

This guidance is intended to remain in effect until November 7, 2023, unless superseded by a revised final guidance before that date. For further information, refer to 88 FR 15417, March 13, 2023, available at <https://www.federalregister.gov/d/2023-05094>.

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Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

March 2020



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 C.F.R. 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," available at COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders (<https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>) and the FDA webpage titled "Search for FDA Guidance Documents" available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 20019 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-SterilizersDisinfectantsPurifiers@fda.hhs.gov.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability and capability of sterilizers, disinfectant devices, and air purifiers during this public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

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In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

SARS-CoV-2 has demonstrated the capability to spread rapidly, leading to significant impacts on health care systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. To respond effectively to the COVID-19 outbreak, appropriate clinical management and infection control in conjunction with implementation of community mitigation efforts are critical.

FDA believes the policy set forth in this guidance will help address these urgent public health concerns by helping to increase the availability of sterilizers, disinfectant devices, and air purifiers during this public health emergency. Increased access to these devices may facilitate rapid turnaround of sterilized or disinfected medical equipment and reduce the risk of viral exposure for patients and health care providers to SARS-CoV-2.

III. Scope

The enforcement policies described in this guidance apply to the following devices and their accessories during the COVID-19 public health emergency. This enforcement policy applies to devices that already have FDA marketing authorization, as well as devices that are not currently marketed but would fall under one of the classification regulations set forth below.

A. Sterilizers

Sterilizers for use in a health care facility are medical devices that are regulated by FDA and are intended to render medical devices sterile (i.e., free from viable microorganisms). Sterilizers vary in both construction (ranging from small table-top sterilizers to large sterilizers intended for large loads) and modality (e.g., steam, ethylene oxide, vaporized hydrogen peroxide, etc.). FDA evaluates and authorizes sterilizers for marketing with specific cycle parameters intended for specific loads and with their own sterilization accessories (e.g., biological indicators, chemical indicators, wraps, trays,

¹ Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

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etc.). The classification regulations and associated product codes for sterilizers are listed in Table 1:

Table 1 – Sterilizers

Classification Regulation	Device Type	Product Code³	Device Classification
21 CFR 872.6730	Endodontic dry heat sterilizer	KOK	III
21 CFR 872.6730	Glass bead sterilizer	ECC	III
21 CFR 880.6100	Ethylene-oxide (EO) gas aerator cabinet	FLI	II
21 CFR 880.6860	Chemical Sterilizer	MLR	II
21 CFR 880.6860	Two or more sterilant sterilizer	PJJ	II
21 CFR 880.6860	EO gas sterilizer	FLF	II
21 CFR 880.6870	Dry heat sterilizer	KMH	II
21 CFR 880.6880	Steam sterilizer	FLE	II
21 CFR 880.6880	Sterilizer automated loading system	PEC	II

B. Disinfectant Devices

Disinfectant devices are intended to kill pathogens and other kinds of microorganisms by chemical means or physical means. Disinfectant devices can kill most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. Disinfectant devices commonly used in health care settings include chemical/physical disinfectant devices and ultraviolet (UV) disinfectant devices.

(1) Chemical/Physical Disinfectant Devices

For the purposes of this guidance, FDA considers chemical/physical disinfectant devices to encompass chemical disinfectant solutions used to disinfect medical devices, as well as medical washer disinfectors or automated endoscope reprocessors (AERs) that utilize chemical disinfectant solutions or physical (e.g., thermal) processes to reprocess⁴ medical devices. The product codes and classification regulations for chemical/physical disinfectant devices, to which the policy in this guidance applies, are listed in Table 2:

Table 2 – Chemical/Physical Disinfectant Devices

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 876.1500	Cleaning accessories for endoscope	FEB	II
21 CFR 880.6885 ⁵	Medical devices sterilant	MED	II

³ For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

⁴ The term “reprocess” refers to validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. See FDA’s Guidance, “[Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

⁵ Subject to special controls.

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Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 880.6992 ⁶	Medical devices disinfectors	MEC	II (exempt from premarket review unless indicated for high level disinfection or for use on endoscopes and accessories)
21 CFR 880.6992 ⁷	Medical devices cleaners	MDZ	II
21 CFR 892.1570	High level disinfection reprocessing instrument for ultrasonic transducers, mist	OIJ	II
21 CFR 892.1570	High level disinfection reprocessing instrument for ultrasonic transducers, liquid	PSW	II

(2) Ultraviolet (UV) Disinfecting Devices

UV disinfecting devices are devices that use UVA or UVC light to produce a germicidal effect. They are intended to augment disinfection of health care environmental surfaces after manual cleaning has been performed. UV disinfecting devices include UV radiation chamber disinfection devices, which are regulated as Class II devices under 21 CFR 880.6600 (product code OSZ).⁸

C. Air Purifiers

Air purifying devices are intended for medical purposes to kill pathogens/microorganisms in the air by exposure to UV radiation or remove them through filtration. The classification regulations and associated product codes for air purifying devices, to which the policy in this guidance applies, are listed in Table 3:

Table 3 – Air Purifiers

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 880.5045	Medical recirculation air cleaner	FRF	II
21 CFR 880.6500	Medical UV air purifier	FRA	II

IV. Policy

In the context of the COVID-19 public health emergency, it is necessary to maintain an adequate

⁶ Subject to special controls.

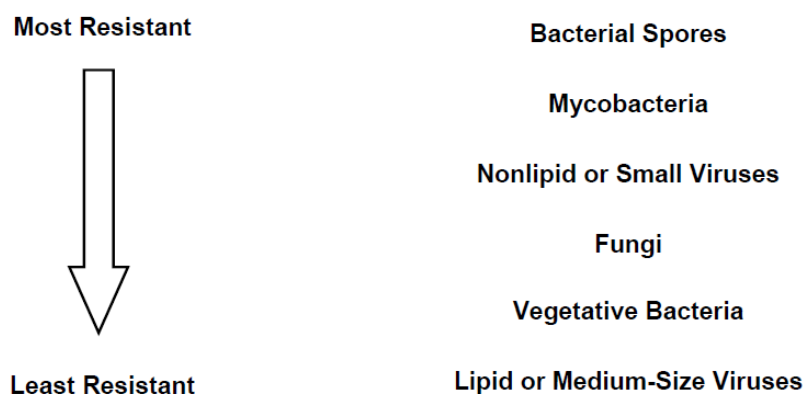
⁷ Subject to special controls.

⁸ Subject to special controls.

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supply of sterilizers, disinfectant devices, and air purifiers that can facilitate rapid turnaround of sterilized or disinfected medical equipment and that help reduce the risk of viral exposure for patients and health care providers to SARS-CoV-2. FDA believes that certain sterilizers, disinfectant devices, and air purifiers falling within the scope of this guidance (see Section III) may help reduce this risk of viral exposure based on our current understanding of these devices and SARS-CoV-2.

Coronaviruses are RNA viruses enveloped in a lipid bilayer.^{9,10} SARS-CoV-2 is a type of coronavirus. As depicted in Figure 1, lipid viruses are the least resistant microorganisms on the scale of descending order of resistance to germicidal chemicals.¹¹ Because sterilization processes render devices free from viable microorganisms including bacterial spores, and because disinfection kills most recognized pathogenic microorganisms, it can generally be inferred that sterilization and disinfection should minimize the viability of SARS-CoV-2 (as one of the least resistant microorganisms) on surfaces and in the air in confined spaces. Moreover, air purifiers can be designed to filter out virus-sized particles.



Modified from Favero, M.S. and Bond, W.W., Chemical Disinfection of Medical and Surgical Materials. In: Disinfection, Sterilization, and Preservation, 5th Ed Phila: Lippincott Williams & Wilkins 2001: 881-917.

Figure 1. Descending Order of Resistance of Microorganisms to Germicidal Chemicals.

In general, manufacturers of sterilizers, disinfectant devices, and air purifiers are required to submit a marketing application to FDA when seeking to market these devices. When these devices are previously approved or cleared, modifications to the indications or functionality of the devices would also generally require premarket authorization. However, to help ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19

⁹ Beniac, D., Andonov, A., Grudeski, E. et al. Architecture of the SARS coronavirus prefusion spike. Nat Struct Mol Biol 13, 751–752 (2006).

¹⁰ Fehr AR, Perlman S. Coronaviruses: an overview of their replication and pathogenesis. Methods Mol Biol. 1282:1–23 (2015).

¹¹ Please see FDA’s Guidance, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

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outbreak, during the declared public health emergency, FDA does not intend to object to limited modifications to the indications or functionality of FDA-cleared or FDA-approved sterilizers, disinfectant devices and air purifiers pertaining to a device's virucidal effectiveness against SARS-CoV-2, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81¹² or submission of a Premarket Approval Application (PMA) Supplement under section 515 of the FD&C Act and 21 CFR 814.39¹³, Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20. FDA believes such devices will not create such an undue risk where the performance and labeling elements in Sections IV.A and IV.B, respectively, are met. As an example, this would apply to a manufacturer that previously received 510(k) clearance for a steam sterilizer that is intended for sterilization of medical devices in health care settings, where the manufacturer would like to include a statement in the labeling that the device is effective in killing SARS-CoV-2 when used in accordance with the validated sterilization processes identified in the labeling.

In addition, during the declared public health emergency, FDA does not intend to object to the distribution and use of sterilizers, disinfectant devices, and air purifiers that are intended to be effective at killing the SARS-CoV-2 virus but do not already have FDA marketing authorization, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81 or submission of a PMA Supplement under section 515 of the FD&C Act and 21 CFR 814.39, Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20. FDA believes such devices will not create such an undue risk where the performance and labeling elements in Sections IV.A and IV.B, respectively, are met. As an example, this would apply to a manufacturer of a new medical air purifier that has not been approved or cleared and that is effective in filtering out dust particles and bacteria, where the manufacturer would like to modify the filter mesh size in order to filter out viruses, including the SARS-CoV-2 virus.

The enforcement policies set forth in this guidance do not apply to sterilizers, disinfectant devices, and air purifiers that are intended to prevent or reduce the risks of hospital acquired infections (HAI) or COVID-19.

A. Performance

This section gives recommendations regarding design, evaluation, and validation of performance relevant to the enforcement policies set forth above. FDA encourages firms to discuss any alternatives to these recommendations with FDA.

¹² For further guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to "Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>.

¹³ For further guidance on modifications that trigger the requirement that a manufacturer submit a PMA supplement to FDA, refer to "Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process>.

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For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm).¹⁴ For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices).”¹⁵

(1) Sterilizers

For the purposes of this guidance, FDA recommends any modifications, including changes to the indications or functionality, to sterilizers and their accessories be designed, evaluated and validated in accordance with FDA-recognized¹⁶ standards, including (as applicable):

- Steam Sterilizers
 - ANSI/AAMI ST8:2013 *Hospital Steam Sterilizers*
 - ANSI/AAMI ST55:2016 *Table-Top Steam Sterilizers*
 - ANSI/AAMI ST79:2019 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*.
- Dry Heat Sterilizers
 - AAMI ST50:2004 (R2018) *Dry Heat (Heated Air) Sterilizers*
 - ANSI/AAMI ST40:2004m (R2018) *Table-Top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Health Care Facilities*
- Ethylene Oxide Sterilizers
 - ANSI/AAMI ST24:1999 (R2018) *Automatic, General Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities, 3ed.*
 - ANSI/AAMI ST41:2008 (R2018) *Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness*
- Other Sterilizers
 - ANSI/AAMI/ISO 14937 *Sterilization of Health Care Products — General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices*
- Chemical Indicators
 - ANSI/AAMI/ISO 11140 – 1 *Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements*
- Sterile Packaging
 - ANSI/AAMI/ISO 11607-1 *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems*
 - ANSI/AAMI/ISO 11607-2 *Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes*

¹⁴ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

¹⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

¹⁶ For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database \(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm\)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm).

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- Rigid Sterilization Containers
 - ANSI/AAMI/ISO ST77:2013 *Containment Devices for Reusable Medical Device Sterilization*
- Biological Indicators
 - ANSI/AAMI/ISO 11138 *Sterilization of Health Care Products—Biological Indicators Series*
 - ANSI/AAMI/ISO 14161 *Sterilization of Health Care Products — Biological Indicators — Guidance for the Selection, Use and Interpretation of Results*

Manufacturers must document changes to their device in their device master record and change control records and make this information available to FDA, if requested, consistent with 21 CFR 820.30 and 21 CFR 820.180.

(2) Disinfectant devices

For the purposes of this guidance, FDA recommends any modifications to disinfectant devices be designed, evaluated and validated in accordance with FDA-recognized standards, including (as applicable):

- AAMI ST58:2013 (R2018) *Chemical Sterilization and High-Level Disinfection in Health Care Facilities*
- Association of Official Analytical Chemists (AOAC) 6.3.05:2013 *Official Method 966.04 Sporidical Activity of Disinfectants*
- AOAC 6.3.06:2012 *Official Method 965.12 Tuberculocidal Activity of Disinfectants*
- AOAC 6.3.02:2006 *Official Method 955.17 Fungicidal activity of Disinfectants Using Trichophyton Mentagrophytes*
- AOAC 6.2.01:2013 *Official Method 955.14, Testing Disinfectants Against Salmonella Choleraesuis, Use-Dilution Method*
- AOAC 6.2.04:2013 *Official Method 955.15, Testing Disinfectants Against Staphylococcus Aureus, Use-Dilution Method*
- AOAC 6.2.06:2013 *Official Method 964.02, Testing Disinfectants Against Pseudomonas Aeruginosa, Use-Dilution Method*

In addition, for the purposes of this guidance, FDA recommends that manufacturers of disinfectant devices evaluate whether the product meets the level of disinfection consistent with its intended use and labeling, when combined with typical cleaning/reprocessing practices.¹⁷ In doing so, FDA recommends the following, which are commonly used as part of the clearance or approval of disinfecting devices:

- a) For Low Level Disinfection:
 - Definition: A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.

¹⁷ See FDA's Guidance "[Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling)" available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

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- Recommendation for Performance: Demonstrate a 6-log reduction of each of the following typical vegetative organisms: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, and representatives of the *Klebsiella* and *Enterobacter* genus
- b) For Intermediate Level Disinfection:
 - Definition: A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores.
 - Recommendation for Performance: Demonstrate a 6-log reduction of each of the vegetative organisms and a 3-log reduction of an appropriate species of the genus *Mycobacterium*.
- c) For High Level Disinfection:
 - Definition: A lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.
 - Recommendation for Performance: Demonstrate a 6-log reduction of each of the vegetative organisms and a 6-log reduction of an appropriate species of the genus *Mycobacterium*. FDA recommends that performance also include potency testing, simulated use testing, and in-use testing to support the effectiveness of the device.¹⁸

If the device includes a UV lamp, FDA recommends that the manufacturer evaluate whether the product controls for time, UV radiation dose, and intensity of UV dose, and validates the cleaning and disinfection procedures.

If the device generates ozone, FDA recommends that the manufacturer evaluate whether the product is within the maximum acceptable level of ozone given in 21 CFR 801.415.

Manufacturers must document changes to their device in their device master record and change control records and make this information available to FDA, if requested, consistent with 21 CFR 820.30 and 21 CFR 820.180.

(3) Air Purifiers

For the purposes of this guidance, FDA recommends that manufacturers of air purifiers evaluate or perform the following:

- 1) Demonstration of a 4 log reduction (through a combination of capture or destruction) of claimed particulates.
- 2) If intended for use against bacteria, effectiveness against representative gram positive and gram negative species.
- 3) If intended for use related to SARS-CoV-2, effectiveness against a representative virus
- 4) If the device generates ozone, the maximum acceptable level of ozone per 21 CFR 801.415.
- 5) If intended for use in areas that have a sterile field or controlled air flow, a risk assessment to address turbulent air flow and/or potential site contamination.

¹⁸ For information regarding these tests, please see FDA's Guidance, "[Content and Format of Premarket Notification \[510\(k\)\] Submissions for Liquid Chemical Sterilants/High Level Disinfectants](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level)," <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level>.

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Manufacturers must document changes to their device in their device master record and change control records and make this information available to FDA, if requested, consistent with 21 CFR 820.30 and 21 CFR 820.180.

B. Labeling

In addition, FDA recommends that the devices described above include labeling that helps users better understand the device modifications, such as:¹⁹

- 1) A clear description of the available data on the device's new indications or functions related to SARS-CoV-2 or co-existing conditions, such as:
 - a) Device performance; and
 - b) Potential risks (e.g., risk of UV exposure)
- 2) A clear distinction delineating FDA-cleared or FDA-approved indications from those that are not FDA-cleared or FDA-approved. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.
- 3) For all disinfectant devices, a clear statement of the level of disinfection.
- 4) For UV disinfecting devices:
 - a) A caution that UV disinfection will reduce the number of pathogens on the device, but it will not eliminate them completely.
 - b) A statement that the device is an adjunct to currently existing reprocessing practices and not a replacement or modification to such practices.
 - c) A statement regarding the time, distance, and maximum area over which the device has been evaluated for effectiveness.
 - d) An appropriate UV hazard warning label.
 - e) Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed.
 - f) Procedures to follow if the UV lamp malfunctions or fails.
 - g) Description of the preparation of equipment or the room for disinfection
 - h) A statement that the equipment intended to be disinfected is UV compatible.
 - i) Identification of the UV dose.

C. Additional Helpful Resources

The following online resources may be helpful regarding FDA's policies on sterilization and disinfection:

Sterilization

- [Submission and Review of Sterility Information in Premarket Notification \(510\(k\)\) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff²⁰](#)
- [Guidance on Premarket Notification 510\(k\) for Sterilizers Intended for Use in Health](#)

¹⁹ For modifications to cleared devices that are subject to special controls relating to labeling, FDA believes that manufacturers meeting those special controls would also be consistent with the recommended labeling elements in Section IV.B.

²⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>

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Care Facilities²¹

- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff²²

Disinfection

- Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff²³
- Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities²⁴
- Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants - Guidance for Industry and FDA Reviewers²⁵
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff²⁶

²¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-premarket-notification-510k-sterilizers-intended-use-health-care-facilities>

²² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>

²³ <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/medical-washers-and-medical-washer-disinfectors-class-ii-special-controls-guidance-document-medical>

²⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-premarket-notification-510k-submissions-automated-endoscope-washers-washerdisinfectors-and>

²⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level>

²⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>