April 12, 2021

Michael Adams
Chief Executive Officer
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Dear Mr. Adams:

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.[1] 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.[2]

On December 18, 2020, based on your request,[3] the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the SCONE[4] by healthcare providers (HCP)[5] as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne

[1] 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).
[2] 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).
[3] For ease of reference, this letter will use the term "you" and related terms to refer to Scone Medical Solutions Inc.
[4] The SCONE is a negative pressure, clear plastic enclosure which is placed over a patient's head, neck, and shoulders and can be attached to hospital beds, surgical beds, and stretchers. The enclosure contains four arm access holes, sealed by vinyl access covers when not in use, to allow for isolated patient access. The negative pressure environment is generated via wall-mounted hospital vacuum lines or negative pressure pumps equipped with in-line HEPA filter(s). The SCONE is not intended to replace the need for PPE or room sanitation and disinfection procedures. The SCONE is not approved or cleared for marketing in the U.S. In the December 18, 2020 letter, the maximum duration of use was 30 minutes.
[5] 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.

particulates by providing isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing airway-related medical procedures,[6] or during certain transport[7] of such patients for a maximum duration of use of 30 minutes, during the COVID-19 pandemic.[8]

On January 21, 2021, you requested to amend your EUA. Based on your request, and having concluded that revising the December 18, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the December 18, 2020, letter in its entirety with the scope of authorization revised to allow the SCONE to be used longer than 30 minutes only if constant monitoring of vital signs[9] is maintained and only for as long as required to complete the indicated procedures. If constant End-Tidal CO_2 monitoring is not possible, then use of the SCONE is limited to a maximum of 30 minutes with negative pressure suction on and under direct observation, while electrocardiogram (ECG/EKG) and Oxygen saturation (SpO2%) must be monitored at all times. The authorized labeling (identified below) was updated accordingly.

The SCONE has not been previously cleared or approved by FDA for any indication. In addition, 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 SCONE 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 aerosol clearance rate, patient oxygenation and CO_2 retention testing evaluating the safety of the SCONE when used over a patient's head and neck, and a usability study with anticipated users of the SCONE, FDA has concluded that the SCONE may be effective, and that the known and potential benefits outweigh the known and potential risks, when the SCONE 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 isolation of hospitalized patients with suspected or confirmed cases of COVID-19, as described below.

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[6] Non-transport use of the SCONE 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).

[7] Use of the SCONE 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. The patient should always have supplemental oxygen during all authorized uses of the SCONE. In the December 18, 2020 letter, the total duration of transport and/or non-transport use was limited to 30 minutes.

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

[9] For the purposes of this EUA, vital signs include electrocardiogram (ECG/EKG), oxygen saturation (SpO_2%), and end tidal carbon dioxide ($EtCO_2$).

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 SCONE, 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 SCONE, 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 SCONE 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 of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of SCONE for such use outweigh its known and potential risks; and,

3. There is no adequate, approved, and available alternative to the emergency use of SCONE.[10]

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 SCONE by HCPs 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,[11] 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, SCONE 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. For all authorized uses, the patient should always have supplemental oxygen during use of SCONE. The SCONE is authorized to be used longer than 30 minutes only if constant monitoring of vital signs is maintained and only for as long as required to complete the indicated procedures. If End-Tidal CO_2 monitoring is not possible, then use of the SCONE is limited to a maximum of 30 minutes with negative pressure suction on and under direct observation, while electrocardiogram

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

(ECG/EKG) and Oxygen saturation (SpO_2%) must be monitored at all times. SCONE is an adjunct to PPE for HCPs during the COVID-19 pandemic and does not replace the need for PPE or room sanitation and disinfection procedures.

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.

SCONE is not authorized for use on:

- Patients needing emergent endotracheal intubation with severe hypoxemia;
- Patients with anticipated or known history of difficult airway;
- 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.).
- Patients with anticipated or known history of claustrophobia
- Patients with communication disorders that might interfere with clinical care
- Bariatric patients
- Patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure
- Patients in elderly care centers (non-hospital environment)
- Patients in ambulance transport

Authorized Product

SCONE is a single-use, negative pressure, clear plastic chamber which is placed over a patient's head, neck, and shoulders and can be attached to hospital beds, surgical beds, and hospital stretchers. The chamber is made of a clear plastic cover film installed on a foldable aluminum frame; SCONE is provided fully assembled. It has four arm access holes, sealed by vinyl access covers when not in use, to allow for isolated patient access. The front of the transparent covering is draped onto and secured over the patient's torso with adjustable hook-and-loop fastener straps to create an enclosed environment while allowing easy access for tubes and other medical equipment under the covering (e.g., nasal cannula). The negative pressure environment is generated via wall-mounted hospital vacuum lines or 1-2 negative pressure pump(s) equipped with in-line HEPA filter(s) (able to filter 0.3 μm particulates or smaller) which are connected to two of the barbed air management ports on the side of the chamber. When a nasal cannula with supplemental oxygen is not being used on a patient, a wall-mounted or portable oxygen line should be connected to the third barbed air management port.

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

- Portable or wall-mounted vacuum source (if using portable vacuum pump(s), an inline HEPA filter is required for each pump);
- Portable or wall-mounted 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.

SCONE is authorized for use as described in this section.

The above described SCONE is authorized to be accompanied with the "Instructions for Healthcare Providers and Facilities: SCONE Device," (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 HCPs and patients, respectively:

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

The above described product, when accompanied with the "Instructions for Healthcare Providers and Facilities: SCONE 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 SCONE 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 SCONE 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 SCONE, 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 SCONE 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 SCONE 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:

Scone Medical Solutions Inc., as Sponsor of the Authorized Product

A. Scone Medical Solutions Inc. may request changes to this EUA for the SCONE, 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.[12]

B. Scone Medical Solutions Inc. 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. Scone Medical Solutions Inc. must have a process in place for reporting adverse events in accordance with 21 CFR Part 803. Scone Medical Solutions Inc. must report any adverse events of which it becomes aware to FDA in accordance with 21 CFR Part 803. Scone Medical Solutions Inc. must establish a process to collect adverse event information from healthcare facility customers.

D. Scone Medical Solutions Inc. must notify FDA of any authorized distributor(s)[13] of the SCONE, 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

[12] 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. All changes to the authorization require review and concurrence from OHT4/OPEQ/CDRH. 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.

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

updates.

Scone Medical Solutions Inc. and any Authorized Distributor(s)

E. Scone Medical Solutions Inc. and authorized distributors must distribute SCONE with the authorized labeling only to healthcare facilities with HCPs who are adequately equipped, trained, and capable of using SCONE.

F. Scone Medical Solutions Inc. and authorized distributors must make the authorized labeling available on their websites.

G. Authorized distributors must make Scone Medical Solutions Inc. aware of any adverse events of which they become aware.

H. Through a process of inventory control, Scone Medical Solutions Inc. and authorized distributors must maintain records of the healthcare facilities to which they distribute SCONE and the number of products they distribute.

I. Scone Medical Solutions Inc. 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.

Scone Medical Solutions Inc., any Authorized Distributor(s), and Healthcare Facilities

J. Scone Medical Solutions Inc., 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 SCONE 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 SCONE must make Scone Medical Solutions Inc. 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 SCONE.

N. Healthcare facilities must maintain records of SCONE usage.

Conditions Related to Printed Materials, Advertising and Promotion

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

of SCONE 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 SCONE may represent or suggest that this product is 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 SCONE shall clearly and conspicuously state that:

- SCONE has not been FDA-approved or cleared 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, or when performing any airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic, but has been authorized by FDA under an EUA; and,

- The emergency use of SCONE 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures