June 6, 2020

Monte Brown, MD
Vice President of Administration and Secretary
Duke University Health System
107B Davison Building
Durham, NC 27710

Dear Dr. Monte Brown:

On May 7, 2020, based on your[1] request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of your product[2] for use in decontaminating compatible N95 respirators[3] for multiple-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 June 6, 2020, in response to public health and safety concerns about the appropriateness of decontaminating certain respirators, FDA is reissuing the May 7, 2020 letter in order to revise

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Duke University Health System.
[2] For ease of reference, this letter will use the term "your product" or "Duke Decontamination System" to refer to the Duke Decontamination System for Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor.
[3] In the May 7, 2020 letter, "compatible N95 respirators" were defined as any N95 or N95-equivalent respirators that do not contain cellulose-based materials. The May 7, 2020 letter also defined "N95-equivalent respirators" as respirators identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators and identified in Appendix A of the EUA for Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
[4] Multiple-user reuse means that healthcare personnel may receive a different respirator following decontamination than the one they had previously used. In the May 7, 2020 letter, this was not explicitly stated as "multiple-user" reuse. FDA has revised this to be clearer in the letter and notes that this clarifying edit does not change the Scope of Authorization.
[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).

which compatible N95 respirators[6] this decontamination system is authorized to decontaminate. As described in the revised Scope of Authorization (Section II), the Duke Decontamination System is no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA or authorized respirators that have exhalation valves. Having concluded that revising the May 7, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(g)(2)(C)), FDA is reissuing the May 7, 2020 letter in its entirety with the revisions[7] incorporated.

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.[8] 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.[9]

Your product has not been previously cleared or approved by FDA for any indication. Additionally, there are no FDA approved or cleared devices for decontaminating compatible N95 respirators to help address availability concerns of compatible N95 respirators for HCP use during the COVID-19 emergency. FDA reviewed the totality of scientific evidence available for this EUA, including: scientific literature characterizing the effect of vaporous hydrogen peroxide (VHP) on compatible N95 respirators contaminated with viruses and the most difficult to inactivate bacterial spores; the effect of VHP on multiple types of viruses and the most difficult to inactivate bacterial spores; filtration efficiency and breathability testing following multiple decontamination cycles; historical biological indicator inactivation data for your product; testing regarding hydrogen peroxide residuals after decontamination; and fit testing for decontaminated, compatible N95 respirators.

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 Duke Decontamination System, as

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[6] For the purposes of this revised EUA, "compatible N95 respirators" are non-cellulose containing respirators that do not have an exhalation valve that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[7] The revisions to the May 7, 2020 letter include the following: (1) the Scope of Authorization has been revised such that this decontamination system is no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA or authorized respirators that have an exhalation valve; and (2) FDA has made some clarifications to the Conditions of Authorization (Section IV).

[8] 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).

[9] 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).

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 Duke Decontamination System, 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 Duke Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-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 Duke Decontamination System for decontamination of compatible N95 respirators to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, during FFR shortages during the COVID-19 pandemic.[10,11]

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 Duke Decontamination System, 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 10 decontamination cycles per respirator, for multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Authorized Duke Decontamination System

The Duke Decontamination System is a self-contained decontamination product that uses vapor phase hydrogen peroxide (VHP) for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic organisms.

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

[11] 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.

N95 respirators containing cellulose-based materials and respirators that have exhalation valves are incompatible with the Duke Decontamination System.

The Duke Decontamination System is a combination of Bioquell VHP systems, Drager X-am 5100, and PortaSens II/PortaSens III hydrogen peroxide monitoring equipment, and five rooms within the Duke University Health System, that are specifically designated for use with each Bioquell VHP system.

- The Duke Regional Biocontainment Lab (RBL) is used in conjunction with the Bioquell Clarus C system; the RBL contains its own exhaust system to remove residual hydrogen peroxide from the room.
- The other four rooms are used in conjunction with Bioquell Z-2 and ProteQ systems, which have integrated aeration units to process room air to remove hydrogen peroxide. Each room contains a number of 18" x 36" shelves, dependent on the size of the room, for placing individual compatible N95 respirators for subsequent decontamination.
- Drager X-am 5100 H_2O_2 global sensors are used to monitor hydrogen peroxide concentrations inside the room; PortaSens II and III gas leak detectors are also used to confirm H_2O_2 levels.

Depending on the room, with larger rooms generally accommodating more shelves, the number of compatible N95 respirators that can be placed in this manner ranges as shown in Table 1:

Table 1

Decontamination chamber name	**VHP generator(s)**	**Compatible N95 Respirators per cycle**
RBL	Bioquell Clarus C, Bioquell Z-2	1,260
Duke University Hospital (DUH) 1	Bioquell ProteQ, Bioquell Z-2	1,323
DUH 2	Bioquell ProteQ, Bioquell Z-2	1,764
Duke Regional Hospital (DRH)	Bioquell ProteQ, Bioquell Z-2	1,470
Duke Raleigh Hospital (DRaH)	Bioquell ProteQ, Bioquell Z-2	882

Each decontamination cycle in the Duke Decontamination System consists of injecting VHP into the decontamination room until achieving a saturated atmosphere indicated by micro condensation; maintaining the VHP exposure for a 20-minute dwell time; and allowing the VHP to off gas to a level below 1 ppm prior to post decontamination processing. A minimum of one biological indicator is dispersed throughout the system to indicate a successful decontamination cycle. This decontamination system enables the multiple-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not reused or decontaminated.

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/emergency-situations-medical-devices/emergency-use-authorizations) pertaining to emergency use, and is required to be made available to healthcare providers and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by Duke Health Using the Duke Decontamination System with Hydrogen Peroxide Vapor;
- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by Duke Health Using the Duke Decontamination System with Hydrogen Peroxide Vapor; and
- Instructions for Duke Decontamination Facility: Decontamination of Compatible N95 Respirators with Hydrogen Peroxide Vapor.

In addition, following decontamination, compatible N95 respirators decontaminated by the Duke Decontamination System must be accompanied by the following labeling, developed by Duke University Health System, upon return of the respirators to HCP:

- Fact Sheet for Healthcare Personnel: Duke Decontamination System for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, and Instructions for Duke Decontamination Facility 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 Duke Decontamination System, 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 Duke Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-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 Duke Decontamination System (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 Duke Decontamination System 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 Duke Decontamination System 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 sections 520(f)(1). 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:

Duke University Health System ("Duke")

A. Duke 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. Duke 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 Devices/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

C. Duke may make changes to the scope of this EUA, upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery Devices/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of Chief Scientist (OCS)/Office of the Commissioner (OC).

D. Use of the Duke Decontamination System 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.

E. Duke will have a process in place to report adverse events of which they become aware to FDA related to the Duke Decontamination System and compatible N95 respirators that have undergone decontamination using the Duke Decontamination System ("the decontaminated, compatible N95 respirators") in accordance with 21 CFR Part 803. This includes monitoring personnel using the Duke Decontamination System 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.

F. H. Duke will have a process in place to collect information on the performance of the Duke Decontamination System, 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.

G. Duke 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.

H. Duke 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.

I. Duke shall make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Face Sheet for Healthcare Personnel and Instructions for Healthcare Personnel that are required to be provided.

J. Duke personnel using the decontaminated, compatible N95 respirators must inspect the decontaminated, compatible N95 respirators following the decontamination process using the Duke Decontamination System. Duke shall maintain records regarding discoloration or other signs of degradation of a decontaminated, compatible N95 respirator, and the healthcare facility must discard the respirator.

K. Duke must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of 10 decontamination cycles per compatible N95 respirator. Duke shall maintain documentation for use of the Duke Decontamination System consistent with current healthcare facility protocols.

L. The Duke Decontamination System shall only be operated by Duke University Health System in the Duke RBL, DUH 1, DUH 2, DRH, and DRaH decontamination chambers, and shall not be distributed to third parties.

M. Duke shall not distribute decontaminated, compatible N95 respirators to any other healthcare facility.

N. Duke is authorized to decontaminate up to 1,260, 1,323, 1,764, 1,470, and 882 compatible N95 respirators per chamber load in the Duke RBL, DUH 1, DUH 2, DRH, and DRaH decontamination chambers, respectively, based on chamber dimensions and geometry for supporting shelving units, consistent with data provided to FDA. Duke 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.

O. Duke is authorized to add additional decontamination chambers on the condition that Duke shall provide in advance to FDA information on validation data to demonstrate that additional chambers have met the following critical parameters: 1) minimum concentration of 480 ppm and minimum gas dwell time of 20 minutes, 2) 6-log reduction in biological

indicator or equivalently validated chemical indicator, and 3) residual hydrogen peroxide below the permissible exposure limit of 1 ppm on the compatible N95 respirators.

P. Duke must use biological indicators and chemical indicators to confirm that decontamination cycles have been effectively conducted. Duke is authorized to release decontaminated, compatible N95 respirators by parametric release based on chemical indicators.

Q. Duke is authorized to decontaminate compatible N95 respirators for up to a maximum of 10 decontamination cycles, consistent with the data provided to FDA. Duke is authorized to increase the maximum number of decontamination cycles up to 20 decontamination cycles per compatible N95 respirator on the condition that Duke provide in advance to FDA information regarding strap integrity testing as demonstrated by visual inspection and respirator fit testing.

Conditions Related to Advertising and Promotion

R. 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.

S. 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 multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.

T. Except for the authorized labeling described in Section II, all descriptive printed matter, including advertising and promotional materials, relating to the use of your product clearly and conspicuously shall state that:

- the Duke Decontamination System has neither been cleared or approved for the decontamination of compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;
- the Duke Decontamination System has been authorized by FDA under an EUA;
- the Duke Decontamination System is 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 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