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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

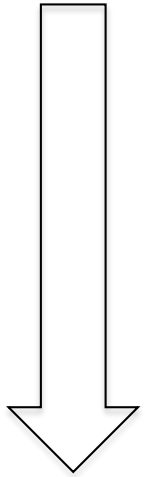
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

December 8, 2020

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

Descending Order of Resistance of Microorganisms to Germicidal Chemicals

Most Resistant



Least Resistant

Bacterial Spores

Mycobacteria

Nonlipid or Small Viruses

Fungi

Vegetative Bacteria

Lipid or Medium-Size Viruses

- Sterilization renders devices free from viable microorganisms.
- Disinfection kills most recognized pathogenic microorganisms.
- It can be inferred these should generally minimize the viability of SARS-CoV-2.
- Air purifiers can be designed to filter out virus-sized particles.
- During the declared public health emergency, the 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.

Enforcement Policy: Sterilizers

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

The 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-recognized standards including, as applicable, those listed in the guidance.

Enforcement Policy: Chemical/Physical Disinfectants

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 876.1500	Cleaning accessories for endoscope	FEB	Class II
21 CFR 880.6885	Medical devices sterilant	MED	Class II
21 CFR 880.6992	Medical devices disinfectors	MEC	Class II
21 CFR 880.6992	Medical devices cleaners	MDZ	Class II
21 CFR 892.1570	High level disinfection reprocessing instrument for ultrasonic transducers, mist	OUJ	Class II
21 CFR 892.1570	High level disinfection reprocessing instrument for ultrasonic transducers, liquid	PSW	Class II

- The FDA recommends any modifications to disinfectant devices be designed, evaluated and validated in accordance with FDA-recognized standards including, as applicable, those listed in the guidance.
- The 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.

Enforcement Policy: UV Disinfection Devices

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 880.6600	Ultraviolet (UV) radiation chamber disinfection device	OSZ	Class II

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

Enforcement Policy: Air Purifiers

The FDA recommends that manufacturers of air purifiers evaluate or perform the following:

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

- Demonstration of a **4 log reduction** (through a combination of capture or destruction) of claimed particulates.
  - 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.
- If intended for use against **bacteria**, effectiveness against representative gram positive and gram negative species.
- If intended for use related to **SARS-CoV-2**, effectiveness against a representative virus.
- If the device generates **ozone**, the maximum acceptable level of ozone per 21 CFR 801.415.
- 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.

Resources

- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease

- Submission and Review of Sterility Information in Premarket Notification (510(k)): Submissions for Devices Labeled as Sterile: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled

- 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

- Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants - Guidance for Industry and FDA Reviewers: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level

Questions?

Email:

CDRH-COVID19-SterilizersDisinfectantsPurifiers@fda.hhs.gov

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