June 13, 2020

Erick Knezek, PE
Oceanetics, Inc.
520 Ridgely Avenue
Annapolis, MD 21401

Dear Mr. Knezek:

This letter is in response to your request on behalf of Oceanetics, Inc., that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the Negative-pressure Respiratory System with Advanced Ventilation Return[1] (hereafter "NRSAVR-100") 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, or when performing medical procedures[3], or during transport[4] of such patients during the COVID-19 pandemic.

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.[5] Pursuant to section 564 of the Act, and on the basis of such determination,

[1] The NRSAVR-100 is a negative pressure, clear, rigid chamber which attaches to standard hospital or surgical beds and is placed around the head, neck, and shoulders of the patient. Access holes, sealed by rubber shrouds, are built into the chamber and allow for isolated patient access. The negative pressure environment is generated via a portable suction or negative pressure pumps equipped with in-line HEPA filters suction device with an in-line filter or via the wall-mounted suction. The NRSAVR-100 is not intended to replace the need for PPE.

[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 NRSAVR-100 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).

[4] Authorized use of the NRSAVR-100 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, and the patient should always have supplemental oxygen during use of the NRSAVR-100.

[5] 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).

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.[6]

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 NRSAVR-100 would allow 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). Based on FDA's review of literature data and bench performance testing to test leaks and aerosol evacuation, FDA has concluded that the NRSAVR-100 may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE 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 NRSAVR-100, 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 NRSAVR-100, 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 NRSAVR-100 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 NRSAVR-100 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 NRSAVR-100.[7]

II. Scope of Authorization

[6] 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).

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

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 NRSAVR-100 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), 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 NRSAVR-100 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 NRSAVR-100.

The NRSAVR-100 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 NRSAVR-100

The NRSAVR-100 is authorized for use by HCP as an extra layer of barrier protection to prevent HCP exposure to pathogenic biological airborne particulates; it is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

The NRSAVR-100 is a negative pressure, clear, rigid chamber that attaches to standard hospital or surgical beds and is placed around the head, neck, and shoulders of the patient. Access holes, sealed by rubber shrouds, are built into the chamber allow for isolated patient access. The negative pressure environment is generated via a portable suction or negative pressure pump equipped with an in-line high-efficiency particulate air (HEPA) filter or via the healthcare facility wall-mounted suction.

The NRSAVR-100 is comprised of and assembled from Base Form Assembly (including clear, rigid side walls, hinges, screws, corner stiffeners, strap down hooks, handles, spring clamps, T-handles and seam sealant), one rubber Body Shroud, one interior body shroud plate, and six of each exterior arm shroud plates, interior flap plates, exterior arm shrouds, and interior flaps. All components of the NRSAVR-100 are intended to be reusable and must be cleaned and disinfected with a hospital-approved, EPA-registered isopropyl alcohol-based disinfectant. The NRSAVR-100 must be assembled, disassembled, and disinfected according to the "Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection of the NRSAVR-100 Device."

The NRSAVR-100 requires the following components that are not included as part of the NRSAVR-100 system:

- Portable suction or negative pressure pump with an in-line HEPA filter or healthcare facility wall-mounted suction; and
- Portable or wall-mounted medical air or oxygen.

The NRSAVR-100 is authorized for use as described in the Scope of Authorization (Section II). To transport patients on ventilators, all valves and ports are closed. To transport patients who are not on ventilators, the NRSAVR-100 maintains negative pressure via portable self-contained, suction or negative pressure pumps equipped with HEPA 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 NRSAVR-100.

The above described NRSAVR-100, is authorized to be accompanied with the "Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection of the NRSAVR-100 Device," and "Instructions for Healthcare Personnel: Use of the NRSAVR-100 Device" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), 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 Respiratory System with Advanced Ventilation Return (NRSAVR-100)
- Fact Sheet for Patients: Emergency Use of the Negative-pressure Respiratory System with Advanced Ventilation Return (NRSAVR-100)

The above described product, when accompanied with the Instructions for Healthcare Facilities and Instructions for Healthcare Personnel (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 NRSAVR-100 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 NRSAVR-100 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 NRSAVR-100, 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 NRSAVR-100 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 NRSAVR-100 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:

Oceanetics, Inc., as Sponsor of Authorized Product

A. Oceanetics, Inc., will make the NRSAVR-100 available with authorized labeling. Oceanetics, Inc., may request changes to the authorized labeling. Such changes require review and concurrence from Office of Health Technology 4 (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

B. Oceanetics, Inc., may request changes to the Scope of Authorization (Section II in this letter) of the authorized NRSAVR-100. Such requests will be made by Oceanetics, Inc., in consultation with OHT4/OPEQ/CDRH and require 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. Oceanetics, Inc., may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT4/OPEQ/CDRH.

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

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

F. Oceanetics, Inc., will notify FDA of any authorized distributor(s)[8] of the NRSAVR-100, 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.

Oceanetics, Inc. and any Authorized Distributor(s)

G. Oceanetics, Inc., and authorized distributors will distribute the authorized NRSAVR-100 with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the NRSAVR-100.

H. Oceanetics, Inc., and authorized distributors will make authorized labeling available on their websites.

I. Authorized distributors will make Oceanetics, Inc., aware of any adverse events of which they become aware.

J. Through a process of inventory control, Oceanetics, Inc., and authorized distributors will maintain records of the healthcare facilities to which they distribute the NRSAVR-100 and the number of each product they distribute.

K. Oceanetics, 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.

Oceanetics, Inc., any Authorized Distributor(s), and Healthcare Facilities

L. Oceanetics, Inc., 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 NRSAVR-100 must make available to patients the accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet.

N. Healthcare facilities using the NRSAVR-100 must make Oceanetics, Inc., and FDA aware of any adverse events under 21 CFR Part 803.

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

O. Healthcare facilities will ensure HCP are adequately equipped, trained, capable to use the NRSAVR-100, 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 NRSAVR-100, 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 NRSAVR-100, may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.

R. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized NRSAVR-100 shall clearly and conspicuously state that:

- The NRSAVR-100 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, or when performing medical procedures or during transport of such patients during the COVID-19 pandemic;

- The NRSAVR-100 has been authorized for emergency use by FDA under an EUA; and,

- The NRSAVR-100 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