FDA is committed to ensuring digital accessibility for people with disabilities. We are continually improving the user experience for everyone and applying the relevant accessibility standards. At the time of initial posting on **December 16, 2025**, the attached **FDA presentation** may not be fully accessible to users using assistive technology. A fully accessible version of the **FDA presentation** is in preparation and will be posted as soon as it is ready. We regret any inconvenience that this may cause our readers.

Please let us know if you encounter accessibility barriers by contacting **Evella Washington at: Evella.Washington@fda.hhs.gov**

Opening Remarks

RDML Raquel Peat, PhD, MPH, USPHS
Acting Director
Office of Health Technology 4: Office of Surgical and Infection Control Devices
U.S. Food & Drug Administration
Center for Devices and Radiological Health
General Hospital and Personal Use Devices Panel Meeting

Introduction & Background

Katharine Segars, Ph.D.
Office of Health Technology 4: Office of Surgical and Infection Control Devices
U.S. Food & Drug Administration
Center for Devices and Radiological Health
General Hospital and Personal Use Devices Panel Meeting

Key Topics

- Germicidal Ultraviolet Radiation (GUV) Introduction
- Medical Device Definition
- Regulatory History of GUV Medical Devices
- Panel Purpose
- References

Germicidal Ultraviolet Radiation

- Ultraviolet radiation
  - UV-A, UV-B, and UV-C
- Microbicidal properties
  - Exposure to UV-C
- Infection Control Applications
  - Microbial reduction Indications for Use may include:
    - Adjunctive to existing, validated reprocessing methods
  - Microbicidal Indications for Use may include:
    - Disinfection (low-, intermediate, or high-level disinfection depending on log reduction achieved)

Section 201(h)(1)

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
2. *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
3. *intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.*

The term "device" does not include software functions excluded pursuant to section 520(o).

GUV Regulatory Background

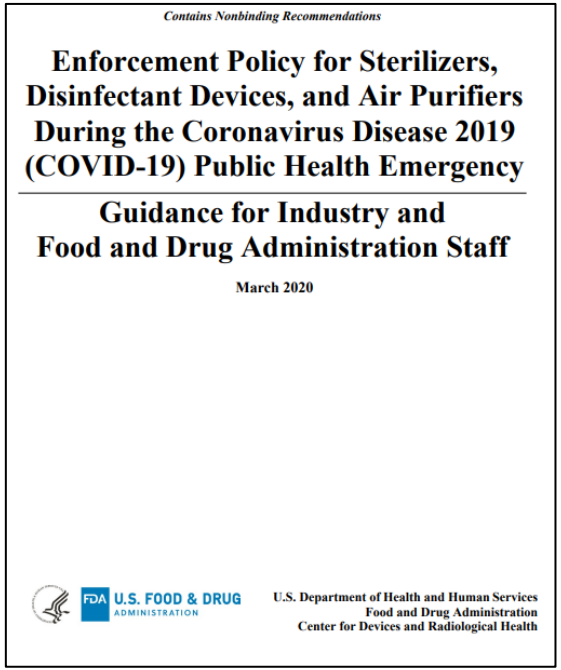
Regulation	Identification and Classification
880.6710 **Medical Ultraviolet Water Purifier**	A medical ultraviolet water purifier is a device intended for medical purposes that is used to destroy bacteria in water by exposure to ultraviolet radiation. Class II (performance standards)
880.6600 **Ultraviolet (UV) Radiation Chamber Disinfection Device**	An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV radiation disinfection devices intended for whole room disinfection in a health care environment. Class II (special controls)
880.6500 **Medical Ultraviolet Air Purifier**	A medical ultraviolet air purifier is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation. Class II (performance standards)

GUV Regulatory Background

- Emergency Preparedness
  - Emergency Use Authorization

GUV Regulatory Background

- Emergency Preparedness
  - Emergency Use Authorization
  - Enforcement Policy



Contains Nonbinding Recommendations

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

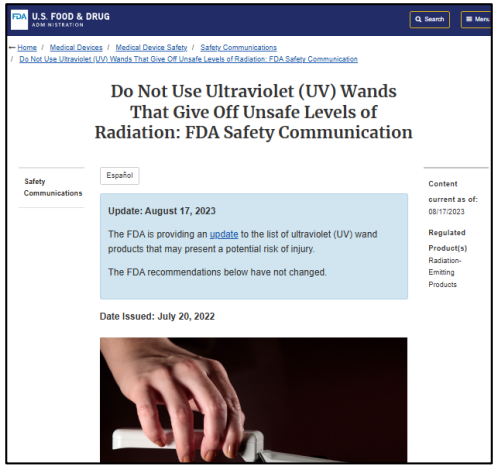
March 2020

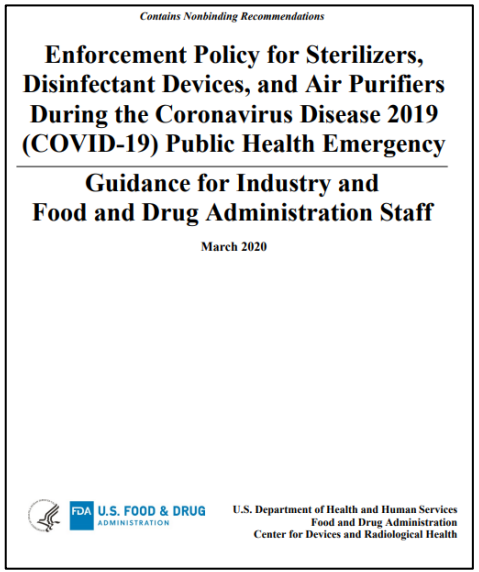
FDA U.S. FOOD & DRUG ADMINISTRATION

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

GUV Regulatory Background

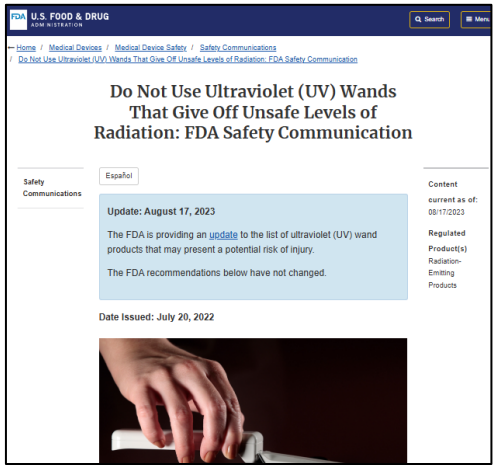
- Emergency Preparedness
  - Emergency Use Authorization
  - Enforcement Policy
  - Safety considerations

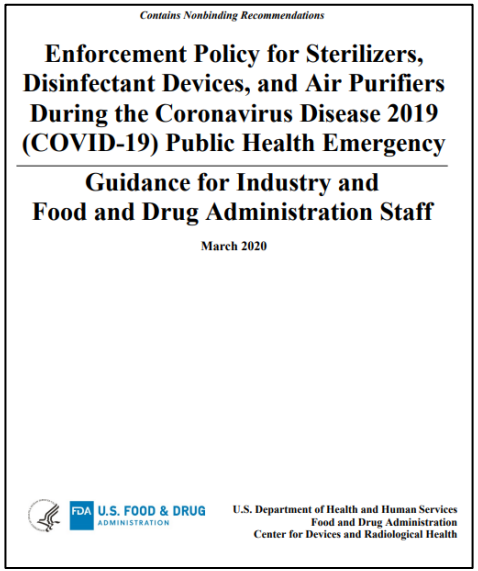




GUV Regulatory Background

- Emergency Preparedness
  - Emergency Use Authorization
  - Enforcement Policy
  - Safety considerations
- Current Focus Area
  - Medical device reprocessing
  - Novel technologies





Panel Purpose

Emergency Preparedness

- Novel technologies
- Scientific and safety-focused evaluation
- Timely access

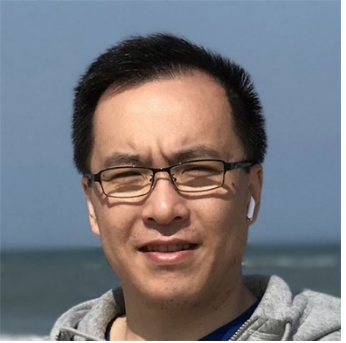
Panel Feedback

- Germicidal UV Technology
  - Hierarchy of microbial resistance
  - Antimicrobial stewardship
  - Other considerations

References

1. U.S. Food and Drug Administration. Emergency Use Authorization. Available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. Accessed August 22, 2025.
2. U.S. Food and Drug Administration. *Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.* Withdrawn or Expired Guidance. Available at: https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/withdrawn-or-expired-guidance. Accessed August 22, 2025.
3. U.S. Food and Drug Administration. 510(k) Premarket Notification Medical Device Database. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. Accessed August 24, 2025.
4. U.S. Food and Drug Administration. Beware of Ultraviolet Wands That Give Off Unsafe Levels of UV Radiation. Available at: https://www.fda.gov/consumers/consumer-updates/beware-ultraviolet-wands-give-unsafe-levels-uv-radiation. Accessed August 24, 2025.
5. U.S. Food and Drug Administration. Ultraviolet (UV) Radiation. Available at: https://www.fda.gov/radiation-emitting-products/tanning/ultraviolet-uv-radiation. Accessed August 24, 2025.
6. U.S. Food and Drug Administration. "Historical Information About Device Emergency Use Authorizations." FDA.gov, www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#decontamination. Accessed 26 Aug. 2025.


FDA
U.S. FOOD & DRUG
ADMINISTRATION



Overview of Medical Device Reprocessing

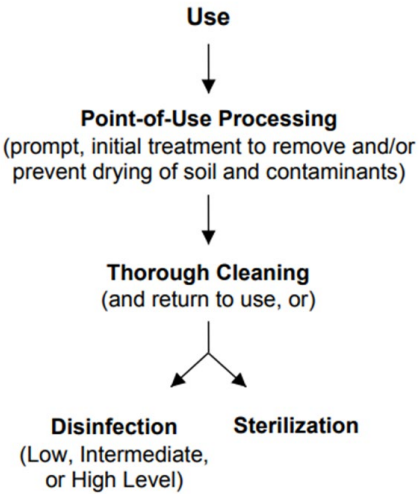
Yong Xue, Ph.D.
Office of Health Technology 4: Office of Surgical and Infection Control Devices
U.S. Food & Drug Administration
Center for Devices and Radiological Health
General Hospital and Personal Use Devices Panel Meeting

Key Topics

- Medical Device Reprocessing – Definitions and Context
- Spaulding Classification Framework
- Regulatory & Validation of Reprocessing
- GUV Microbicidal Mechanisms
- Challenges for GUV Technologies in Reprocessing
- Clinical Practice Applications
- Clinical Benefits and Risks

Medical Device Reprocessing

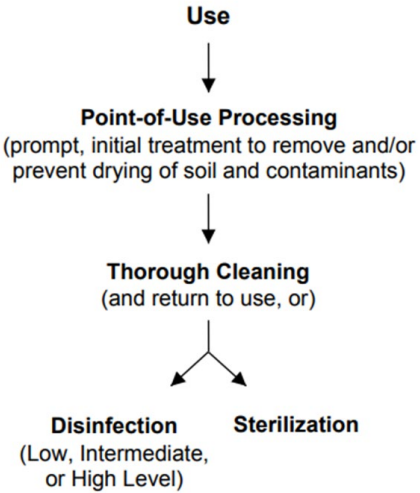
Reprocessing: Validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.



Terminology	Definition
Cleaning	Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use
Disinfection	A process that destroys pathogens and other microorganisms by physical or chemical means • **High-level disinfection:** A lethal process utilizing a sterilant under less than sterilizing conditions that kills all forms of microbial life except for large numbers of bacterial spores. • **Intermediate-level disinfection:** A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores. • **Low-level disinfection:** A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.
Sterilization	A validated process used to render product free from viable microorganisms

Medical Device Reprocessing

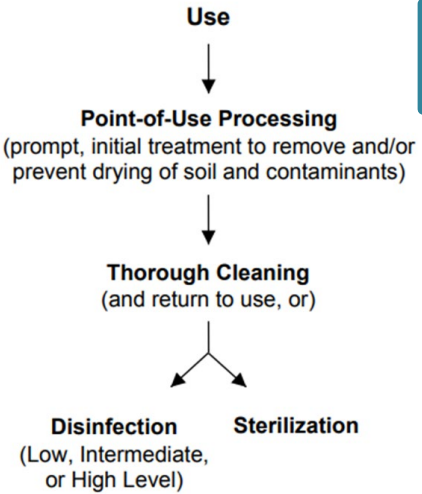
Reprocessing: Validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.



Terminology	Definition
Cleaning	Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use
Disinfection	A process that destroys pathogens and other microorganisms by physical or chemical means • **High-level disinfection:** A lethal process utilizing a sterilant under less than sterilizing conditions that kills all forms of microbial life except for large numbers of bacterial spores. • **Intermediate-level disinfection:** A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores. • **Low-level disinfection:** A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.
Sterilization	A validated process used to render product free from viable microorganisms

Medical Device Reprocessing

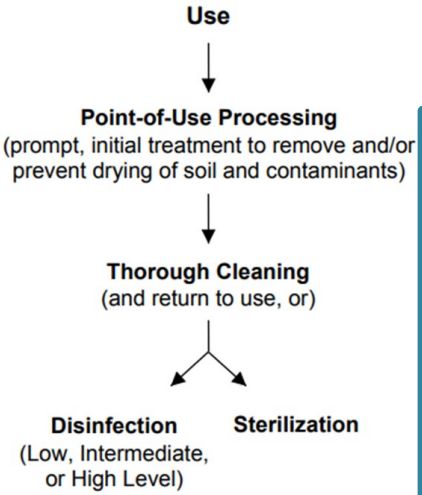
Reprocessing: Validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.



Terminology	Definition
Cleaning	Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use
Disinfection	A process that destroys pathogens and other microorganisms by physical or chemical means • **High-level disinfection:** A lethal process utilizing a sterilant under less than sterilizing conditions that kills all forms of microbial life except for large numbers of bacterial spores. • **Intermediate-level disinfection:** A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores. • **Low-level disinfection:** A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.
Sterilization	A validated process used to render product free from viable microorganisms

Medical Device Reprocessing

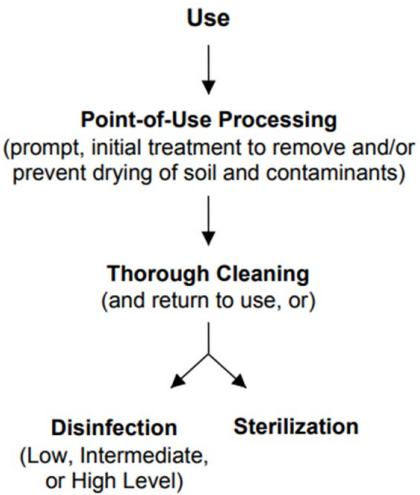
Reprocessing: Validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.



Terminology	Definition
Cleaning	Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use
Disinfection	A process that destroys pathogens and other microorganisms by physical or chemical means • **High-level disinfection:** A lethal process utilizing a sterilant under less than sterilizing conditions that kills all forms of microbial life except for large numbers of bacterial spores. • **Intermediate-level disinfection:** A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores. • **Low-level disinfection:** A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.
Sterilization	A validated process used to render product free from viable microorganisms

Medical Device Reprocessing

Reprocessing: Validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.



Terminology	Definition
Cleaning	Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use
Disinfection	A process that destroys pathogens and other microorganisms by physical or chemical means • **High-level disinfection:** A lethal process utilizing a sterilant under less than sterilizing conditions that kills all forms of microbial life except for large numbers of bacterial spores. • **Intermediate-level disinfection:** A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores. • **Low-level disinfection:** A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.
Sterilization	A validated process used to render product free from viable microorganisms

Spaulding Classification

FDA uses the modified Spaulding Classification scheme to describe the potential risk of infection caused by the device and the appropriate microbicidal processes

Classification	Definition	Reprocessing
Critical Devices	Introduced directly into the bloodstream, or contact a normally sterile tissue or body-space during use	• Cleaning • Sterilization
Semi-Critical Devices	Contact intact mucous membranes or non-intact skin. Do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body	• Cleaning • Sterilization or • High-level disinfection (HLD)
Non-Critical Devices	Contact intact skin and do not penetrate it	• Cleaning • Intermediate-level disinfection (ILD) or • Low-level disinfection (LLD)

Spaulding Classification

FDA uses the modified Spaulding Classification scheme to describe the potential risk of infection caused by the device and the appropriate microbicidal processes

Classification	Definition	Reprocessing
Critical Devices	Introduced directly into the bloodstream, or contact a normally sterile tissue or body-space during use	• Cleaning • Sterilization
Semi-Critical Devices	Contact intact mucous membranes or non-intact skin. Do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body	• Cleaning • Sterilization or • High-level disinfection (HLD)
Non-Critical Devices	Contact intact skin and do not penetrate it	• Cleaning • Intermediate-level disinfection (ILD) or • Low-level disinfection (LLD)

Spaulding Classification

FDA uses the modified Spaulding Classification scheme to describe the potential risk of infection caused by the device and the appropriate microbicidal processes

Classification	Definition	Reprocessing
Critical Devices	Introduced directly into the bloodstream, or contact a normally sterile tissue or body-space during use	• Cleaning • Sterilization
Semi-Critical Devices	Contact intact mucous membranes or non-intact skin. Do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body	• Cleaning • Sterilization or • High-level disinfection (HLD)
Non-Critical Devices	Contact intact skin and do not penetrate it	• Cleaning • Intermediate-level disinfection (ILD) or • Low-level disinfection (LLD)

Spaulding Classification

FDA uses the modified Spaulding Classification scheme to describe the potential risk of infection caused by the device and the appropriate microbicidal processes

Classification	Definition	Reprocessing
Critical Devices	Introduced directly into the bloodstream, or contact a normally sterile tissue or body-space during use	• Cleaning • Sterilization
Semi-Critical Devices	Contact intact mucous membranes or non-intact skin. Do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body	• Cleaning • Sterilization or • High-level disinfection (HLD)
Non-Critical Devices	Contact intact skin and do not penetrate it	• Cleaning • Intermediate-level disinfection (ILD) or • Low-level disinfection (LLD)

Regulatory & Validation of Reprocessing

Category	Regulatory Expectations
Purpose	Germicidal UV may be used to reprocess reusable medical devices to return them to suitable condition for reuse
Regulatory Framework	21 CFR 820.30 requires manufacturers of Class II and III medical devices, and most Class I devices to establish design control procedures
Validation Requirements	• Reprocessing instructions should meet validation requirements • Validate cleaning separately from disinfection/sterilization
FDA Review Scope	• Some devices: FDA reviews only reprocessing steps in Instructions for Use • Other devices: Reprocessing instructions and validation test reports
Submission Requirements	• PMA, HDE, De Novo – Reprocessing instructions and validation data • 510(k): Appendix E codes – Reprocessing instructions and validation data • Other 510(k)s – Reprocessing instructions; validation data kept on file per QSR
Risk-Based Considerations	Validation data expectations influenced by risk/likelihood of microbiological contamination based on intended use and reuse conditions

Regulatory & Validation of Reprocessing

Category	Regulatory Expectations
Purpose	Germicidal UV may be used to reprocess reusable medical devices to return them to suitable condition for reuse
Regulatory Framework	21 CFR 820.30 requires manufacturers of Class II and III medical devices, and most Class I devices to establish design control procedures
Validation Requirements	• Reprocessing instructions should meet validation requirements • Validate cleaning separately from disinfection/sterilization
FDA Review Scope	• Some devices: FDA reviews only reprocessing steps in Instructions for Use • Other devices: Reprocessing instructions and validation test reports
Submission Requirements	• PMA, HDE, De Novo – Reprocessing instructions and validation data • 510(k): Appendix E codes – Reprocessing instructions and validation data • Other 510(k)s – Reprocessing instructions; validation data kept on file per QSR
Risk-Based Considerations	Validation data expectations influenced by risk/likelihood of microbiological contamination based on intended use and reuse conditions

Regulatory & Validation of Reprocessing

Category	Regulatory Expectations
Purpose	Germicidal UV may be used to reprocess reusable medical devices to return them to suitable condition for reuse
Regulatory Framework	21 CFR 820.30 requires manufacturers of Class II and III medical devices, and most Class I devices to establish design control procedures
Validation Requirements	• Reprocessing instructions should meet validation requirements • Validate cleaning separately from disinfection/sterilization
FDA Review Scope	• Some devices: FDA reviews only reprocessing steps in Instructions for Use • Other devices: Reprocessing instructions and validation test reports
Submission Requirements	• PMA, HDE, De Novo – Reprocessing instructions and validation data • 510(k): Appendix E codes – Reprocessing instructions and validation data • Other 510(k)s – Reprocessing instructions; validation data kept on file per QSR
Risk-Based Considerations	Validation data expectations influenced by risk/likelihood of microbiological contamination based on intended use and reuse conditions

Regulatory & Validation of Reprocessing

Category	Regulatory Expectations
Purpose	Germicidal UV may be used to reprocess reusable medical devices to return them to suitable condition for reuse
Regulatory Framework	21 CFR 820.30 requires manufacturers of Class II and III medical devices, and most Class I devices to establish design control procedures
Validation Requirements	• Reprocessing instructions should meet validation requirements • Validate cleaning separately from disinfection/sterilization
FDA Review Scope	• Some devices: FDA reviews only reprocessing steps in Instructions for Use • Other devices: Reprocessing instructions and validation test reports
Submission Requirements	• PMA, HDE, De Novo – Reprocessing instructions and validation data • 510(k): Appendix E codes – Reprocessing instructions and validation data • Other 510(k)s – Reprocessing instructions; validation data kept on file per QSR
Risk-Based Considerations	Validation data expectations influenced by risk/likelihood of microbiological contamination based on intended use and reuse conditions

GUV Microbicidal Mechanisms

- **Mechanism of Action:** UV-C photons absorbed by microbial genetic material, causing DNA/RNA damage through cyclobutane pyrimidine dimer formation
- **Peak Effectiveness:** 250-270 nm range provides optimal germicidal properties
- **Resistance Hierarchy (Limited studies):** Vegetative bacteria and viruses inactivated at lower doses; bacterial and fungal spores require higher UV exposure
- **Dose Dependency:** Sufficient fluence (dose) required to achieve microbial inactivation

Challenges for GUV Technologies in Reprocessing

- **Line-of-Sight Requirement:** Only directly illuminated surfaces receive treatment; shadowed areas remain untreated
- **Penetration Limitations:**
  - Cannot penetrate lumens or porous materials
  - Cannot penetrate organic matter, dirt, or biological residues that shield microorganisms
- **Variable Dose Delivery:** Effectiveness varies with distance, surface angles, and lamp placement
- **Microbial Repair & Tolerance:**
  - Microbes can repair DNA damage(photoreactivation, excision repair)
  - Sub-lethal exposure may allow survival and potential UV-tolerant traits
  - Stewardship needed to avoid selecting UV-tolerant microbes

Clinical Perspective: Applications, Benefits, and Risks of Germicidal UV in Reprocessing

Elizabeth Bulger, M.D.

Adult and Pediatric Infectious Disease, Internal Medicine
U.S. Food & Drug Administration
Center for Devices and Radiological Health

General Hospital and Personal Use Devices Panel Meeting
October 29, 2025

Germicidal UV -Clinical Benefits

Benefits	Description
Safety Profile	Utilizes non-ionizing radiation with limited concerns about residual chemicals remaining on reusable medical devices, offering improved safety compared to traditional chemical disinfectants that may be hazardous to patients or end users
Residue Concerns	Eliminates issues with hazardous chemical residues that may remain after traditional cleaning/disinfection methods
Process Standardization	Appropriately validated, automated GUV devices provide more standardized microbial reduction processes when used as an adjunct to complex, labor-intensive manual disinfection procedures
Error Reduction	Automated germicidal UVC can potentially lower reprocessing error rates by reducing human error associated with increasingly complex device reprocessing and manufacturer instructions
Application Scope	Effective for microbial reduction or disinfection in multiple use applications for reusable medical devices
Automation Advantage	Provides an automated option that may reduce complexity compared to manual chemical disinfection processes

Germicidal UV -Clinical Risks

Risk Category	Description	Key Concerns
Material Compatibility	UV radiation exposure can **damage medical device surfaces** and components	• Degradation of plastics, rubber, and fabrics over time• Potential impact on device functionality• Importance of material compatibility testing for safety
UV Exposure Health Risks	**Direct health hazards** from UV radiation exposure to users and patients	• Burn damage to skin and eyes• Respiratory challenges• Delayed cancers (basal cell, squamous cell, melanoma)• Cataracts and macular degeneration• Increased risks with photosensitizing medications• Ozone and reactive oxygen species toxicity
Unsupported Clinical Claims	Marketing of devices with **unsubstantiated performance** claims	• Unproven effectiveness against specific diseases• Lack of demonstrated clinical benefit• Uncertainty about broad-spectrum efficacy• Potential adverse health outcomes for patients and healthcare workers
Microbial Resistance Hierarchy	**Different resistance patterns** compared to chemical disinfectants	• Pigmented fungal spores may be more resistant than bacterial endospores• Increased infection risk for vulnerable populations (diabetic, immunocompromised)• Different effectiveness profile than traditional chemical germicides
Inadequate Device Performance	**Technical limitations** of UV disinfection technology	• Shadowing effects limiting coverage• Low penetration capability• Limited to direct exposure sites only• Challenges with complex device geometries• Difficulty supporting standalone disinfection claims


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Regulatory History of Germicidal UV Medical Devices

Stephen Anisko, MS
Office of Health Technology 4: Office of Surgical and Infection Control Devices
U.S. Food & Drug Administration
Center for Devices and Radiological Health
General Hospital and Personal Use Devices Panel Meeting

Discussion Points

- Existing Regulatory Framework for GUV Medical Devices
- FDA-Established GUV Medical Device Classifications
- Comprehensive Special Controls and Risk Mitigation

Regulatory Framework for GUV Medical Devices

- Existing Compliance Requirements
  - Electronic Radiation Product Control (EPRC) regulations (21 CFR 1000-1050)
  - Standard medical device regulations
  - Establishment registration and premarket submissions
- Multi-layered Safety Approach
  - Ensures comprehensive safety oversight
  - Provides clear pathways for manufacturers
  - Minimizes potential harm to public health

GUV Medical Device Existing Classifications

- 21 CFR 880.6500 – Medical UV Air Purifiers
  Previous medical device clearances go back to the 1980s (35 total)

- 21 CFR 880.6600 – UV Chamber Disinfection Devices
  Not frequently used, only 1 authorized product currently under this regulation

- 21 CFR 880.6510 – Whole Room Microbial Reduction Device
  De Novo granted 2023, only 2 authorized products currently under this regulation

- 21 CFR 880.6511 – UV Disinfection Chamber Device
  De Novo granted 2024, only 1 authorized product currently under this regulation

GUV Medical Device Regulations

Medical UV air purifiers
21 CFR 880.6500

- **Identification**: A medical ultraviolet air purifier is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation
- Class II
- May contain both filtration and UV radiation exposure
- Essential performance: 4 log reduction of claimed microorganisms (room volume/fan speed/time)

UV Chamber Disinfection Devices
21 CFR 880.6600

- **Identification**: An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV radiation disinfection devices intended for whole room disinfection in a health care environment.
- Class II
- Special Controls

GUV Medical Device Regulations

Whole room microbial reduction device
21 CFR 880.6510

- **Identification**: A whole room microbial reduction device is a medical device to be used to reduce microbial load on medical device surfaces following cleaning and disinfection.
- Class II
- Special Controls

UV Disinfection Chamber Device
21 CFR 880.6511

- **Identification**: An ultraviolet radiation disinfection chamber device is intended to disinfect patient contacting medical devices using UV radiation after the device has been cleaned. Disinfection of the medical device is achieved within an enclosed chamber through the exposure to UV radiation.
- Class II
- Special Controls
- Essential performance: Microbial reduction of claimed microorganisms (appropriate to specific disinfection claims)

Comprehensive Special Controls and Risk Mitigation

- Key Special Control Requirements:
  - Non-clinical performance testing with worst-case conditions
  - Microbial hierarchy and resistance testing
  - Photobiological safety validation
  - Material compatibility assessment
  - Safety interlock systems
- Addressed Risk Categories:
  - UV radiation exposure (skin/eye damage)
  - Patient cross-contamination
  - Material incompatibility
  - Device failure scenarios


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Current Challenges for Germicidal UV (GUV) Medical Devices

Lianji Jin, Ph.D.
Office of Health Technology 4: Office of Surgical and Infection Control Devices
U.S. Food & Drug Administration
Center for Devices and Radiological Health
General Hospital and Personal Use Devices Panel Meeting

Key Topics

- New Technology Considerations
- Hierarchy of Resistance
- Infection Prevention Intended Uses
- Antimicrobial Stewardship
- Pandemic Preparedness

New Technology Considerations

Subject	Details
Current Challenges	• Lack of accepted standard test methods for UV-C devices • Existing protocols (AOAC, ASTM) designed for liquid chemical disinfectants • Physical constraints with shadowing and penetration • Reliance on manufacturer-designed studies • Absence of standardized performance criteria
Points for Discussion	• Develop standardized test methods specifically for germicidal UV-C devices • Establish uniform acceptance criteria for medical device reprocessing claims • Create UV-specific performance testing protocols to thoroughly evaluate germicidal UV as a reprocessing agent • Address technical limitations related to shadowing and penetration in UV testing

Hierarchy of Resistance

Subject	Details
Current Knowledge Gaps	• Resistance Hierarchy not full characterized • Most resistant unclear which organisms represent “worst case” • Least resistant not clearly defined • Resistance patterns differ between UC-C and chemical disinfectants
Key Challenges Identified	• Lack of standardization • Different resistance patterns • Limited comparative data • Validation uncertainty
Panel Input Needed	Development of a scientifically justified, clinically relevant UV resistance hierarchy to: • Standardize testing expectations • Support development of consensus standards • Guide future research

Infection Prevention Intended Uses

Subject	Details
Current Challenge	Healthcare Associated Infections (HAIs) are significant, preventable sources of patient morbidity and mortality acquired during medical care
Regulatory Status	• GUV devices for HAI reduction not yet classified by FDA • HAI reduction intended uses typically require clinical data • FDA role limited to device safety/effectiveness evaluation
Study Design Challenges	• Hospital size and level of care • Seasonal and geographic variation in HAI • Differences in resistance patterns, antibiotic usage, and periodic infection outbreaks • Clinically relevant organisms associated with infection, and • Differences in infection control adherence, practices, procedures and cleaning protocols
Panel Input Needed	Study designs to assist FDA in evaluating HAI reduction or prevention intended uses

Antimicrobial Stewardship

Subject	Description	Application to GUV Technology
Definition	Coordinated interventions designed to establish appropriate use of antimicrobial agents by promoting optimal dose regimens in clinical settings	Principles extend to all antimicrobial technologies, including emerging GUV germicidal devices
Agency Priority	Develop current thinking while technology evolves	Monitor potential signs of microbial resistance development that could eventually limit the efficacy of GUV Technology
Key Objective	Thoroughly evaluate GUV devices integration into established hospital cleaning and disinfection protocols	Guard against potential antimicrobial resistance following prolonged GUV exposure
Evaluation Areas	• Appropriate Use and Clinical Selection • Dose Optimization and Standardization • Safety and Risk Management • Integration with Infection Control Protocols	
Panel Input Needed	• Susceptibility testing • UV exposure limitations • Dose regimens	

Pandemic Preparedness

Subject	Details
Prior Emergency Response Experience	• Created time-limited emergency policies • Allowed device modifications without typical authorization process • Enabled introduction of new UV devices and air purifiers • Maintained specific safety and performance expectations
Real-World Outcomes	• Provided performance data in actual healthcare settings • Revealed potential benefits of UV technologies • Demonstrated importance of proper training and safety measures
Future Preparedness Goals	• Leverage COVID-19 experience • Strengthen pandemic preparedness capabilities • Create adaptable regulatory approaches for health emergencies
Expert Panel Input Needed	• Standardize testing methods for UV technologies • Establish clear effectiveness measurement guidelines • Address performance against clinically relevant bacteria and viruses
Regulatory Objectives	• Quick adaptation during health emergencies • Maintain established safety standards for GUV devices • Balance emergency needs with regulatory oversight


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Questions for the Panel

Dolly Singh, Ph.D.
Office of Health Technology 4: Office of Surgical and Infection Control Devices
U.S. Food & Drug Administration
Center for Devices and Radiological Health
General Hospital and Personal Use Devices Panel Meeting

Panel Question 1:

To date, the Agency has only authorized UV devices to support medical device reprocessing for general microbial reduction or high-level disinfection under specific conditions. The Agency believes device innovation may support additional indications in the future, such as standalone disinfection, which may result in different disinfection practices in healthcare settings. However, the FDA also believes that UV as a germicide for medical device reprocessing has known technological limitations (i.e., shadowing, low penetration) which may challenge the ability for manufacturers to support standalone disinfection intended uses with appropriate safety and effectiveness data.

a) Does the Panel have recommendations on performance testing specific for UV radiation reprocessing of medical devices that may support a standalone disinfection intended use?

Panel Question 1 (continued):

b) In addition, manufacturers may also be interested in reducing or preventing Healthcare-Associated Infections (HAIs) indications. The Agency has typically recommended a clinical study to support such indications. However, the FDA recognizes there may be challenges in designing this type of clinical study such as inconsistent infection control practices across clinical settings, variability in reprocessing techniques, and appropriate control conditions. What recommendations does the Panel have regarding study design considerations to support indications such as reduction or prevention of HAIs?

Panel Question 2:

To support appropriate performance testing, the Agency currently asks manufacturers to determine an appropriate hierarchy of microbial resistance to germicidal UV for reprocessing of medical devices. To avoid development of a level of evidence that may be specific to individual UV devices, FDA is seeking recommendations on a scientifically justified consensus for level of evidence that should be established for germicidal UV hierarchy that could be applied across the device type without individual manufacturers developing new hierarchy testing for each new device.

Does the panel have recommendations on what information would be needed to support a general hierarchy of resistance for UV?

Panel Question 3:

With increasing use of germicidal UV devices to reprocess medical devices in clinical settings - as with any frequently used antimicrobial agent - increased antimicrobial resistance is a major public health consideration. As it relates to UV safety and effectiveness of medical devices, what susceptibility testing, exposure limitations, and/or review aspects should be considered to support antimicrobial stewardship to guard against potential emergence of UV resistance amongst clinically relevant microorganisms? Does the Panel have suggestions of ways UV devices could be used in conjunction with existing practices that would help mitigate the rise of UV resistance?

Panel Question 4:

During the COVID-19 public health emergency, certain Emergency Use Authorizations (EUAs) utilized UV as the primary microbiocidal agent (e.g., UV decontamination systems used to reprocess personal protective equipment (PPE)). In addition, the Agency has seen an increase in innovation related to UV technologies as a mode of disinfection for medical devices. Increased innovation could lead to confusion regarding how such products fit within the overall landscape of devices intended for infection control.

What information is helpful to healthcare providers to promote transparency and improve comprehension for the intended uses for which these technologies are currently authorized?

Panel Question 5:

What other considerations for innovations in germicidal UV reprocessing of medical devices does the Panel recommend?


FDA
U.S. FOOD & DRUG
ADMINISTRATION