May 8, 2020

Jeffrey K. Shapiro
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, DC 20005-5929

Dear Mr. Shapiro:

This letter is in response to your request on behalf of Comunale that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the Comunale Patient Isolation Transport Unit[1] (hereafter "PITU") intended to be used by healthcare providers (HCPs)[2] for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19 requiring airborne or droplet isolation precautions in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment (PPE).[3]

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.[4] 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, due to shortages during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[5]

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[1] The Comunale PITU is not approved or cleared for distribution in the United States.
[2] For this EUA, HCPs refers to practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or allied health professionals that have a role in using such a device.
[3] The PITU is not intended to replace PPE, room sanitation and disinfection procedures. Under the circumstances of this public health emergency, it would not be feasible to require HCPs to limit the use of the PITU only to patients with suspected or confirmed COVID-19; therefore, this authorization does not restrict use to such patients.
[4] 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).
[5] 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).

There is a shortage of FDA approved or cleared device treatments to isolate and transport patients with suspected or confirmed diagnosis of COVID-19, as well as a reduced capacity of negative pressure rooms for isolation of patients with COVID-19. Use of the PITU would allow for an immediately available, temporary solution for negative pressure isolation of suspected/confirmed COVID-19 infected patients. The use of the PITU would reduce or eliminate the need to keep a prepared room for such patients while awaiting transport to an appropriate biosafety level unit. Medical personnel can attend to the patient via multiple, integrated, sealed, glove ports.

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 PITU, 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 PITU, 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, 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 PITU may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, and that the known and potential benefits of such products, when used by HCP for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19 requiring airborne or droplet isolation precautions in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, outweigh the known and potential risks of the PITU; and,

3. There is no adequate, approved, and available alternative to the emergency use of the PITU.[6]

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 PITU by HCPs for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19 requiring airborne or droplet isolation

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

precautions in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE. The PITU is not intended to be used during surgical procedures or to replace PPE, room sanitation and disinfection procedures.

Authorized Product

The PITU is intended for the temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19 requiring airborne or droplet isolation precautions.

The PITU is a negative pressure, clear tent enclosure which attaches to standard hospital beds or gurneys. The PITU utilizes integrated, battery-powered ventilation blower motors and High Efficiency Particulate Air (HEPA) filtered exhaust to generate a negative pressure environment in order to temporarily isolate the patient. The device also enables HCP to maintain patient isolation while allowing for transportation and the ability to attend to the patient through glove ports in the sides of the unit. The PITU enclosure is large enough for a patient to sit up, eat, read, and perform other activities of daily living while remaining isolated on the hospital bed or gurney.

The PITU is comprised of the following components:

- Aluminum frame (provided disassembled; reusable)
- Clear transparent vinyl, flame resistant, disposable enclosure
- 3M™ P100 filters (disposable)
- Powered Air Purifying Respirator (PAPR) blower motors with rechargeable batteries (reusable)

The PITU is a negative pressure enclosure that functions in a similar manner to a hospital negative pressure, Airborne Infection Isolation Room (AIIR). The enclosure is constructed of a flame retardant, clear, medical grade vinyl material that is single patient use and disposable as medical waste. The enclosure is suspended from a reusable, adjustable aluminum frame that fits standard hospital beds or gurneys. Negative pressure is created inside the enclosure by the operation of one to three, reusable, battery-powered ventilation blower motors mounted at the top of the foot wall of the enclosure. The motors draw air in through vents at the foot of the tent and exhaust air to the environment at the head of the tent after passing through NIOSH approved disposable HEPA filters. In addition, air is exhausted from the enclosure through disposable HEPA filters attached to the intake side of the blower motors. Each blower motor has its own battery.

The above described PITU, is authorized to be accompanied with the "PITU User Manual-Information for Patient and HCP," and "PITU Set Up and Operation Guide," (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), together with the following product-specific information pertaining to the emergency use, which is required to be made available to HCP and patients:

- Fact Sheet for Healthcare Providers: Emergency Use of the Patient Isolation and

Transport Unit (PITU)
- Fact Sheet for Patients: Emergency Use of the Patient Isolation and Transport Unit (PITU)

The "PITU User Manual-Information for Patient and HCP," and "PITU Set Up and Operation Guide," and the two Fact Sheets are referred to as "authorized labeling." The above described PITU, when accompanied with the described labeling is authorized to be distributed to 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 PITU when used and labeled consistently 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 authorized PITU may be effective in preventing HCP exposure to pathogenic biological airborne particulates, 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, including the information supporting the conclusions described in Section I above**Error! Reference source not found.**, and concludes that the authorized PITU, 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 PITU 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) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the PITU is authorized to be used and distributed as set forth in this EUA.

III. Waiver of Certain FDA Requirements

Pursuant to 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). FDA grants that waiver, including the quality system requirements under 21 CFR 820.

IV. Conditions of Authorization

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

Comunale, as Sponsor of Authorized Product

A. Comunale will make the PITU available with authorized labeling. Comunale may request changes to the authorized labeling. Such changes require review and concurrence from OHT4/OPEQ/CDRH.

B. Comunale may request changes to the Scope of Authorization (Section II in this letter) of the authorized PITU. Such requests will be made by Comunale, in consultation with and concurrence of the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and OHT4/OPEQ/CDRH.

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

D. Comunale 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. As such, compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

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

F. Comunale will notify FDA of any authorized distributor(s)[7] of the PITU, 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.

Comunale and any Authorized Distributor(s)

G. Comunale and authorized distributors will distribute the authorized PITU with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the PITU.

H. Comunale and authorized distributors will make authorized labeling available on their websites.

I. Authorized distributors will make Comunale aware of any adverse events of which they become aware.

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

J. Through a process of inventory control, Comunale and authorized distributors will maintain records of the healthcare facilities to which they distribute the PITU and the number of each product they distribute.

K. Comunale 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.

Comunale, Any Authorized Distributors, and Healthcare Facilities

L. Comunale, 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

M. Healthcare facilities using the authorized PITU must make available to patients the accompanying Patient Fact Sheet and make available to HCPs the accompanying Healthcare Provider Fact Sheet.

N. Healthcare facilities using the PITU must make Comunale and FDA aware of any adverse events under 21 CFR Part 803.

O. Healthcare facilities will ensure HCPs are adequately equipped, trained, capable to use the PITU, and will maintain records of device usage.

Conditions Related to Printed Materials, Advertising and Promotion

P. All descriptive printed matter, including advertising and promotional material relating to the use of the authorized PITU, 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.

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

R. All descriptive printed matter, include advertising and promotional materials relating to the use of the authorized PITU shall clearly and conspicuously state that:

- The PITU has neither been FDA-cleared or approved;
- The PITU has been authorized for emergency use by FDA under an EUA; and,
- The PITU 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 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