May 6, 2021

Dr. Wisam Breegi
CEO & Founder
Breegi Scientific, Inc.
120 Bedford Rd.
Woburn, MA 01801

Dear Dr. Wisam:

This letter is in response to your request on behalf of Breegi Scientific, Inc., that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the Negative Pressure SteriDome (hereafter "NPS")[1] by healthcare providers (HCP)[2] as a single-use 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 COVID-19, at the time of definitive airway management, or when performing medical procedures[3], or during certain transport[4] of such patients during the COVID-19 pandemic.[5]

[1] The NPS is a non-sterile single-use, negative pressure, containment device made of a clear plastic chamber and is designed to cover a patient's head and neck without undue pressure on the patient's neck. The NPS has arm sleeves to allow for isolated patient access, an access portal, two connecting ports, and airlocks to facilitate procedures and to transfer objects in and out of the NPS chamber. The negative pressure environment is generated within the NPS via a vacuum source with a high-efficiency particulate air (HEPA) filter or healthcare facility wall suction system that evacuates the vacuumed air safely to the outside environment. The device is for use in addition to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE or room sanitation and disinfection procedures. The maximum duration of use is one hour. The NPS is not approved or cleared for marketing in the U.S.

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

[4] Authorized use of the NPS 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. If end-tidal CO_2 monitoring is not available, then the use of the NPS 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 use of the NPS. The total duration of transport and/or non-transport use is limited to one hour.

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

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 NPS may provide for 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 scientific literature data and bench performance testing to test leaks and aerosol evacuation, particulate clearance, HCP to patient communication, internal environment, and HEPA filter performance, and when evaluating the safety and usability of the NPS Device when used over a patient's upper body, and a usability study of the NPS Device, FDA has concluded that the NPS may be effective, and that the known and potential benefits outweigh the known and potential risks, when the NPS 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 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 the NPS, 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 NPS, 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 NPS may be effective in preventing HCP exposure to pathogenic biological

[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).

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 for a maximum duration of use of one hour, of patients with suspected or confirmed diagnosis of COVID-19[8] and that the known and potential benefits of the NPS 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 NPS.[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 NPS 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 certain patient transport. When being used for transport of such patients, the NPS 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 NPS. The total duration of transport and non-transport use is limited to one hour.

This product should be removed if it impedes the ability to care for a patient, the ability to perform a medical procedure, or the communication between the HCP and the patient.

The NPS is not authorized for the following uses:

- During surgical procedures
- On patients needing emergent endotracheal intubation with severe hypoxemia or respiratory compromise
- On pregnant women in the 2nd or 3rd trimester
- On patients with morbid obesity
- On patients with anticipated or known history of difficult airway
- On patients with severe claustrophobia and/or confined space anxiety
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On patients with communication disorders that might interfere with clinical care
- On children under 45 pounds
- On bariatric patients
- On patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure

[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] Refer to footnote 5.

- On patients requiring procedures that involve exceeding the maximum direct access slits or holes as stated in the Instructions for Use (IFU)
- In elderly care centers – it is only for use in a hospital environment
- In ambulance transport

Authorized Product

The NPS is a non-sterile, single-use, negative pressure, containment device made of a clear plastic (PVC sheet) chamber and is designed to cover a patient's head and neck without undue pressure on the patient's neck. The NPS is comprised of and assembled from an enclosure, frame rods and hub, and the kit of accessories (suction tube connector, in-line bacterial/viral filter, and suction tubing). The NPS has arm sleeves to allow for isolated patient access, an access portal, two connecting ports, and airlocks to facilitate procedures and to transfer objects in and out of the NPS chamber. The negative pressure environment is generated within the NPS via a vacuum source: (portable suction unit for transport use) with a HEPA filter or healthcare facility wall suction system (bedside), both of which evacuate the vacuumed air safely to the outside environment. The NPS can be attached to a standard hospital bed or gurney. The zippered access portal allows access to the patient and may also be closed and sealed to facilitate patient isolation. The enclosure is coupled to a healthcare-facility provided 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. After use, the NPS should be disposed of. The maximum duration of use of the NPS is one hour.

Use of the NPS requires the following products which are not included:

- Adhesive tape;
- Wall-mounted vacuum or portable vacuum pump with in-line HEPA filter capable of 30 liters per minute flow rate, and with a pressure regulator reading at least 200 mm Hg;
- Portable or wall-mounted patient oxygen source;
- $EtCO_2$ line;
- Oxygen mask; and
- Nasal cannula.

The above described NPS is authorized to be accompanied with the "Negative Pressure SteriDome (NPS): Instructions for Healthcare Facilities and Providers" (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 Negative Pressure SteriDome
- Fact Sheet for Patients: Emergency Use of the Negative Pressure SteriDome

The above described product, when accompanied with the "Negative Pressure SteriDome (NPS): Instructions for Healthcare Facilities and Providers" 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 NPS 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 NPS 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 NPS, 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 NPS 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 NPS 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:

Breegi Scientific, Inc., as Sponsor of Authorized Product ("hereafter Breegi Scientific")

A. Breegi Scientific may request changes to this EUA for NPS,[11] including changes to the

[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

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

D. Breegi Scientific must notify FDA of any authorized distributor(s)[12] of the NPS, 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.

Breegi Scientific and any Authorized Distributor(s)

E. Breegi Scientific and authorized distributors must distribute the authorized NPS with the authorized labeling only to healthcare facilities with HCPs who are adequately equipped, trained, and capable of using the NPS.

F. Breegi Scientific and authorized distributors must make the authorized labeling available on their websites.

G. Authorized distributors must make Breegi Scientific aware of any adverse events of which they become aware.

H. Through a process of inventory control, Breegi Scientific and authorized distributors must maintain records of the healthcare facilities to which they distribute the NPS and the number of products they distribute.

I. Breegi Scientific 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.

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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] Breegi Scientific is currently the sole distributor of the NPS. "Authorized Distributor(s)" are identified by the sponsor in an EUA submission as an entity allowed to distribute the device.

Breegi Scientific, any Authorized Distributor(s), and Healthcare Facilities

J. Breegi Scientific, 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 NPS 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 NPS must make Breegi Scientific 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 NPS.

N. Healthcare facilities must maintain records of the NPS usage.

Conditions Related to Printed Materials, Advertising and Promotion

O. All descriptive printed matter, advertising, and promotional materials relating to the use of the NPS 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 NPS 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 NPS shall state that:

- The NPS 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 NPS 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