U.S. FOOD & DRUG ADMINISTRATION

February 12, 2021

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

Re: Revocation of EUA201745

Dear Mr. Eisenhut:

This letter is in response to NovaSterilis, Inc.'s letter dated November 24, 2020, informing FDA that it is withdrawing the Emergency Use Authorization (EUA201745) for the Nova2200 using the NovaClean decontamination process (hereafter referred to as "Nova2200") issued on August 20, 2020. We interpret this letter to mean that NovaSterilis, Inc. will no longer make the Nova2200 available for the authorized emergency use. The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). FDA hereby notifies NovaSterilis, Inc. of the revocation of the EUA201745 for the Nova2200 pursuant to section 564(g)(2)(B) of the Act and section 564(g)(2)(C) of the Act.

On August 20, 2020, FDA authorized the emergency use of the Nova2200 for use in decontaminating compatible N95 respirators[1] 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[2] by healthcare personnel (HCP)[3] to prevent exposure to pathogenic biological airborne particulates during the Coronavirus Disease 2019 (COVID-19) pandemic. Based on the totality of scientific evidence available at the time, FDA concluded that it was reasonable to believe that the Nova2200 may be effective at

[1] For purposes of this EUA, "compatible N95 respirators" are limited to the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators.

[2] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination.

[3] 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).

decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of filtering facepiece respirators (FFRs) resulting from the COVID-19 pandemic, and that the known and potential benefits of Nova2200 outweigh the known and potential risks of its use.

Since then, FDA has become aware of new data and evidence suggesting that 3M Model 1860 and Halyard FLUIDSHIELD N95 respirators, the only compatible N95 respirators identified in this EUA, may not maintain adequate fit and filtration efficiency following one (1) decontamination cycle using the Nova2200. Specifically, FDA has reviewed new data indicating that 3M Model 1860 N95 respirators may not maintain adequate fit and filtration efficiency after undergoing one (1) decontamination cycle using the Nova2200.[4] Additionally, FDA has become aware of preliminary evidence suggesting that duckbill N95 respirators, such as Halyard FLUIDSHIELD N95 respirators, may not maintain adequate fit to support reuse.[5]

As such, FDA can no longer conclude that it is reasonable to believe that Nova2200 may be effective in preventing HCP exposure to pathogenic biological airborne particulates. Additionally, based on this new information, FDA can no longer conclude that the known and potential benefits of the Nova2200 outweigh the known and potential risks of its use; thus, the criteria under section 564(c) of the Act for issuance of an EUA are no longer met. Moreover, based on the same information, and the potential risks to HCP from using decontaminated respirators with reduced fit and filtration performance, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes EUA201745 for the Nova2200, pursuant to section 564(g)(2)(B) and section 564(g)(2)(C) of the Act. As of the date of this letter, the Nova2200 is no longer authorized for emergency use by FDA.

FDA encourages NovaSterilis Inc. to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

[4] Detailed test results can be found in the publicly-available test report at https://www.cdc.gov/niosh/npptl/respirators/testing/results/Decon_039_Redacted-508.pdf.

[5] Degesys NF, Wang RC, Kwan E, Fahimi J, Noble JA, Raven MC. Correlation Between N95 Extended Use and Reuse and Fit Failure in an Emergency Department. JAMA. 2020;324(1):94–96. doi:10.1001/jama.2020.9843.