U.S. FOOD & DRUG ADMINISTRATION

April 1, 2021

Dr. J. Peter Rubin
c/o Samantha K. Zappia, MS, RAC
SK Regulatory Solutions, LLC
14 Malden Street, Suite 100
West Boylston MA 01583
(617) 943-6094
samanthak@skregulatorysolutions.com

cc:
Innovative Electronics Corporation
750 Trumbull Dr.
Pittsburgh, PA 15205
(412) 276-0711

Dear Ms. Zappia:

This letter is in response to your request on behalf of J. Peter Rubin, MD, MBA, FACS (hereafter "Dr. Rubin") at the University of Pittsburgh[1], that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the Individual Biocontainment Unit[2] (hereafter "IBU") by healthcare providers (HCP)[3] 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

[1] Dr. Rubin, Chair of the Department of Plastic Surgery, UPMC Endowed Professor of Plastic Surgery, and Professor of Bioengineering at the University of Pittsburgh, is the product sponsor/EUA holder and distributor of the IBU with the resources and support of the University of Pittsburgh to help meet the Conditions of Authorization of this EUA. Innovation Electronics Corporation is the manufacturer and distributor of the IBU under a vendor contract with the University of Pittsburgh.

[2] The IBU is a negative pressure, rigid chamber made of transparent materials (e.g., transparent polycarbonate sheet) with aluminum framing and is designed to cover a patient's head and upper body. A single sealable access window is built into the rear of the isolation chamber, which allows for isolated patient access. The negative pressure environment is generated within the IBU via a smoke evacuator device with an in-line ultra-low particulate air/high-efficiency particulate air (UPLA/HEPA) filter. This product should be removed if it impedes the ability to care for or perform a medical procedure on a patient, or impedes the communication between HCP and patients. The device is for use in addition to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

[3] 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.

(COVID-19), at the time of definitive airway management, or when performing medical procedures,[4] or during certain transport[5] of such patients during the COVID-19 pandemic.[6]

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.[7] 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.[8]

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 IBU would allow for a greater level of protection for HCP during transport or 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). Based on FDA's review of literature data, usability testing and bench performance testing for leaks and aerosol evacuation, FDA has concluded that the IBU may be effective, and that the known and potential benefits outweigh the known and potential risks, when the IBU is used 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 cases of COVID-19, as described in the Scope of Authorization (section II) of this letter.

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 IBU, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

---

[4] Authorized non-transport use of IBU is only for airway management (e.g., intubation, extubation and suctioning airways), or when performing any aerosol generating medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or CPAP/BiPAP (continuous positive airway pressure / bi-level positive airway pressure) mask use, airway suctioning, percussion and postural drainage).

[5] Authorized use of the IBU during patient transport is only 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. The patient should always have supplemental oxygen during all authorized uses of the IBU. Duration of transport is limited to 30 minutes if end-tidal CO_2 monitoring is not available.

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

[7] 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).

[8] 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).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the IBU, 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 IBU 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 medical procedures, or during transport of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of the IBU 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 IBU.[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 IBU 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,[10] at the time of definitive airway management (e.g., intubation, extubation, and suctioning airways), or when performing any aerosol generating 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 patient transport. When being used for transport of such patients, the IBU 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. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), SpO_2%, and $EtCO_2$ if available throughout transport, and the patient should always have supplemental oxygen during use of the IBU. If end-tidal CO_2 monitoring is not available during transport, duration of use is limited to 30 minutes. The IBU 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 care for or perform a medical procedure on the patient or impedes communication between the HCP and the patient.

---

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

[10] See footnote 6 stating that it would not be feasible to require HCP to limit the IBU use for patients with suspected or confirmed COVID-19 during this public health emergency; therefore, the authorization does not restrict use to such patients.

The IBU is not authorized for the following uses:

- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with communication disorders that might interfere with clinical care
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On children under 45 pounds (lbs.)

Authorized IBU Product Description

The IBU consists of a rigid enclosure made of transparent materials (e.g., transparent polycarbonate sheet) and aluminum framing, which is placed over the head, face, and neck of a patient laying in a hospital bed (supine, prone, or upright) creating a physical barrier between the patient and the healthcare provider. The IBU attaches to a standard hospital or surgical bed. There is a single sealable access window in the rear of the enclosure which allows access to the patient and may also be closed and sealed to facilitate patient isolation. The enclosure is coupled to a vacuum source which provides continuous negative pressure inside the enclosure; a battery-powered version of the vacuum source allows for patient transport while maintaining negative pressure within the enclosure. An inline ultra-low particulate air (ULPA)/high efficiency particulate air (HEPA) filter is included between the enclosure and the vacuum source to continuously filter the air and trap any aerosol or particulates, which must be replaced between uses according to manufacturer instructions.

The IBU is comprised of and assembled from one Top Panel Assembly, one Rear Panel Assembly, two Side Panel Assemblies, translucent drape, pre-filter tubing, fasteners. All rigid components of the chamber are intended to be reusable and must be cleaned and disinfected with a hospital-approved, EPA-registered isopropyl alcohol-based disinfectant. The IBU must be assembled, disassembled, and disinfected according to the "Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection of the Individual Biocontainment Unit." Flexible pre-filter tubing, drapes, and filters are for single patient use.

The IBU requires the following components that are not included as part of the IBU system:

- Negative pressure-generating sources that meet authorized specifications (A vacuum source with an affixed ULPA filter, such as a surgical smoke evacuator, where the vacuum source generates a minimum flow rate of 25 cubic feet per minute (CFM) through a hose of at least 7/8 inch internal diameter (ID). For example Buffalo (ConMed) PlumeSafe/ViroVac Smoke Evacuator and Stryker Neptune Waste Management System); and
- Portable or wall-mounted medical air or oxygen;
- Healthcare facility standard oxygen line;
- Healthcare facility standard suction hose lines (minimum 1/4 inch inner diameter)
- A blanket for the patient;
- Endo-tracheal tube;
- O_2 mask;
- Nasal cannula.

To transport patients on ventilators, all valves and ports are closed. To transport patients who are not on ventilators, the IBU maintains negative pressure via portable self-contained, suction or negative pressure pumps equipped with ULPA filters. Adequate oxygen flow and maintenance of negative pressure with adequate air flow must be assured. Patients should have constant monitoring of vital signs, electrocardiogram (EKG), SpO_2%, $EtCO_2$ if available throughout transport, and the patient should always have supplemental oxygen during use of the IBU.

The above described IBU, is authorized to be accompanied with the "Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection of the Individual Biocontainment Unit," and "Instructions for Healthcare Providers: Use of the Individual Biocontainment Unit" (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 HCP and patients, respectively:

- Fact Sheet for Healthcare Providers: Emergency Use of the Individual Biocontainment Unit
- Fact Sheet for Patients: Emergency Use of the Individual Biocontainment Unit

The above described product, when accompanied with the Instructions for Healthcare Facilities and Instructions for Healthcare Providers (identified above) and the two Fact Sheets (collectively referred to as "authorized labeling") is authorized to be distributed and administered 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 IBU 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 authorized IBU may be effective as described within, 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, and concludes that the authorized IBU, 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 IBU 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 IBU 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) of the Act. 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:

Dr. Rubin, as Sponsor of the Authorized Product/EUA Holder

A. Dr. Rubin may request changes to this EUA for the IBU, including changes to the authorized labeling. Any request for changes to this EUA must be submitted to 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.[11]

B. Dr. Rubin will notify FDA of any authorized distributor(s)[12] of the IBU, 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.

Dr. Rubin and Innovative Electronics Corporation, (hereafter "IEC")[13]

C. Dr. Rubin and IEC 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.

[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.

[12] Dr. Rubin and IEC are currently the sole distributors of the IBU. "Authorized Distributor(s)" are identified by the product sponsor/EUA holder in an EUA submission as an entity allowed to distribute the device.

[13] Dr. Rubin is the product sponsor/EUA holder. Innovative Electronics Corporation is the manufacturer. Both parties are distributors of the IBU device.

D. Dr. Rubin must have a process in place for reporting adverse events in accordance with 21 CFR Part 803. Dr. Rubin must report to FDA adverse events of which IEC and/or Dr. Rubin become aware. Dr. Rubin will establish a process to collect adverse event information from IEC and healthcare facility customers.

Dr. Rubin, IEC, and any Other Authorized Distributor(s)

E. Dr. Rubin, IEC, and other authorized distributors will distribute the authorized IBU with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the IBU.

F. Dr. Rubin, IEC, and other authorized distributors will make authorized labeling available on their websites.

G. Other authorized distributors will make Dr. Rubin and IEC aware of any adverse events of which they become aware.

H. Through a process of inventory control, Dr. Rubin, IEC, and other authorized distributors will maintain records of the healthcare facilities to which they distribute the IBU and the number of each product they distribute.

I. Dr. Rubin, IEC, and other 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.

Dr. Rubin, IEC, and any Other Authorized Distributor(s), and Healthcare Facilities

J. Dr. Rubin, IEC, 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

K. Healthcare facilities using the authorized IBU must make available to patients the accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet.

L. Healthcare facilities using the IBU must make Dr. Rubin and FDA aware of any adverse events under 21 CFR Part 803.

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

Conditions Related to Printed Materials, Advertising and Promotion

N. All descriptive printed matter, advertising, and promotional materials relating to the use

of the authorized IBU 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.

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

P. All descriptive printed matter, advertising, and promotional materials relating to the use of the authorized IBU shall state that:

- The IBU 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 medical procedures, or during transport of such patients during the COVID-19 pandemic; and

- The emergency use of the IBU is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under section 564(b)(1) of the 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