients with known or suspected COVID-19, at the time of definitive airway management (e.g., intubation, extubation and suctioning airways), 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, COVIAGE is limited to use within a hospital setting for temporary transfer (less than 40 minutes, at which time the battery may be depleted) 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%, and $EtCO_2$, if available, throughout transport. For all authorized uses, the patient should always have supplemental oxygen during use of COVIAGE.

COVIAGE is not authorized for use on:

- Patients needing emergent endotracheal intubation with severe hypoxemia
- Patients with anticipated or known history of difficult airway;
- Combative or non-cooperative patients
- Patients with communication disorders that might interfere with clinical care;
- Patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes; or
- Children under 45 pounds (lbs).

Authorized COVIAGE

COVIAGE is authorized for use by HCP as an extra layer of barrier protection to prevent HCP exposure to pathogenic biological airborne particulates by providing isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19 at the time of definitive airway management, when performing any airway-related medical procedures, or during certain patient transport; it is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE or room sanitation and disinfection procedures.

COVIAGE is a protective barrier enclosure that operates under a negative pressure gradient and filters pathogenic biological airborne particulates. The enclosure is comprised of a reusable, adjustable aluminum frame, that fits most hospital beds and stretchers. The enclosure is constructed of a transparent, medical grade polyurethane material that is single patient use and disposable as medical waste. The enclosure contains sleeves with attached gloves, entry zippers, and a two-way access box through which medical supplies, food, water, etc. can be passed into

[9] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

and out of the enclosure. Negative pressure is created inside the enclosure by a reusable ventilation fan mounted at the head bracket of the hospital bed. The fan draws air in through an inlet at the top of the foot wall of the tent and exhausts air to the environment at the head wall of the tent after passing through a high efficiency particulate air (HEPA) filtration system, which uses two in-line filters to achieve HEPA-level filtration (99.999% filtration efficiency). The ventilation system is capable of continuous operation when connected to wall power, and a battery pack allows for portable short-term use during transportation up to 40 minutes.

Use of COVIAGE requires the following components that are included:

- Ventilation system with fan, battery for portable operation (reusable), and two in-line filters (disposable)
- Plastic (thermoplastic polyurethane) tent (disposable)
    - Sleeves (polyether polyurethane) (disposable)
    - Gloves (polyether polyurethane) (disposable)
    - Two-way access box (polyether polyurethane) (disposable)
    - Zippers (disposable)
    - Grommets (disposable)
    - Prefilter (polyester) (disposable)
- Zip ties (disposable)
- Carabiners (reusable)
- Aluminum frame (reusable)

Use of COVIAGE requires the following components that are not included:

- Tools required for assembly:
    - 10 mm ratchet wrench;
    - 4mm Allen key;
    - M6 Hex nut driver;
- Portable or wall-mounted oxygen;
- Endo-tracheal tube;
- O_2 mask;
- Nasal Cannula.

COVIAGE is authorized for use as described in the Scope of Authorization (Section II).

The above described COVIAGE is authorized to be accompanied with the "Instructions for Healthcare Facilities: Assembly, Disassembly, and Disinfection of COVIAGE," and "Instructions for Healthcare Personnel (HCP): Use of COVIAGE" (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices), together with the following product-specific information pertaining to the emergency use, which is required to be made available to HCP and patients, respectively:

- Fact Sheet for Healthcare Providers: Emergency Use of the Duke University COVIAGE
- Fact Sheet for Patients: Emergency Use of the Duke University COVIAGE

The above described product, when accompanied with the Instructions for Healthcare Facilities and Instructions for Healthcare Personnel 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 COVIAGE 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 COVIAGE 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 COVIAGE, 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 COVIAGE 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, COVIAGE 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:

Duke University, as Sponsor of Authorized Product

A. Duke University may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or 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) and require appropriate authorization from FDA prior to implementation.

B. Duke University may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT4/OPEQ/CDRH.

C. Duke University 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.

D. Duke University must have a process in place for reporting adverse events pursuant to 21 CFR Part 803. Adverse events of which Duke University becomes aware will be reported to FDA. Duke University will establish a process to collect adverse event information from healthcare facility customers.

E. Duke University will notify FDA of any authorized distributor(s)[10] of COVIAGE, 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.

Duke University and any Authorized Distributor(s)

F. Duke University and authorized distributors will distribute COVIAGE with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the COVIAGE.

G. Duke University and authorized distributors will make authorized labeling available on their websites.

H. Authorized distributors will make Duke University aware of any adverse events of which they become aware.

I. Through a process of inventory control, Duke University and authorized distributors will maintain records of the healthcare facilities to which they distribute COVIAGE and the number of each product they distribute.

J. Duke University and authorized distributor(s) are authorized to make available

[10] "Authorized Distributor(s)" are identified by the sponsor in an EUA submission as an entity allowed to distribute the device.

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.

Duke University, any Authorized Distributor(s), and Healthcare Facilities

K. Duke University, any authorized distributor(s), and healthcare facilities will 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

L. Healthcare facilities using COVIAGE must make available to patients the accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet.

M. Healthcare facilities using COVIAGE must make Duke University and FDA aware of any adverse events pursuant to 21 CFR Part 803.

N. Healthcare facilities will ensure HCP are adequately equipped, trained, capable to use COVIAGE, and will maintain records of device usage.

Conditions Related to Printed Materials, Advertising and Promotion

O. All descriptive printed matter, including advertising and promotional material, relating to the use of COVIAGE shall be consistent with the authorized labeling as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

P. No descriptive printed matter, including advertising or promotional material, relating to the use of COVIAGE may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.

Q. All descriptive printed matter, including advertising and promotional materials, relating to the use of COVIAGE shall clearly and conspicuously state that:

- COVIAGE has neither been cleared or approved 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 isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, when performing any airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic;

- COVIAGE has been authorized for emergency use by FDA under an EUA; and,

- COVIAGE 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 authorization is terminated or 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures