August 20, 2020

Mr. Tony Eisenhut
NovaSterilis, Inc.
3109 N. Triphammer Rd.
Lansing, NY 14882

Dear Mr. Eisenhut:

This letter is in response to your[1] request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of your product[2] for use in decontaminating compatible N95 respirators[3] for single-user reuse[4] by healthcare personnel (HCP)[5] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of face-filtering respirators (FFRs) resulting from the Coronavirus Disease 2019 (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.[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]

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[1] For ease of reference, this letter will use the term "you" and related terms to refer to NovaSterilis, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the Nova2200 using the NovaClean decontamination process.
[3] For purposes of this EUA, "compatible N95 respirators" are limited to the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators.
[4] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination.
[5] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).
[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).

Your product has not been previously cleared or approved by FDA for any indication. In addition, there are no FDA approved or cleared devices for decontaminating compatible N95 respirators, which are needed for use by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. In evaluating this EUA, FDA reviewed the totality of scientific evidence available, which includes the history of your product's safe use as a sterilizer for tissue products; performance data for decontamination of compatible N95 respirators, such as viricidal testing, sporicidal testing, worst-case challenge; residual peracetic acid testing; and compatible N95 respirator use and fit testing, including strap mechanical strength testing, qualitative and quantitative fit testing, particle filtration efficacy testing, and inhalation and exhalation testing.

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 Nova2200 using the NovaClean decontamination process, 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 Nova2200 using the NovaClean decontamination process (hereafter referred to as "Nova2200"), 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 Nova2200 may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Nova2200 for decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic.[8,9]

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

[9] There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of N95 respirators, HCP may need to treat patients without personal protective equipment (PPE) or use a bandana or other less effective masks unless single-use N95 respirators can be decontaminated for reuse. Providing a method for decontaminating compatible N95 respirators reduces stress on the supply chain and helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with FFRs is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

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 Nova2200, for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of one (1) decontamination cycle per respirator, for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Authorized Nova2200

The Nova2200 consists of the Nova2200 equipment platform, a chemical additive (NovaKill), supercritical carbon dioxide, and a software-controlled decontamination cycle, which are all required to perform the NovaClean decontamination process. The Nova2200 requires a footprint of 46”x 24”x70” space within the healthcare facility and is operational in a room with at least two (2) air changes per hour.

Prior to decontamination, compatible N95 respirators are packaged in gas permeable packaging (Tyvek pouch, referred to as a NovaPouch). Two NovaPouches, each containing 25 compatible N95 respirators, are authorized to be decontaminated per cycle in the Nova2200. 3M Attest 1295 Biological Indicators must be placed on the outside of one of the NovaPouches so that the Biological Indicators can be used to verify successful decontamination.

When exposed to relatively low pressures and temperatures in the Nova2200, liquid carbon dioxide (CO_2) that is added to the system transitions to a supercritical state (above 1099 psi, 31.1°C), and acts as a carrier for the NovaKill additive, a chemical additive containing a mixture of peracetic acid (PAA) and hydrogen peroxide. This supercritical state allows for penetration of materials by the supercritical CO_2/NovaKill mixture, which acts to inactivate spores and viruses through membrane damage, alteration of fatty acids, and inactivation of ion transport proteins and key metabolic enzymes. Once the temperature and pressure reach the appropriate setpoints (35 °C and 1450 psi) while CO_2 is pumped into the Nova2200, the cycle is held for 90 minutes, after which the Nova2200 vessel exhausts the CO_2 to reduce the pressure. The Nova2200 monitors the specific parameters for decontamination (temperature, pressure, stir speed) and provides a printout of the parameters at the end of the cycle, which notes if the decontamination run passed or failed the specific parameters needed for decontamination. In addition, 3M Attest Biological Indicators will be used in every decontamination cycle to demonstrate the effectiveness of the decontamination cycle.

Nova2200 is authorized for use with the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators. These N95 respirators contain polypropylene/polyester-based materials and are authorized to be decontaminated using the Nova2200 through one (1) decontamination cycle. Nova2200 is not authorized for use with any other N95 respirator models.

The above described product is authorized to be accompanied with the following product-specific information (that will be made available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-

devices/decontamination-systems-personal-protective-equipment-euas) pertaining to emergency use, and is required to be made available to HCP and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Preparation of 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for Decontamination Using the Nova2200 with NovaClean decontamination process;

- Instructions for Healthcare Facilities: Decontamination of 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators Using the Nova2200 with NovaClean decontamination process; and

- Instructions for Decontamination Personnel: Nova2200 Equipment Platform for NovaClean decontamination process.

In addition, following decontamination, compatible N95 respirators decontaminated by the Nova2200 must be accompanied by the following labeling, developed by NovaSterilis, Inc., upon return of the respirators to HCP:

- Fact Sheet for Healthcare Personnel: Nova2200 for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, and Instructions for Decontamination Personnel are collectively referred to as "authorized labeling." The above described product, when accompanied with the described labeling is authorized to be distributed to 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 Nova2200, when used and labeled consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such 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 Nova2200 may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic, when used consistently with the Scope of Authorization (Section II) of this letter, 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 of this letter, and concludes that the Nova2200 (as described in the Scope of Authorization (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the Nova2200 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, Nova2200 is authorized for emergency use, as described in the Scope of Authorization (Section II).

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 practices 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 Part 820.

IV. Conditions of Authorization

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

NovaSterilis, Inc.

A. NovaSterilis, Inc. must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions), as well as those described in Section II of this letter, the Scope of Authorization.

B. NovaSterilis, Inc. must provide to all healthcare facility customers the authorized labeling before the decontamination process begins.

C. NovaSterilis, Inc. must notify all healthcare facility customers about the conditions of this authorization applicable to healthcare facilities before the decontamination process begins.

D. NovaSterilis, Inc. may make changes to the process, procedures, and/or labeling for the authorized product, upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery (DHT4B)/Office of Health Technology 4: Office of Surgical and Infection Control Devices (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

E. NovaSterilis, Inc. may make changes to the scope of this EUA, upon request and subject to review and concurrence of the DHT4B/OHT4/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of Chief Scientist (OCS)/Office of the Commissioner (OC).

F. NovaSterilis, Inc. must submit (a) material compatibility data, (b) decontamination validation data, (c) filtration data, (d) residual testing, (e) fit data, and (f) stability testing for FDA review

in order to revise the scope of this EUA for any of the following: i) Inclusion of additional types/models of N95 respirators; ii) Inclusion of additional NovaSterilis sterilizer models or decontamination cycles; iii) Increase in the number of decontamination cycles per compatible N95 respirator; or iv) Any change to the decontamination process or additive.

G. NovaSterilis, Inc. must submit data related to the stability studies on the NovaKill additive to FDA, when available.

H. Use of the Nova2200 on other types of personal protective equipment is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.

I. NovaSterilis, Inc. will have a process in place to report adverse events of which they become aware to FDA related to the Nova2200 and compatible N95 respirators that have undergone decontamination using the Nova2200 ("the decontaminated, compatible N95 respirators") in accordance with 21 CFR Part 803. This includes reports from healthcare facilities concerning infection or potential infection of personnel involved in the use of the Nova2200 and users of the decontaminated, compatible N95 respirators.

J. NovaSterilis, Inc. will have a process in place to collect information on the performance of Nova2200, including information regarding degradation of decontaminated, compatible N95 respirators, and evaluate this information to determine if adverse event reporting in accordance with 21 CFR Part 803 is warranted.

K. NovaSterilis, Inc. 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.

L. NovaSterilis, Inc. is 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.

M. NovaSterilis, Inc. will ensure that healthcare facility personnel, designated as decontamination personnel, are adequately trained in the use of the Nova2200, as described in Section II of this letter, and shall maintain records of such training.

N. NovaSterilis, Inc. will install and confirm the operation of the Nova2200 upon receipt at a healthcare facility. NovaSterilis, Inc. will also perform monthly maintenance visits to ensure the continued operation of the Nova2200.

Healthcare Facilities

O. Healthcare facilities shall notify NovaSterilis, Inc. when they intend to use the Nova2200 for the emergency use, consistent with Section II of this letter.

P. Healthcare facilities shall make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Fact Sheet for Healthcare Personnel and Instructions for Healthcare Personnel that is required to be provided by NovaSterilis, Inc.

Q. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the Nova2200 and the decontaminated, compatible N95 respirators in accordance with 21 CFR Part 803. This includes monitoring personnel using the Nova2200 and HCP using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections.

R. Healthcare facilities using the decontaminated, compatible N95 respirators must inspect the decontaminated, compatible N95 respirators. Any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator shall promptly be reported to NovaSterilis, Inc. After contacting NovaSterilis and providing the requested information, the healthcare facility must quarantine the N95 respirator until instructed by NovaSterilis, Inc. to dispose of it. During the monthly maintenance visits, NovaSterilis staff may collect quarantined N95 respirators for further investigation.

S. Healthcare facilities must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of one (1) decontamination cycle per compatible N95 respirator. Healthcare facilities must review the printout report from the Nova2200 and use 3M Attest Biological Indicators to confirm decontamination cycles were effectively conducted. Healthcare facilities must ensure that the decontaminated, compatible N95 respirator is returned to its previous user. Healthcare facilities shall maintain documentation for use of Nova2200 consistent with current healthcare facility protocols.

Conditions Related to Printed Materials, Advertising and Promotion

T. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product 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.

U. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product may represent or suggest that such products are safe or effective for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.

V. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product clearly and conspicuously shall state that:

- Nova2200 has neither been cleared or approved for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;

- Nova2200 has been authorized by FDA under an EUA;

- Nova2200 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 authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization 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